項目名	和訳結果(SIDS Dossier)	原文(SIDS Dossier)

1. 一般情報
GENERAL INFOMATION

1.01 物質情報
SUBSTANCE INFOMATION

CAS番号	108-46-3	108-46-3
物質名(日本語名)	1,3-ベンゼンジオール	
物質名(英名)		1,3-Benzenediol
別名等		
国内適用法令の番号		
国内適用法令物質名		
OECD/HPV名称		
分子式	C6H6O2	C6H6O2
構造式		
備考		

1.02 安全性情報収集計画書/報告書作成者に関する情報
SPONSOR INFOMATION

機関名	OECD/HPVプログラム(SIAM27)により収集された情報 (http://cs3-hq.oecd.org/scripts/hpv/)	OECD/HPV Program, SIDS Dossier, assessed at SIAM 27-OCT-2007 http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=hpv
代表者名		
所在地及び連絡先		
担当者氏名		
担当者連絡先(住所)		
担当者連絡先(電話番号)		
担当者連絡先(メールアドレス)		
報告書作成日		
備考	スポンサー国:日本	Sponsor Country: Japan

1.03 カテゴリー評価
DETAILS ON CHEMICAL CATEGORY

1.1 一般的な物質情報
GENERAL SUBSTANCE INFOMATION

物質のタイプ	有機物	organic
物質の色・におい・形状等の情報	色:白色 臭い:わずかに特異臭	Colour : white Odour : Slight characteristic odor
物理的状態(20℃、1013hPa)	固体	solid
純度(重量/重量%)	90 - 100 % w/w	90 - 100 % w/w
出典	(170)	(170)
備考	物質の純度は、製造方法によって異なる。	The purity of the material is dependent on the manufacturing method.

1.2 不純物
IMPURITIES

1.3 添加物
ADDITIVES

1.4 別名
SYNONYMS

1.5 製造・輸入量
QUANTITY

製造・輸入量	10000 - 50000 トン	10000 - 50000 tonnes in
報告年		
出典	EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)	EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
備考	全世界	World-wide

1.6 用途情報
USE PATTERN

主な用途情報	用途タイプ:タイプ カテゴリ:閉鎖系で使用	Type of use : type Category : Use in closed system
工業的用途		
用途分類		
出典	EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)	EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
備考		

主な用途情報	用途タイプ:工業 カテゴリ:個人的及び家庭内用途	Type of use : industrial Category : Personal and domestic use
工業的用途		

用途分類		
出典	EUROPEAN COMMISSION – European Chemicals Bureau Ispra (VA)	EUROPEAN COMMISSION – European Chemicals Bureau Ispra (VA)
備考		

1.7 環境および人への暴露情報
SOURCES OF EXPOSURE

1.8 追加情報
ADDITIONAL INFOMATION

2. 物理化学的性状
PHYSICAL CHEMICAL DATA

2.1 融点
MELTING POINT

試験物質名	1.1 – 1.4で規定	as prescribed by 1.1 – 1.4
CAS番号		
純度等		
注釈		
方法	データなし	no data
GLP	データなし	no data
試験を行った年	1981	1981
試験条件		
結果		
融点: ℃	110 ° C	110 ° C
分解: ℃	いいえ	no
昇華: ℃	はい	yes
結論		
注釈		
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	信頼できる2次情報源	Reliable secondary literature source
出典		
引用文献	(157) (183)	(157) (183)
備考	フラグ : SIDSエンドポイントに重要な試験	Flag : Critical study for SIDS endpoint

2.2 沸点
BOILING POINT

試験物質名	1.1 – 1.4で規定	as prescribed by 1.1 – 1.4
CAS番号		
純度等		
注釈		
方法	データなし	no data
GLP	データなし	no data
試験を行った年		
試験条件		
結果		
沸点: ℃	277.5 ° C	277.5 ° C
圧力	at 1013 hPa	at 1013 hPa
分解: ℃		
結論		
注釈	この値は℃に変換されたものである	This value was converted into degrees C
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	信頼できる2次情報源からのデータ	Reliability of 2 assigned because data are taken from a reliable secondary literature source
出典		
引用文献	(349)	(349)
備考	フラグ : SIDSエンドポイントに重要な試験	Flag : Critical study for SIDS endpoint

2.3 密度(比重)
DENSITY(RELATIVE DENSITY)

試験物質名	1.1 – 1.4で規定	as prescribed by 1.1 – 1.4
CAS番号		
純度等		
注釈		
方法	データなし	no data
GLP	データなし	no data
試験を行った年	2001	2001
試験条件		
結果	1.278 g/cm³	1.278 g/cm³
タイプ	密度	density
温度(℃)	20 ° C	20 ° C
注釈		
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions

信頼性の判断根拠	信頼できる2次情報源からのデータ	Reliability of 2 assigned because data are taken from a reliable secondary literature source
出典		
引用文献	(202)	(202)
備考	フラグ：SIDSエンドポイントに重要な試験	Flag : Critical study for SIDS endpoint

2.4 蒸気圧
VAPOUR PRESSURE

試験物質名	1.1 - 1.4で規定	as prescribed by 1.1 - 1.4
CAS番号		
純度等		
注釈		
方法	その他(計算)	other (calculated)
GLP	データなし	no data
試験を行った年	1994	1994
試験条件		
結果		
蒸気圧	.00065 hPa	.00065 hPa
温度： ℃	25 ° C	25 ° C
分解： ℃		
結論		
注釈	(0.000489 mmHg @ 25C)	(0.000489 mmHg @ 25C)
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	信頼できる2次情報源からのデータ	Reliability of 2 assigned because data are taken from a reliable secondary literature source
出典		
引用文献	(296) (323) (347) (348)	(296) (323) (347) (348)
備考	フラグ：SIDSエンドポイントに重要な試験	Flag : Critical study for SIDS endpoint

2.5 分配係数(log Kow)
PARTITION COEFFICIENT

試験物質名	1.1 - 1.4で規定	as prescribed by 1.1 - 1.4
CAS番号		
純度等		
注釈	分配係数：オクタノール/水	Partition coefficient : octanol-water
方法	その他(測定)	other (measured)
GLP	いいえ	no
試験を行った年	1981	1981
試験条件		
結果		
Log Kow	0.8	0.8
温度： ℃		
結論		
注釈	データは実験値としてEPISUITEv3.12にも掲載されている	Data are also cited as an experimental value in EPISUITEv3.12
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	英文参照	ISHOW - Information System for Hazardous Organics in Water Details. Sample Record ISHOW, sponsored by the Office of Toxic Substances of the EPA, was developed by the EPA laboratory in Duluth, Minnesota in conjunction with the University of Minnesota. This database of 17,159 records includes physical property data on more than 5,700 different chemicals with bibliographic references to the original sources. Not all properties are recorded for all substances.
出典		
引用文献	(41) (97) (119) (120) (200)	(41) (97) (119) (120) (200)
備考	フラグ：SIDSエンドポイントに重要な試験	Flag : Critical study for SIDS endpoint

2.6.1 水溶解性（解離定数を含む）
WATER SOLUBILITY & DISSOCIATION CONSTANT

試験物質名	1.1 - 1.4で規定	as prescribed by 1.1 - 1.4
CAS番号		
純度等		
注釈	水溶解度	Solubility in : Water
方法	その他(測定)	other (measured)
GLP	データなし	no data
試験を行った年	1992	1992
試験条件		
結果		
水溶解度	717 g/l	717 g/l
温度： ℃	25 ° C	25 ° C
pH		
pH測定時の物質濃度		
結論		
注釈	分解性生物：いいえ	Deg. product : no
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions

信頼性の判断根拠	より詳細な情報無し。質と、20℃でなく実際に近い温度(25℃)条件に基づく重要な試験として推定プログラムのために選ばれた。	No additional details available. Selected as critical study for estimation programs based on quality and temperature relevance (25C) instead of 20C.
出典		
引用文献	(296) (323) (344)	(296) (323) (344)
備考	フラグ:SIDSエンドポイントに重要な試験	Flag : Critical study for SIDS endpoint
解離定数		
試験物質		
同一性		
方法		
温度:　℃	25 ° C	25 ° C
GLP		
試験条件		
試験を行った年		
結果		
結論		
注釈		
信頼性スコア		
信頼性の判断根拠		
出典		
引用文献		
備考		

試験物質名		
CAS番号		
純度等		
注釈		
方法		
GLP		
試験を行った年		
試験条件		
結果		
水溶解度		
温度:　℃		
pH		
pH測定時の物質濃度		
結論		
注釈		
信頼性スコア		
信頼性の判断根拠		
出典		
引用文献		
備考		
解離定数		
試験物質	1.1 - 1.4で規定	as prescribed by 1.1 - 1.4
同一性		
方法	その他:測定	other: measured
温度:　℃		
GLP	データなし	no data
試験条件		
試験を行った年	1979	1979
結果	試験目的: 酸性解離 Valueタイプ　: 測定値 pK1: 9.32 注釈: 不確実性　1-10%	Study Purpose: Acid Dissociation Value Type: MEASURED pK1: 9.32 Remarks: UNCERTAINTY 1-10%
結論		
注釈		
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	信頼できる2次情報源	Reliable secondary literature source
出典		
引用文献	(278) (296)	(278) (296)
備考		

2.6.2 表面張力
SURFACE　TENSION

2.7 引火点(液体)
FLASH　POINT(LIQUIDS)

試験物質名	1.1 - 1.4で規定	as prescribed by 1.1 - 1.4
CAS番号		
純度等		
注釈	密度	density
方法	ASTM D-92-97: 開放式 ASTM D-93-97: 開放式	ASTM D-92-97: open cup ASTM D-93-97: closed cup
GLP	データなし	no data
試験を行った年	1981	1981

試験条件		
結果		
引火点: ℃	127℃	127℃
試験のタイプ	密閉式	closed cup
	168℃。、開放式	168C; open cup
結論		
注釈		
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	信頼できる2次情報源からのデータ	Reliability of 2 assigned because data are taken from a reliable secondary literature source
出典		
引用文献	(94) (183)	(94) (183)
備考	フラグ:SIDSエンドポイントに重要な試験	Flag : Critical study for SIDS endpoint

2.8 自己燃焼性 （固体／気体）
AUTO FLAMMABILITY（SOLIDS/GASES）

2.9 引火性
FLAMMABILITY

試験物質名	1.1 - 1.4で規定	as prescribed by 1.1 - 1.4
CAS番号		
純度等		
注釈		
方法	その他	other
GLP	データなし	no data
試験を行った年	1986	1986
試験条件		
結果		
固体の場合		
引火性が高い		
気体の場合		
水との接触		
結論		
注釈	200℃における燃焼限界は1.4%(容量)であった	flammable limit 1.4% by volume in air @ 200C
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	信頼できる2次情報源からのデータ	Reliability of 2 assigned because data are taken from a reliable secondary literature source
出典		
引用文献	(231)	(231)
備考	フラグ:SIDSエンドポイントに重要な試験	Flag : Critical study for SIDS endpoint

2.10 爆発性
EXPLOSIVE PROPERTIES

試験物質名	1.1 - 1.4で規定	as prescribed by 1.1 - 1.4
CAS番号		
純度等		
注釈		
方法	BS 5958: Part 1: 1991 Control of Undesirable Static Electricity VDI Forschritt-Berichte Reihe 3: Verfahrenstechnik Nr 134 ISO 爆発防護システム Part 1: 空気中の可燃性ダストの爆発インデックスの測定; ISO 6184/1, ISO Geneva (1985)	BS 5958: Part 1: 1991 Control of Undesirable Static Electricity VDI Forschritt-Berichte Reihe 3: Verfahrenstechnik Nr 134 ISO Explosion Protection Systems Part 1: Determination of Explosion Indices of Combustible Dusts in Air; ISO 6184/1, ISO Geneva (1985)
GLP	データなし	no data
試験を行った年	1995	1995
試験条件		
結果		
火により爆発		
m-ジニトロベンゼンより摩擦に敏感		
m-ジニトロベンゼンより衝撃に敏感		
爆発性ない		
その他		
結論		
注釈	resorcinol dustの最低着火温度 が、ダスト濃度 kg/m3のとき、3 mj であると報告された。resorcinol dustの 爆燃インデックスは134と報告され、これは St-1.というダスト分類に対応する。	Minimum ignition temperature measured for resorcinol dust was reported at 3 mj at dust concentration of 8 kg/m3. The deflagration index reported for resorcinol dust was 134 which is a dust classification of St-1.
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions

信頼性の判断根拠	ガイドライン試験、GLP考慮のデータなし	Guideline study; No data regarding GLP
出典		
引用文献	(47) (48)	(47) (48)
備考		

2.11 酸化性
OXIDISING PROPERTIES

2.12 酸化還元ポテンシャル
OXIDATION/REDUCTION POTENTIAL

2.13 その他の物理化学的性状に関する情報
ADDITIONAL INFOMATION

試験物質名		
CAS番号		
純度等		
注釈	Henry則定数	Henry's Law Constant
方法		
GLP		
試験を行った年		
試験条件	SIDSエンドポイントに重要なキースタディとして選ばれた値に基づく推定データ VP/WS = 0.000489 mmHg/7.17 xE+5 mg/L 蒸気圧/水溶解度からの計算値。この方法は水溶解度の低いものに限定される。水に混和する化合物は方法の1つとして直接定量することを推奨する。しかしながら、直接の定量値は利用できない。	Estimated data based on key values selected as Critical for SIDS endpoint for VP/WS = 0.000489 mmHg/7.17 xE+5 mg/L Calculated from vapor pressure/water solubility estimations. This method is limited to substances of low water solubility. For water miscible substances, in which this is one, direct measurement is recommended. However, no direct measurements were available
結果	9.881x E-11 atm-m^3/mole	9.881x E-11 atm-m^3/mole
結論		
注釈		
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	推定プログラムからのデータ	Data are from an estimation program
出典		
引用文献	(31) (121) (296) (323)	(31) (121) (296) (323)
備考		

3. 環境運命と経路
ENVIRONMENTAL FATE AND PATHWAYS

3.1 安定性
STABILITY

3.1.1. 光分解
PHOTODEGRADATION

試験物質名	レゾルシノール (Cas No. 108-46-3)	Resorcinol (Cas No. 108-46-3)
CAS番号		
純度等		
注釈		
方法	AOPWIN v1.91を用いる推定プログラムEPISUITE v3.12からのデータ。入力パラメータ: 融点=110℃, 沸点=277℃, 水溶解度=7.17E+005 mg/L, 蒸気圧=0.000489 mmHg, Log Kow = 0.80	Data are from an estimation program EPISUITE v3.12 using AOPWIN v1.91. Estimated value. Input parameters: MP=110C, BP=277C, WS=7.17E+005 mg/L, VP=0.000489 mmHg, Log Kow = 0.80
タイプ	大気	air
GLP	いいえ	no
試験を行った年	2006	2006
光源と波長(nm)		
太陽光強度に基づいた相対強度	太陽光強度に基づく	based on intensity of sunlight
物質のスペクトル		
試験条件		
結果		
物質濃度		
温度(℃)		
直接光分解		
半減期t1/2		
分解度(%)と時間		
量子収率 (%)		
間接光分解		
増感剤(タイプ)	OH	OH
増感剤濃度	500000 molecule/cm^3	500000 molecule/cm^3
速度定数	.00000000020028 cm^3/(molecule*sec)	.00000000020028 cm^3/(molecule*sec)
半減期t1/2	0.1日間	.1 day(s)
分解生成物		

	結果は、1日に12時間反応するOHラジカル濃度が 1.5 10^6 分子/cm3.のとき、OH速度定数は 200.2800 E-12 cm3/分子-秒、半減期は 0.053 日 (38.16 分間) である事を示している。	Results indicate the overall OH rate constant to be 200.2800 E-12 cm3/molecule-sec and a half-life of 0.053 days (38.16 minutes) for a 12-hour day with a hydroxyl radical concentration of 1.5 10^6 molecule/cm3.
結論		
注釈	硝酸ラジカルとの反応も重要である	Reaction with Nitrate radicals may be important
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	推定プログラムからのデータ	Data are from an estimation program
出典		
引用文献	(323)	(323)
備考	フラグ：SIDSエンドポイントに重要な試験	Flag : Critical study for SIDS endpoint

3.1.2. 水中安定性（加水分解性）
STABILITY IN WATER

試験物質名	データなし	no data
CAS番号		
純度等		
注釈	タイプ：非生物学的	Type : abiotic
方法	その他	other
GLP	データなし	no data
試験を行った年	2006	2006
試験条件		
結果		
設定濃度		
実測濃度		
所定時間後の分解度(%)、pH、温度		
半減期		
分解生成物		
結論		
注釈	レゾルシノールは加水分解を受ける可能性のある化学構造を持たないため、推定プログラム HYDROWIN v1.67はフェノールの加水分解速度を 推定できない。	Resorcinol does not pocess any functional groups that are regarded as being susceptible to hydrolysis, the soft ware prediction programme HYDROWIN v1.67 cannot estimate hydrolysis rate constants for phenols.
信頼性スコア	(4) 信頼性を評価できない	(4) not assignable
信頼性の判断根拠	技術ディスカッション；推定プログラムからのデータ	Technical discussion; Data are from an estimation program
出典		
引用文献	(323)	(323)
備考	フラグ：SIDSエンドポイントに重要な試験	Flag : Critical study for SIDS endpoint

3.1.3. 土壌中安定性
STABILITY IN SOIL

3.2. モニタリングデータ（環境）
MONITORING DATA（ENVIRONMENT）

試験物質名		
CAS番号		
純度等		
注釈		
方法		
測定タイプ（地点）	その他	other
媒体	食物及びタバコの煙	food and cigarette smoke
結果	レゾルシノールは焙煎大麦、シロップ及びコーヒー中から検出された 測定タイプ ：汚染地域 媒体 ： 大気 結果 ： 8 ug /タバコ 注釈 ：レゾルシノールはタバコの煙中から定量された。	Resorcinol was detected in roasted barley, in syrup and in coffee type of measurement: at contaminated site media: air result: 8 ug per cigarette remark: resorcinol was quantitativley determined in cigarette smoke
結論		
注釈		
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	2次情報源からのデータ。更なる詳細データなし	Data are taken from a secondary literature source. No additional details are available
出典		
引用文献	(63) (127) (283) (285) (335)	(63) (127) (283) (285) (335)
備考		

3.3. 移動と分配
TRONSPORT AND DISTRIBUTION

3.3.1 環境区分間の移動
TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

試験物質名		
CAS番号		
純度等		
注釈	タイプ : フガシティモデル level III	Type : fugacity model level III
方法	推定プログラム EPISUITE v3.12からのデータ。推定値. 入力パラメータ : 融点=110C, 沸点=277C, 水溶解度 =7.17E+005 mg/L, 蒸気圧=0.000489 mmHg, Log Kow = 0.80 排出量 1000 kg/hr とした場合のBIOWIN 推定。.	Data are from an estimation program EPISUITE v3.12. Estimated value. Input parameters: MP=110C, BP=277C, WS=7.17E+005 mg/L, VP=0.000489 mmHg, Log Kow = 0.80 using BIOWIN calculations and 1000 kg/hr emissions.
	大気 : % (Fugacity Model Level I) 水 : % (Fugacity Model Level I) 土壌 : % (Fugacity Model Level I) 生物相 : % (Fugacity Model Level II/III) 土壌 : % (Fugacity Model Level II/III)	Air : % (Fugacity Model Level I) Water : % (Fugacity Model Level I) Soil : % (Fugacity Model Level I) Biota : % (Fugacity Model Level II/III) Soil : % (Fugacity Model Level II/III)
結果		
媒体	大気/水/土壌/底質	air/water/soil/sediment
環境分布予測と媒体中濃度 (levelII/III)	容量 量 (%) 排出 (kg/hr) 大気: 0.00222 % 1000 水: 36.1% 1000 土壌: 63.8% 1000 生物相: : 0.07% 0 容量 量 (%) 排出 (kg/hr) 大気: 0.00572 % 1000 水: 23% 0 土壌: 77% 0 生物相: 0.0446% 0	Mass Amount (%) Emissions (kg/hr) Air : 0.00222 % 1000 Water : 36.1% 1000 Soil : 63.8% 1000 Biota : 0.07% 0 Mass Amount (%) Emissions (kg/hr) Air : 0.00572 % 1000 Water : 23% 0 Soil : 77% 0 Biota : 0.0446% 0
	容量 量 (%) 排出 (kg/hr) 大気: 3.99 e-009 % 0 水: 99.8% 1000 土壌: 5.37 e-005 % 0 生物相: 0.194 % 0 Mass 量 (%) 排出 (kg/hr) 大気: 8.92e-007 % 0 水: 19.1% 0 土壌: 80.9% 1000 生物相: 0.037% 0	Mass Amount (%) Emissions (kg/hr) Air : 3.99 e-009 % 0 Water : 99.8% 1000 Soil : 5.37 e-005 % 0 Biota : 0.194 % 0 Mass Amount (%) Emissions (kg/hr) Air : 8.92e-007 % 0 Water : 19.1% 0 Soil : 80.9% 1000 Biota : 0.037% 0
	Mass 量 (%) 排出 (kg/hr) 大気: 0.00382 % 1000 水: 48.4% 1000 土壌: 51.5% 0 生物相: 0.0939% 0 Mass 量 (%) 排出 (kg/hr) 大気: 0.00275 % 1000 水: 21% 0 土壌: 79% 1000 生物相: 0.	Mass Amount (%) Emissions (kg/hr) Air : 0.00382 % 1000 Water : 48.4% 1000 Soil : 51.5% 0 Biota : 0.0939% 0 Mass Amount (%) Emissions (kg/hr) Air : 0.00275 % 1000 Water : 21% 0 Soil : 79% 1000 Biota : 0.
結論		
注釈		
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	推定プログラムからのデータ	Data are from an estimation program
出典		
引用文献	(323)	(323)
備考	フラグ : SIDSエンドポイントに重要な試験	Flag : Critical study for SIDS endpoint

3.3.2 分配
DISTRIBUTION

3.4 好気性生分解性
AEROBIC BIODEGRADATION

試験物質名	1.1 - 1.4で規定	as prescribed by 1.1 - 1.4
CAS番号		
純度等		

注釈	タイプ：好気性	Type : aerobic
方法	OECD ガイドライン302 B "本質的生分解性: 修正Zahn-Wellens 試験"	OECD Guide-line 302 B "Inherent biodegradability: Modified Zahn-Wellens Test"
培養期間		
植種源	活性汚泥、順化	activated sludge, adapted
GLP	いいえ	no
試験を行った年	1990	1990
試験条件	英文参照	The biodegradability of 161 mono- and disubstituted benzene-derivatives (including Resorcinol) was determined in the static test (Zahn-Wellens) as described in DIN Standard 38412 (L12) or in the OECD Guideline 302B. The principle of this procedure consists of aeration of the test substance under stirring in a mineral medium with inoculum. The test substance is the only source of carbon. The degradation process is followed by the regular determination of the solved carbon content (DOC) or the chemical oxygen demand (COD) adn is described in a degradation graph. From the graph the data can be derived.
	英文参照	The inoculum was taken from the biological waste water treatment plant of HOECHST AG as was dose in a way that 1.1 + 0.1 g/l of dry inoculum was in a test batch. The test substance was added based on stock solutions in such amounts as to acheive DOC concentrations of 50 - 400 mg/L or COD concentrations of 200 - 1000 mg/L. The procedure allows only for testing of water soluble (solubility >100 mg/L) substance, which are non-volatile. The degradation is controlled, as previously mentioned, via the DOC/COD values.
試験物質濃度	COD (科学的酸素要求量)として	related to COD (Chemical Oxygen Demand)
汚泥濃度		
培養温度 ℃		
対照物質および濃度(mg/L)		
分解度測定方法		
分解度算出方法		
結果		
最終分解度(%) 日目	4日後で97 (±) %	97 (±) % after 4 day(s)
分解速度-1		
分解速度-2		
分解速度-3		
分解速度-4		
分解生成物		
上記結果以外の分解度測定方法及びその結果	レゾルシノールは本試験条件下では本質的な生分解性を示した。Tabakらの公表結果と比較することにより、この結果がより確かなものとなる	Resorcinol is inherently biodegradable under the conditions of this test. Comparison of this data with that published by Tabak, H.H et al has confirmed this finding.
対象物質の7，14日目の分解度		
その他		
結論	本質的に生分解性	inherently biodegradable
注釈	英文参照	In this literature, there is an error in reporting the nomenclature of the dihydroxybenzenes. The article indicates the common name resorcinol to be associated with 1,3-Dihydroxybenzene Brenzcatechin as oppossed to 1,2-Dihyrdroxybenzene. The above study summary has corrected this error and reported the data appropriately, the data from 1,3- dihydroxybenzene are associated with resorcinol.
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	ガイドライン試験、GLPでない	Guideline Study; Not GLP
出典		
引用文献	(337)	(337)
備考	フラグ：SIDSエンドポイントに重要な試験	Flag : Critical study for SIDS endpoint

3.5. BOD-5、CODまたはBOD-5／COD比
BOD-5、COD OR RATIO BOD-5/COD

試験物質名		
CAS番号		
純度等		
注釈		
BOD5の算出方法	84/449/EEC指令, C.8 "生分解: 生物学的酸素要求量"	Directive 84/449/EEC, C.8 "Biodegradation: Biochemical Oxygen Demand"
GLP	いいえ	no
試験を行った年	1976	1976
試験条件		
結果		
濃度	66.7 mg/l	66.7 mg/l related to Test substance

結果 mgO_2/L	BOD5 : = 100 mg/l	BOD5 : = 100 mg/l
BOD/COD比	約 1.74	ca. 1.74
その他	英文参照	Resorcinol was one of 123 organic compounds that were tested with respect to the decrease of organic substance in t erms of COD. The test was performed in a batch system. The tested substance is dissolved in a beaker of biological medium in a concentration corresponding to 200 mg 1−1 COD. The tested substance is the sole source of organic carbon for the microbes of the inoculum. To the biological medium such amount of thickened adapted activated sludge is added to make dry matter of the inoculum 100 mg 1−1. The beaker is placed in a dark room with a roughly constant temperature of 20C +/− 3C on an electromagnetic stirrer. The initial value of COD or organic carbon of the liquid phase are determined.
	英文参照	Samples, filtered or centrifuged before analysis are taken at suitable intervals. The decrease of the tested substance in the liquid phase is evaluated by deteremind COD or organic carbon. The results are compared with those of a blank test and standard decomposition. With the degree of degradation also the average specific rate of degradation is determined, expressed in terms of mg COD (or organic carbon) removed by a gramme of dry matter of the activated sludge per hour. For volatile substances a test without the inoculum is to be carried out as well in order to differentiate the actual biological degradation and the losses due to volatilization. At conviently chosen time intervals always ca., 50 − 80 ml of the sample are taken for analysis. Generally it is sufficient to take samples once or twice a day. The values of the blank test are subtracted. The experiment is carried out till there is no decrease of COD. After that time the total percentage of COD removed and the rate of degradation are evaluated. The time of the experiment is 120 hours.
	英文参照	Biological Medium: In ca. 800 ml of distilled water solutions of calcium chloride (27.5 g CaCl2 in 1 l, distilled water), magnesium sulphate (22.5 g MgSO4; 7 H20 in 1 l, distilled water) and ferric chloride (0.25 g FeCl3; 6 H20 in 1 l distilled water) are added in 1 ml portions each. Then 5 ml ammonium sulphate solution [10 g (NH4)2SO4 in 1 l distilled water], 20 ml of a phosphate buffer of pH 7.2 (8.5 g KH2PO4, 21.8 g K2HPO4: 12 H20 in 1 l, distilled water) and 100 ml of tap water for securing the content of trace elements, are added. The solution thus prepared is made up to 1000 ml with distilled water. Inoculum: Activated sludge taken from a sewage plant is cultivated in a 1000 ml volumetric cylinder. The mixture is aerated with pressure air. Every day 200 ml of the mixture is driven off so that the sludge age is 5 days.
		After driving off the 200 ml of the mixture aeration is interupted and after sedimentation ca. 600 ml of the liquid phase is driven off. The residue (200 ml of the thickened activated sludge) is diluted with tap water to the volume of ca. 800 ml and 600 mg/l of starch or glucose, 600 mg/l of peptone, 25 ml of a phosphate buffer pH 7.2, and the solution of the tested compound are added. Then the mixture in the cylinder is made up to 1000 ml with tap water and aerated for 23 h (the recirculation ration is 0.25). After this period the procedure is repeated. The concentration of the test substance is gradually increased so that after 20 days of adaptation it reaches the equivalent value of 200 mg/l COD. During this period an occasional biological analysis is made and the change of biocenosis is evaluated. In case the substance is a toxic one, the sludge must be adapted at lower initial concentrations, and the concentration of hte compound in the actual experiment on degradability is to be decreased equally.

	一般的な試験条件: 順化活性汚泥, 200 MG/L COD 試験物質(唯一の炭素源), ミネラル塩, 暗所、撹拌, 約120時間まで 温度 [C]: 20 測定法: COD システム: 水 分析法: COD 培養期間: 5 日間 順化期間: 20日間 酸素条件: 好気性 微生物量: 100 (MG/L) pH: 7.2 注釈: 動的なシステム	General Test Conditions: ACCLIM ACTIV SLUDGE, 200 MG/L COD TEST CMPD AS SOLE C SOURCE, MINERAL SALTS, DARK, STIRRED, UP TO APPROX 120 HR Temperature [C]: 20 Method: COD System: WATER Analysis method: COD Incubation time: 5 days Acclimation period: 20 days Oxygen Condition: AEROBIC Microbial Population: 100 (MG/L) pH: 7.2 Remarks: VIGOROUS SYSTEM
結論	平均分解速度: 57.5 mg of COD/G/Hr. 分解の程度: 5日間で90% CODによる. 順化により分解速度は上昇	Average rate of Degration: 57.5 mg of COD/G/Hr. Degree of Degradation: 90% within 5 days with respect to COD. Biodegrades fast with acclimation
注釈	方法 : COD 除去 実施年 : 1976 GLP : データなし	Method : COD removal Year : 1976 GLP : no data
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	基本データ及び信頼できる2次情報源からのデータ	Provides basic data and data are from a reliable secondaryliterature source
出典		
引用文献	(247)	(247)
備考		

3.6 生物濃縮性
BIOACCUMULATION

試験物質名	1.1 - 1.4で規定	as prescribed by 1.1 - 1.4
CAS番号		
純度等		
注釈		
方法	BCFWIN v2.15を用いるEPIWIN v3.12	EPIWIN v3.12 using BCFWIN v2.15
生物種		
暴露期間 (日)		
曝露濃度		
排泄期間		
GLP	no	no
試験を行った年	2006	2006
分析方法		
試験条件		
被験物質溶液		
対照物質		
対照物質名及び分析方法		
試験方式/実施		
結果		
死亡率/行動		
脂質含有量 (%)		
試験中の被験物質濃度		
濃縮係数(BCF)	3.16	3.16
取込/排泄定数		
排泄時間		
代謝物		
その他の観察		
結論	Log BCF = 0.500 (BCF = 3.162)	Log BCF = 0.500 (BCF = 3.162)
注釈		
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	推定プログラムからのデータ	Data are from an estimation program
出典		
引用文献	(323)	(323)
備考		

項目名	和訳結果(SIDS Dossier)	原文(SIDS Dossier)

4-1 魚への急性毒性
ACUTE TOXICITY TO FISH

試験物質	レゾルシン DS、分析用試薬(99%レゾルシノール)	Resorcin DS, Technical grade (99% resorcinol)
同一性		
方法	※英文参照	other: follows all major guidelines
GLP	データ無し	no data
試験を行った年	1981	1981
魚種、系統、供給者	*Leuciscus idus* (魚類, 淡水)	*Leuciscus idus* (Fish, fresh water)
エンドポイント		
試験物質の分析の有無	有り	yes
試験物質の分析方法		
結果の統計解析手法	LC50はプロビット分析により算出	The LC50 was calculated via Probit Analysis.
試験条件		
試験魚の月齢、体長、体重	体重: 1.5 – 2.7g; 体長: 5.5 – 6.7cm; 肥満因子: 0.65 – 1.07	Body weight: 1.5 – 2.7g; Body length: 5.5 – 6.7cm; Corpulence factor: 0.65 – 1.07
試験用水量あたりの魚体重		
参照物質での感受性試験結果		
じゅん化条件		
希釈水源	脱イオン水道水	Deionised tap water
希釈水の化学的性質	伝導度 <5 µS/cm 添加塩 – 192 mg NaHCO3, 120 mg CaSO4 . 2H2O, 120 mg MgSO4, 8 mg KCl. pH 8.0 – 8.3 総硬度 9.5° d, 炭酸硬度 6.4° d.	Conductivity <5 µS/cm Added Salts – 192 mg NaHCO3, 120 mg CaSO4 . 2H2O, 120 mg MgSO4, 8 mg KCl. pH 8.0 – 8.3 Total hardness 9.5° d, carbonate hardness 6.4° d.
試験溶液(及び保存溶液)とその調製法		
試験物質の溶液中での安定性		
溶解助剤/溶剤の種類とその濃度		
暴露容器	※英文参照	The test tanks were made of glass and were filled with 20 liters of test water. The test temperature was held constant at 20 ±1° C by a water bath. The tanks were ventilated throughout the entire test period by means of glass capillary rods. Approximately 100 ml/min of air was fed through the tanks. The oxygen content was in excess of 7 mg/L. The tanks were lighted from above in a day-night rhythm of 12 hours each. The lighting intensity directly above the tanks was approximately 700 Lux.
暴露期間	96時間	96 hour(s)
試験方式	止水	static
換水率/換水頻度		
連数、1連当たりの魚数		
影響が観察された少なくとも1濃度区及び対照区における水質		
試験温度範囲		
照明の状態		
平均測定濃度の計算方法		
結果		
設定濃度	0, 10, 25, 31.5, 40, 63 及び 100 mg/L.	0, 10, 25, 31.5, 40, 63 and 100 mg/L.
実測濃度		
生物学的影響観察	生物学的観察: 31.5～100 mg/L 群において、暴露後95時間までに5匹が死亡し、次の症状を伴っていた。– 表層遊泳、異常遊泳、異常な動き、横臥位、鰓反射性減少 。25 及び 10 mg/L群では対照群と比較してこれらの異常行動はみられなかった。 100 mg/L 群では、体表に赤い斑点がみられた。剖検では異常はみられなかった。 pH値及び測定酸素濃度はいずれも対照群と同等のレベルであった。	Biological observations: In the 31.5 to 100 mg/L groups 5 fish died up to 95 hours after addition of the test substance, with the following symptoms – surface swimming, unco-ordinated swimming movements, drifting in a lateral position, hyper-reflexivity, reduced frequency of gill action. The fish in the 25 and 10 mg/L groups did not differ in their behaviour from those in the control groups. The fish in the 100 mg/L group presented with punctate red flecks on the body surface. Dissection showed no macroscopically visible changes in all test groups. The pH value and the measured oxygen concentration were in the same range as test values for the control groups

累積死亡率の表	LC0 (96 hr) = 25 mg/L LC50 (96 hr) = 34.7 mg/L LC100 (96 hr) = 63 mg/L NOEC (96 hr) = 25 mg/L 結果は設定濃度に基づく。 LC50 (96 hr): 95% 信頼区間: 34.7 – 46.8 mg/L 濃度　　死亡率 48 時間　　96 時間 Abs./Rel. (%)　　Abs./Rel (%) 0 0/30　0　0/30　0 10 0/10　0　0/10　0 25 0/10　0　0/10　0 31.5 1/10　10　2/10　20 40 6/10　60　9/10　90 63 10/10　100　10/10　100 100 10/10　100　10/10　100 Abs.=絶対 % Rel.=相対 %	LC0 (96 hr) = 25 mg/L LC50 (96 hr) = 34.7 mg/L LC100 (96 hr) = 63 mg/L NOEC (96 hr) = 25 mg/L The results are based on nominal concentrations. LC50 (96 hr): 95% confidence limit range: 34.7 – 46.8 mg/L Concentration Mortality 48 hours　96 hours Abs./Rel. (%)　Abs./Rel (%) 0 0/30 0　0/30 0 10 0/10 0　0/10 0 25 0/10 0　0/10 0 31.5 1/10 10　2/10 20 40 6/10 60　9/10 90 63 10/10 100　10/10 100 100 10/10 100　10/10 100 where: Abs.=absolute % Rel.=relative %
統計的結果		
注釈		
対照区における死亡率		
異常反応		
その他の観察結果		
結論		
結果(96h-LC50)	NOEC : = 25 mg/l LC50 : = 34.7mg/l LC100 : = 63　mg/l	NOEC : = 25 mg/l LC50 : = 34.7mg/l LC100 : = 63　mg/l
信頼性スコア	(2) 制限付で信頼性あり	(2) valid with restrictions
キースタディ		
信頼性の判断根拠	※英文参照	Provides basic data. Study method follows all major guidelines. No data regarding GLP.
出典		
引用文献	(142)	(142)
備考	※英文参照	Conducting the test: Approximately 65 hours prior to the start of the test, 10 fish were added per test tank. The test substance, previously dissolved in test water, was applied to the test tanks and distributed evenly with a glass rod. Immediately prior to the addition of the test substance, as well as at 2, 24, 48, 72 and 96 hours, the parameters of pH, O2 and temperature were measured in each test tank. During the entire test period fish were observed regularly and their behaviour recorded. Dead fish were removed immediately, dissected and macroscopically The LC50 was calculated via Probit Analysis.
備考	フラグ : SIDSエンドポイントにとって重要な試験	Flag : Critical study for SIDS endpoint

4-2 水生無脊椎動物への急性毒性(例えばミジンコ)
ACUTE TOXICITY TO AQUATIC INVERTEBRATES (DAPHNIA)

試験物質	1.1～1.4で規定	as prescribed by 1.1 – 1.4
同一性		
方法	その他	other
GLP	データ無し	no data
試験を行った年	1977	1977
生物種、系統、供給者	*Daphnia magna* (甲殻類)	*Daphnia magna* (Crustacea)
エンドポイント		
試験物質の分析の有無	データ無し	no data
試験物質の分析方法		
結果の統計解析手法	※英文参照	Values for 48 hour LC50 toxicities and 95 percent confidence intervals, expressed as fractional concentrations of the stock solutions, were obtained by computerized PROBIT analytical procedures. Concentrations of resorcinol were then calculated from compositions of the stock solutions.
試験条件		

試験生物の起源、前処理、繁殖方法	※英文参照	Daphnia magna were maintained in laboratory cultures; two to four day old animals were isolated and utilized for the test. No reproduction occurred during the test period. Ten Daphnia were incubated in 250 ml of each toxicant test solution in 400 ml beakers covered with watch glasses. Temperature was maintained at 20 +/- 0.50C in a growth chamber under a 12-hour light/dark fluorescent lighting regime. Ten drops of homogenized "Trout chow" were added initially as food.
参照物質での感受性試験結果		
試験開始時の時間齢		
希釈水源		
希釈水の化学的性質		
試験溶液(及び保存溶液)とその調製法	※英文参照	Reagent-grade dry chemicals were dissolved in membrane filtered spring water to obtain stock solutions. Preliminary 48 hour LC50 values obtained with adult Daphnia were 2.0 mg/L. Stock solutions were then prepared in spring water at concentrations 10 times the preliminary 48 hour LC50 values (resorcinol 20 mg/L). Individual test solutions were formulated by dilution of appropriate aliquots of the five stock solutions with filtered spring water to final volumes of 250 ml. In each test solutiom the sum of the concentrations was equal to 0.06, 0.08, 0.10, 0.12, 0.14 or 0.16 times the sum of the stock solution concentrations; the range was selected to bracket 48 hour LC50 values predicted from inital toxicity data. Control beakers of spring water without added toxicants were included. The pH remained at 7.5 after the addition of the test substances and throughout the duration of the study. Studies were run in duplicate.
試験物質の溶液中での安定性		
溶解助剤/溶剤の種類とその濃度		
暴露容器		
暴露期間	48時間	48 hour(s)
試験方式	止水	static
連数、1連当たりの試験生物数		
対照区と影響が観察された少なくとも1濃度区における水質		
試験温度範囲		
照明の状態		
平均測定濃度の計算方法		
結果		
設定濃度		
実測濃度		
遊泳阻害数		
累積遊泳阻害数の表		
注釈		
対照区における反応は妥当か		
対照区における反応の妥当性の考察		
結論		
結果(48h-EC50)	LC50 : = 1.28 mg/l 95% 信頼区間 0.50-1.62 mg/l	LC50 : = 1.28 mg/l 95% Confidence range 0.50-1.62 mg/l
信頼性スコア	(2) 制限付で信頼性あり	(2) valid with restrictions
キースタディ		
信頼性の判断根拠	基本的データが示されている	Provides basic data
出典		
引用文献	(132)	(132)
備考	※英文参照	Based on lack of indication of analytical monitoring we believe these results to be nominal. To assist in assessing coal conversion effluents mixtures resorcinol and 6-methylquinoline were investigated in daphnia magna. Toxicant test solutions were prepared to to evaluate both test substances individually and together as a mixture. Only individual resorcinol results have been presented in this summary.
備考	フラグ : SIDSエンドポイントにとって重要な試験	Flag : Critical study for SIDS endpoint

4-3 水生植物への毒性(例えば藻類)
TOXICITY TO AQUATIC PLANTS e. g. ALGAE

試験物質	1.1～1.4で規定	as prescribed by 1.1 - 1.4
同一性		
方法	OECDガイドライン201"藻類生長阻害試験"	OECD Guide-line 201 "Algae, Growth Inhibition Test"

方法	※英文参照	Testing was conducted for 72 hours with a temperature of 24 – 25C, pH of 7.0. –7.2 at test initiation and 7.8 to 9.2 at termination, continuous illumination of stock cultures at 650 to 850 footcandles (7000 – 9100 lux) and a shaking rate of 100 rpm. Increase in pH in static algal studies is common due to photosynthesis of the algae. The culture medium that used was Algal Assay Procedure (AAP) medium. Stock solutions were prepared with sterile dionized water. The Total Organic Carbon sample collected was 0.21 mg/L. The pH of the test medium was kept at 7.5 and a temperature of 24 +/– 1C. Stock cultures were grown in 250 ml glass flasks each containing 100 mL of medium. The flasks were covered by stainless steel caps allowing for gas exchange. The AAP medium used to prepare exposure solutions was formulated in the same manner as the culture medium. A 100 mg/L primarly stock solution was prepared by placing 0.2003 g Resorcinol in a 2–L flask and bringing it to volume with AAP medium. The resulting stock solution was clear and colorless with no visible undissolved test substance present.
方法	※英文参照	Three replicates were done per treatment level while six replicates were done per treatment for the controls. After test solutions were added to the flasks, a 0.191mL inoculum of pseudokirchneriella subcapitata cells, at a density of 524 x 10E4 cells/mL were introduced into each flask. This inoculum provided the initial (0) hour cell density of 1.0 x 10E4 cells/mL. At each 24 hour interval cell counts were performed on all three replicates, the treatment solutions and the six control vessels.
GLP	はい	yes
試験を行った年	2006	2006
生物種、系統、供給者	その他の藻類: *Pseudokirchneriella subcapitata* (緑藻) strain 1648	other algae: *Pseudokirchneriella subcapitata* (green algae) strain 1648
エンドポイント	その他:生長及びバイオマス	other: growth and biomass
毒性値算出に用いたデータの種類		
試験物質の分析の有無	有り	yes
試験物質の分析方法	※英文参照	Analytical measurements were done on test and control solutions at test initiation (0 hours) and again at 72 hours. All exposure and control solutions were measured using HPLC/UV. Defined limits for acceptance of quality control performance in subsequent studies were set at 82.5 to 113%. Conditions and procedures used throughout the analysis of exposure solution and QC samples during the study were similiar to those used in the method validation study with the following exceptions: Due to high test concentrations, a higher standard curve was used. Calibrations standards were prepaerd in reagent grade water at concentrations of 0.0500, 0.100, 0.250, 0.300 and 0.500 mg/L. In order to ensure that a similar quantity of material was injected onto the HPLC columne the injection volume was decreased to 100 µL. Test samples were diluted into the standard range with reagant grade water.
結果の統計解析手法	※英文参照	Statistical Analysis: Data were checked for normality using Shapiro–Wilks Test and for homogeneity of variation using Bartletts Test. If the data sets passed the test for homogeneity and normality, Williams test was used to detect treatment levels that were significantly different from the control data. If the data did not pass the test, the Kruskal–Wallis' test was used to determine the NOEC. All statistical determinations were made at the 95% level of certainty except in the case of Shapiro–Wilks and Bartletts test where the 99% level of certainty was applied.
試験条件		
試験施設での藻類継代培養方法		
藻類の前培養の方法及び状況		
参照物質での感受性試験結果		
希釈水源		
培地の化学的性質		
試験溶液(及び保存溶液)とその調製法		

試験物質の溶液中での安定性		
溶解助剤/溶剤の種類とその濃度		
暴露容器		
暴露期間	72時間	72 hour(s)
試験方式		
連数		
各濃度区の少なくとも1連における試験開始時と終了時の水質		
試験温度範囲		
照明の状態		
平均測定濃度の計算方法		
結果		
設定濃度	3.1, 6.3, 13. 25. 50 及び 100mg/L	3.1, 6.3, 13. 25. 50 and 100mg/L
実測濃度	3.0, 5.8, 12, 24, 47 及び 97 mg/L	3.0, 5.8, 12, 24, 47 and 97 mg/L
細胞密度		
生長阻害率(%)		
各濃度区における生長曲線		
その他観察結果	レゾルシノールは水生植物/藻類に有害ではない。	Resorcinol is not anticpated to be toxic to aquatic plants/algae.
注釈	EbC50 > 97 (最高試験実測平均濃度) ErC50 > 97 (最高試験実測平均濃度) NOECb = 47 mg/L NOECr = 97 mg/L (最高試験実測平均濃度) バイオマス: 50%以上阻害のみられた濃度はなかった。 72時間EbC50は実験的に >97 mg/L(最高試験実測平均濃度)と推定された。 72時間NOECは47 mg/L.と決定された。 統計分析 (William's Test)により97mg/l群で対照群と比較してバイオマスの有意な減少が認められた。従って、NOECは47 mg/Lと決定された。. 生長速度: 50%以上阻害のみられた濃度はなかった。 72時間EbC50は実験的に >97 mg/L(最高試験実測平均濃度)と推定された。 72時間NOECは97mg/L.と決定された。 EC50値は実験的推定なので95%信頼区間は算出されなかった。	EbC50 > 97 (highest mean measured dose tested) ErC50 > 97 (highest mean measured dose tested) NOECb = 47 mg/L NOECr = 97 mg/L (highest mean measured dose tested) Biomass: No concentration resulted in > 50% inhibition. The 72 hour EbC50 was empirically estimated to be >97 mg/L, the highest mean measured concentration tested. The 72 hour NOEC was determined to be 47 mg/L. Statistical analysis (William's Test) determined a significant reduction in cell biomass at the 97 mg/L treatment level when compared to the control. Therefore the NOEC was determined to be 47 mg/L. Growth reate: No concentration resulted in > 50% inhibition. The 72 hour ErC50 was empirically estimated to be >97 mg/L, the highest mean measured concentration tested. The 72 hour NOEC was determined to be 97 mg/L. When the EC50 values were empirically estimated, the 95% confidence limits could not be calculated.
対照区での生長は妥当か		
対照区における反応の妥当性の考察		
結論		
結果(ErC50)	EC50 : > 97 mg/l	EC50 : > 97 mg/l
結果(NOEC)	NOECb : = 47 mg/l NOECr : = 97 mg/l	NOECb : = 47 mg/l NOECr : = 97 mg/l
信頼性スコア	(1) 制限なく信頼性あり	(1) valid without restriction
キースタディ		
信頼性の判断根拠	ガイドライン試験	Guideline Study
出典		
引用文献	(295)	(295)
備考	※英文参照	Additional testing was not performed since the highest nominal concentration tested (100 mg/L) was equal to the maximum test concentration required by study guidelines.
備考	フラグ : SIDSエンドポイントにとって重要な試験	Flag : Critical study for SIDS endpoint

4-4 微生物への毒性(例えばバクテリア)
TOXICITY TO MICROORGANISMS e. g. BACTERIA

4-5 水生生物への慢性毒性
CHRONIC TOXICITY TO AQUATIC ORGANISMS

A. 魚への慢性毒性
CHRONIC TOXICITY TO FISH

B. 水生無脊椎動物への慢性毒性
CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

4-6 陸生生物への毒性
TOXICITY TO TERRESTRIAL ORGANISMS

A. 陸生植物への毒性
TOXICITY TO TERRESTRIAL PLANTS

B. 土壌生物への毒性
TOXICITY TO SOIL DWELLING ORGANISMS

C. 他の非哺乳類陸生種（鳥類を含む）への毒性
TOXICITY TO OTHER NON-MAMMALIAN TERRESTRIAL SPECIES （INCLUDING AVIAN）

4-6-1底生生物への毒性
TOXICITY TO SEDIMENT DWELLING ORGANISMS

4-7 生物学的影響モニタリング（食物連鎖による蓄積を含む）
BIOLOGICAL EFFECTS MONITORING （INCLUDING BIOMAGNIFICATION）

4-8 生体内物質変換と動態
BIOTRANSFORMATION AND KINETICS

4-9 追加情報
ADDITIONAL INFORMATION

項目名	和訳結果（SIDS Dossier）	原文（SIDS Dossier）

5-1 トキシコキネティクス、代謝、分布
TOXICOKINETICS, METABOLISM, and DISTRIBUTION

試験物質名	1.1～1.4で規定	as prescribed by 1.1 – 1.4
CAS番号		
純度等	レゾルシノール（AO11）、純度 >95%	Resorcinol (AO11), >95% purity
注釈		
方法		
方法／ガイドライン	その他：OECD TG 408	other: OECD TG 408
試験形態	In vivo トキシコキネティクス	In vivo Toxicokinetics
GLP適合	はい	yes
試験をおこなった年	2004	2004
方法の概略	暴露期間：90日 本試験はOECDガイドライン408、1988年9月21日に準拠するようにデザインされた。 ※英文参照	Exposure time : 90 day(s) The study was designed to comply with OECD Guideline No. 408, 21 September 1998. Three treated groups of 10 male and 10 female Sprague-Dawley rats received the test item, Resorcinol (A011), (batch No. 706030517), daily by gavage at 40, 80 or 250 mg/kg/day for 13 weeks. An additional group of 10 males and 10 females received only the vehicle (purified water) and acted as a control group. At 0 and 250 mg/kg/day (groups 1 and 4), six animals of each sex were treated for 13 weeks and then kept for a 4-week treatment-free period. Six animals of each sex in groups 2, 3 and 4 were used for toxicokinetic investigations; blood samples were taken from the animals on day 1 and in week 13 at the following time-points: 0.5, 1, 2, 4, 8 and 24 hours post-dosing, and each animal was sampled on three occasions. See Section 5.4 for additional details.
方法の概略	※英文参照	Blood samples were taken from the animals on day 1 and in week 13 at the following time-points: . 0.5, 1, 2, 4, 8 and 24 hours post-dosing. For each time-point, three animals/sex/group were sampled (groups 2, 3 and 4), and each animal was sampled on three occasions. Venous blood (approximately 0.5 mL) was taken from the orbital sinus of the animals under light isoflurane anesthesia into a tube containing lithium heparin. The blood was centrifuged, and the plasma was kept frozen in individual tubes at -20° C until analysis after the development and validation of the analytical method.
方法の概略	※英文参照	The toxicokinetic parameters were calculated, according to standard non-compartmental methods, using Excel 2000 software installed on a personal computer. The following parameters were determined: Cmax, maximal plasma concentration measured, tmax, time of occurrence of this maximal plasma concentration, AUCx-t, Area under the concentration-time curve (calculated according to the linear trapezoidal rule) from time 0 to the last quantifiable data-point.
動物種	ラット	rat
試験動物：系統		
性別		
細胞株		
年齢		
体重		
試験動物数	雄： 40匹 雌： 40匹	Males : 40 Females : 40
曝露経路	強制経口	gavage
溶媒（賦刑剤）		
投与量	雄：0、40、80 及び 250 mg/kg/日 雌：0、、40、80 及び 250 mg/kg/日	Males : 0, 40, 80 and 250 mg/kg/day Females : 0, 40, 80 and 250 mg/kg/day
統計手法	統計解析は必要に応じて以下の検定法を用いて行った。Kolmogorov-Lilliefors 検定、Dunn 検定、Mann-Whitney/Wilcoxon 検定、Student 検定、Bartlet 検定 及び Fischer 検定。.	Statistical analysis were peformed using the followng tests when appropriate: Kolmogorov-Lilliefors test, Dunn test, Mann-Whitney/Wilcoxon test, Student test, Bartlet test and Fischer test.
実際に投与された量		
排泄経路		
採取体液		
採取組織		
代謝産物		

代謝産物 CAS No.		
結果		
試験結果	試験物質を40、80及び250 mg/kg/日で投与した2、3及び4群に対して第1日に測定したとき、血漿レゾルシノール (A011)レベルは全ての時点 (8時間の2群の雄、24時間の3群の雄、及び4時間での3群の雌、及び24時間での4群の雄を除く)で少なくとも2匹の動物で定量可能であった。これに対し、13週には試験物質の血漿レベルは2群に対しては全時点で全般的に検出限界(0.5 µg/mL)以下となり、3群及び4群に対しては0.5-2時間でのみ検出可能であった。	When measured on day 1, for groups 2, 3 and 4, which received the test item at 40, 80 and 250 mg/kg/day, plasma levels of Resorcinol (A011) were quantifiable at least for two animals at all time-points (except for group 2 males at 8 hours, for group 3 males at 24 hours and females at 4 hours, and for group 4 males at 24 hours). In contrast, in week 13, plasma levels of the test item were generally below the limit of quantification (0.5µg/mL) at all time-points for group 2, and only quantifiable at 0.5 to 2 hours for groups 3 and 4.
試験結果	全投与群に対して、試験物質の血漿レベルは全般的に第1日の最初の検出可能時点の0.5時間から急激に増加し、0.5-2時間で(最初の)最大値のCmaxに到達した。一部の例では第二のCmaxが8/24時間後にみられた。2群及び3群の雌では24時間後に認められた第二のCmaxが実際、観測された血漿中最高レベルであった。Cmax及びAUC0-tで測定されたように、第1日の暴露量は試験物質の用量レベルとともに明らかな増加を示さなかった。レゾルシノール (A011)の平均濃度は40及び80 mg/kg/日で24時間にわたり安定であり、試験物質が腸肝循環の可能性が示唆された。250 mg/kg/日では0.5時間からCmaxに到達し、血漿レベルは以降徐々に減少した。	For all treated groups, plasma levels of the test item generally increased quickly from the first quantifiable time-point at 0.5 hours on day 1 to reach a (first) maximum Cmax at 0.5-2 hours. In some cases, a second Cmax was seen at 8/24 hours. For groups 2 and 3 females, the second Cmax noted at 24 hours actually was the highest observed plasma level. The exposure on day 1, as measured by the Cmax and by AUC0-t, showed no clear increase with test item dose-level. The mean concentration of Resorcinol (A011) remained stable over the 24 hour-period at 40 and 80 mg/kg/day, which may suggest enterohepatic recycling of the test item. At 250 mg/kg/day, the Cmax was reached from 0.5 hour and plasma levels gradually decreased thereafter.
試験結果	13週には0.5時間での最初の検出可能時点が最大濃度であった。(Cmax及びAUC0-tで測定した通り)13週での暴露量は非直線的な様式で用量に応じて増加した。 レゾルシノール (A011)の血漿レベルは低度から中等度の動物の個体差により特徴づけられた。	In week 13, the first quantifiable time-point at 0.5 hours was the maximal concentration. The exposure in week 13 (as measured by the Cmax and by AUC0-t) increased with dose-level in a supra linear manner. Resorcinol (A011) plasma levels were characterized by a low to moderate interanimal variability.
試験結果	サンプルング期間: 第1日 40 mg/kg/日 雄 雌 動力学パラメータ: C(max) (µg/mL): 1.45 1.31 t(max) (h): 1(p) 24(p) AUC(0-t) (µg*h/mL): 24.0 25.7 比率、C(max)/用量: 0.036 0.0327 比率、AUC/用量 0.600 0.643 80 mg/kg/日 雄 雌 動力学パラメータ: C(max) (µg/mL): 1.13 1.07 t(max) (h): 2(p) 24(p) AUC(0-t) (µg*h/mL): 6.25 18.0 比率、C(max)/用量: 0.014 0.013 比率、AUC/用量 0.078 0.225 250 mg/kg/日 雄 雌 動力学パラメータ: C(max) (µg/mL): 2.37 9.29 t(max) (h): 0.5 0.5 AUC(0-t) (µg*h/mL): 6.12 31.8 比率、C(max)/用量: 0.009 0.037 比率、AUC/用量 0.024 0.127 ここで: p = プラトーのレベルに向けての傾向、0.5-24時間にかけて異なる時点でいくつかのピークが認められたため。	SAMPLING PERIOD: Day 1 40 mg/kg/day Male Female Kinetic parameter: C(max) (µg/mL): 1.45 1.31 t(max) (h): 1(p) 24(p) AUC(0-t) (µg*h/mL): 24.0 25.7 Ratio, C(max)/dose: 0.036 0.0327 Ratio, AUC/dose 0.600 0.643 80 mg/kg/day Male Female Kinetic parameter: C(max) (µg/mL): 1.13 1.07 t(max) (h): 2(p) 24(p) AUC(0-t) (µg*h/mL): 6.25 18.0 Ratio, C(max)/dose: 0.014 0.013 Ratio, AUC/dose 0.078 0.225 250 mg/kg/day Male Female Kinetic parameter: C(max) (µg/mL): 2.37 9.29 t(max) (h): 0.5 0.5 AUC(0-t) (µg*h/mL): 6.12 31.8 Ratio, C(max)/dose: 0.009 0.037 Ratio, AUC/dose 0.024 0.127 where: p = trend towards a plateau level, as several peaks may be noted at different time-points from 05. to 24 hours.

試験結果	サンプリング期間：13週 40 mg/kg/日 雄　雌 動力学パラメータ： C(max) (μg/mL): nc 0.59 t(max) (h): nc 0.5 AUC(0-t) (μg*h/mL): nc 0.15 比率、C(max)/用量: nc 0.015 比率、AUC/用量 nc 0.004 80 mg/kg/日 雄　雌 動力学パラメータ： C(max) (μg/mL): 2.28 4.48 t(max) (h): 0.5 0.5 AUC(0-t) (μg*h/mL): 1.31 3.61 比率、C(max)/用量: 0.029 0.056 比率、AUC/用量 0.016 0.0451 250 mg/kg/日 雄　雌 動力学パラメータ： C(max) (μg/mL): 17.9 13.8 t(max) (h): 0.5 0.5 AUC(0-t) (μg*h/mL): 10.9 27.5 比率、C(max)/用量: 0.072 0.055 比率、AUC/用量 0.044 0.110	SAMPLING PERIOD: Week 13 40 mg/kg/day Male Female Kinetic parameter: C(max) (μg/mL): nc 0.59 t(max) (h): nc 0.5 AUC(0-t) (μg*h/mL): nc 0.15 Ratio, C(max)/dose: nc 0.015 Ratio, AUC/dose nc 0.004 80 mg/kg/day Male Female Kinetic parameter: C(max) (μg/mL): 2.28 4.48 t(max) (h): 0.5 0.5 AUC(0-t) (μg*h/mL): 1.31 3.61 Ratio, C(max)/dose: 0.029 0.056 Ratio, AUC/dose 0.016 0.0451 250 mg/kg/day Male Female Kinetic parameter: C(max) (μg/mL): 17.9 13.8 t(max) (h): 0.5 0.5 AUC(0-t) (μg*h/mL): 10.9 27.5 Ratio, C(max)/dose: 0.072 0.055 Ratio, AUC/dose 0.044 0.110
試験結果	結論として、本トキシコキネティクス試験は40、80又は250 mg/kg/日で強制経口によりレゾルシノール (A011)を投与された動物の十分な暴露量を証明した。投与量、性及び時間及に関連した観察所見からは明確な結論は導けなかった。 5.4章の付属的な詳細を参照。	In summary, this toxicokinetic study demonstrated the adequate exposure of animals given Resorcinol (A011) by gavage at 40, 80 or 250 mg/kg/day. No clear conclusion could be drawn from the dose-, sex- and time-related observations. See Section 5.4 for additional details.
結論		
結論	結論： 結論として、本トキシコキネティクス試験は40、80又は250 mg/kg/日で強制経口によりレゾルシノール (A011)を投与された動物の十分な暴露量を証明した。投与量、性及び時間及に関連した観察所見からは明確な結論は導けなかった。	Conclusion : In summary, the toxicokinetic study demonstrated the adequate exposure of animals given Resorcinol (A011) by gavage at 40, 80 or 250 mg/kg/day. No clear conclusion could be drawn from the dose-, sex- and time-related observations.
信頼性	(1) 制限なく信頼性あり	(1) valid without restriction
信頼性の判断根拠		
出典		
引用文献（元文献）	(55)	(55)
備考		

試験物質名	1.1～1.4で規定	as prescribed by 1.1 - 1.4
CAS番号		
純度等	14C標識試験物質。放射化学純度：97%; 非標識レゾルシン　純度：> 99%	14C radiolabelled test substance. Radiochemical purity: 97%; Non-radioactive resorcinol purity: > 99%
注釈		
方法		
方法／ガイドライン	その他	other
試験形態	In vivo トキシコキネティクス	In vivo Toxicokinetics
GLP適合	データなし	no data
試験をおこなった年	1987	1987
方法の概略	暴露期間：5日間 ※英文参照	Exposure time : 5 day(s) In-house method to determine comparative metabolism and resorcinol in male and female F344 rats. The study was undertaken in two parts: disposition study and repeated exposure. For the disposition study, groups of rats were treated by oral administration of 112 or 225 mg/kg of 14C Resorcinol and sacrificed by carbon dioxide asphyxiation either 4, 8, 12, 16, 20 or 24 hours later and immediately dissected. Samples of each of the major tissues were taken, weighed, and stored at -20° C until assayed.

方法の概略	※英文参照	For the repeated exposure study, rats of both sexes were treated by oral administration of 225 mg/kg of 14C Resorcinol for 5 consecutive days. Male and female Fischer 344 rats (150 −170 g; obtained from Charles River Breeding Laboratories, Raleigh CA) were housed at room temperature in individual metabolism cages for separate collection of urine and feces. Rat urine was collected in a vessel submerged in dry ice to minimize the possible breakdown of metabolites. Water and pelleted NIH 31 rat chow were provided ad libitum. Radiolabeled resorcinol was diluted with unlabeled resorcinol to administer approximately 5 Ci per rat. For oral administration, corn oil was used as a vehicle and saline was used for iv treatment.
方法の概略	※英文参照	14C radioactivity in each tissue was analyzed by combustion of triplicate 50− or 100−mg samples to 14C02 on a Packard TriCarb sample oxidizer The 14CO2 was counted with liquid scintillation counter. Samples of urine (0.02 ml) were counted directly without combustion. Body composition estimates for blood and muscle were 8 and 50%, respectively (Matthews and Anderson, 1975), and for adipose tissue and skin, 11 and 16%, respectively (Birnbaum et al., 1980). All other tissue volumes were determined gravimetrically. Fecal samples were air dried, weighed, and ground to a fine powder with a mortar and pestle before the radioactivity was determined.
方法の概略	※英文参照	CO2 collection. Following oral administration of [14C] resorcinol, each rat was placed in a Metabowl Mark III glass metabolism cage (Jencons Ltd., Hemel Hemstead, Hertfordshire, England) maintained at an air flow rate of 0.4 to 0.5 liters/min. Total air flow through the cage was passed through an ethanol (200 ml) trap for collection of volatiles and then through 200 ml of 2−methoxyethanol: ethanolamine mixture (7:3) for 14CO2 collection. The percentages of the total dose of [14C] resorcinol eliminated as 14C02 and volatiles were determined by counting triplicate 1−ml aliquots of each trapping solution.
方法の概略	※英文参照	Biliary excretion. Excretion of [14C] resorcinol−derived radioactivity in the bile was determined in rats anesthetized with pentobarbital 50 mg/kg ip and 50 mg/kg po (Matthews, 1978). After the common bile duct was cannulated, [14C] resorcinol was injected into a femoral or tail vein and serial bile samples were collected for 6 hr. The radioactivity in each sample was determined by liquid scintillation counting of triplicate I0−µl aliquots.
方法の概略	※英文参照	Metabolism of resorcinol. The metabolites and parent compound in the urine were analyzed by HPLC equipment attached to a Flow−One/Beta Model CT radioactive flow detector Enzymatic and acid hydrolysis of metabolites in urine. Radioactivity excreted in urine was subjected to enzymatic or acid hydrolysis. For enzymatic digestion, the incubation mixture contained urine and ß−glucuronidase, or arylsulfatase in sodium acetate buffer . D−Saccharic acid 1,4−lactone was added to inhibit ß −glucuronidase activity in the arylsulfatase preparation. Similar incubations minus enzyme, served as controls. All incubations were carried out at 37° C for 15 hr. The resulting hydrolysates were analyzed by HPLC.
動物種	ラット	rat
試験動物:系統		
性別		
細胞株		
年齢		
体重		
試験動物数	雄: 3匹 雌: 3匹	Males : 3 Females : 3
曝露経路	その他: 強制経口及び静脈注射	other: gavage and iv injection
溶媒(賦刑剤)	その他: コーン油 (経口投与)、生理食塩水 (静脈内注射)	other: corn oil (oral administration), saline (iv injection)
投与量	雄 : 112 及び 225 mg/kg 雌 : 112 及び 225 mg/kg	Males : 112 and 225 mg/kg Females : 112 and 225 mg/kg

統計手法	データ解析 雄と雌ラットの差異を比較するために、Studentの両側t検定を用いた。	Data analysis. A two-tailed Student's t test was used to compare the difference between male and female rats.
実際に投与された量		
排泄経路		
採取体液		
採取組織		
代謝産物		
代謝産物　CAS　No.	グルクロン酸抱合体	Glucuronide c
結果		
試験結果	試験物質は雌雄ラットにより、消化管から容易に吸収され、急速に代謝されて排泄された。両性ともに、112 mg/kgの経口投与後24時間以内に投与量の大部分 (> 90%)が尿中に排泄され、動物組織での生体蓄積の可能性は殆どないことが示唆された。経口用量の3%未満(1.5 - 2.1%)が糞中に排泄された。血中及び肝臓、皮膚、脂肪、筋肉、大腸内容物及び甲状腺などの主要な組織には残留14C放射能が検出され、生体内蓄積の証拠は得られなかった。胆汁の分析から胆汁中に排泄された投与量の少なくとも50%が腸肝循環を生じ、最終的に尿中に排泄されることが示された。主代謝物 (約65%)はモノグルクロン酸抱合体で、マイナー代謝物としてモノ硫酸抱合体、硫酸-グルクロン酸混合物の抱合体、及びニグルクロン酸抱合体が検出された。親化合物の僅か (<5%)しか尿中に排泄されなかった。投与量の大半は3つの主代謝物及び1つのマイナー代謝物の形であった。排泄された代謝物の相対的な量は時間、及び投与量の変化につれて、軽度にしか変化しなかった。雌雄の尿中の総放射能の約70%がグルクロン酸抱合体の形で存在した。投与量のうち硫酸抱合体が占める割合は雌ラットのほうが雄よりも多く排泄した。雄は硫酸及びグルクロン酸の二抱合体をより多く排泄した。最大5回の1日暴露量の反復暴露と単回投与後に観察された吸収、代謝、及び排泄のパターンには明らかな変化はなかった。	The test substance was readily absorbed from the gastrointestinal tract, rapidly metabolized and excreted by male and female rats. In both sexes, most of the dose (> 90%) was excreted in the urine within 24 hours after oral administration of 112 mg/kg, indicating little potential for bioaccumulation in animal tissues. Less than 3% (1.5 - 2.1%) of an oral dose was excreted in the faeces. The remaining 14C activity was detected in blood and major tissues such as liver, skin, fat, muscle, large intestine content and thyroid gland, and gave no indication of bioaccumulation. An analysis of bile indicated that at least 50% of the dose excreted in bile undergoes enterohepatic circulation to be eventually excreted in urine. The major metabolite (ca. 65 %) was a monoglucuronide conjugate and minor metabolites included a monosulphate conjugate, a mixed sulfate-glucuronide conjugate, and a diglucuronide conjugate. Little (<5%) of the parent compound was excreted in urine; most of the dose was in the form of three major and one minor metabolite. The relative amounts of metabolites excreted changed only slightly with time and dose administered. Approximately 70% of the total radioactivity in the urine of both sexes was in the form of glucuronide conjugate. Female rats excreted a greater portion of the dose as a sulfate conjugate than males. Males excreted more of a diconjugate both sulfate and glucuronide groups. Repeated exposure to up to five daily doses resulted in no apparent alteration of the pattern of absorption, metabolism and excretion observed after a single dose.
試験結果	これらのデータから、著者らはレゾルシノールをグルクロン酸化する能力は雄ラットが雌よりも高いと結論した。225 mg/kg体重投与後、又は225 mg/kg体重の1日用量を5日連続投与後の同一の試験において、同様の結果が得られた。ラットではレゾルシノールは主に尿を介して排泄された。	From these data the authors concluded that male rats have a higher capacity for glucuronidation of resorcinol than females. In the same study after dosing with 225 mg/kg bw or daily doses of 225 mg/kg bw for 5 consecutive days, comparable results were obtained; in rats, resorcinol was excreted primarily through the urine.
結論		
結論		
信頼性	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	データは信頼性のある二次情報源から得られているので、2の信頼性を割り当てた。	Reliability of 2 assigned because data are taken from a reliable secondary literature source
出典		
引用文献(元文献)	(181)	(181)
備考		

試験物質名	1.1～1.4で規定	as prescribed by 1.1 - 1.4
CAS番号		
純度等		
注釈	14C放射標識レゾルシノール	14C radiolabelled resorcinol
方法		
方法／ガイドライン	その他	other
試験形態	In vivo 代謝	In vivo Metabolism
GLP適合	データなし	no data
試験をおこなった年	1982	1982
方法の概略	暴露期間:　30日間 ※英文参照	Exposure time : 30 day(s) To select the dose levels for the pharmacokinetic excretion and tissue distribution studies, male rats (Charles River, COBS, CD(SD)), weighing 269 to 352 g, were divided into 5 groups of 5 rats each. Animals were injected subcutaneously with doses of resorcinol of 55, 88, 140, 220 and 350 mg/kg. The animals were then observed for treatment-related effects. Pharmacokinetic studies were performed with groups of adult, male Sprague-Dawley rats weighing 200-250 g. They were given a single subcutaneous dose of resorcinol (10 or 50 or 100 mg/kg) containing trace amounts of 14Cresorcinol. Two or three rats were sacrificed at 1, 3, 6 and 24 hours after injection for the collection of blood and specimens of kidney, liver, brain, intestines, spleen, and muscle. Urine and feces were obtained when available. Retro-orbital blood was collected from the rats at early and intermediate times after dosing.

方法の概略	※英文参照	For multiple-dose studies, rats were treated daily with unlabeled resorcinol at a total dose of 100 mg/kg, given subcutaneously in two divided doses of 50 mg/kg, each given 6 hours apart. After 14 days and 30 days of treatment, groups of rats were injected with a single 50 mg/kg dose of resorcinol containing trace amounts of 14C-resorcinol. Then, 3 rats were sacrificed 1, 3, 6 and 24 hours after injection for the collection of tissues, blood, feces and urine. Blood samples also were obtained from the retro-orbital sinus at intervals of 15 minutes for the first hour, and at 2, 3, and 6 hours.
方法の概略	※英文参照	All tissues and organs were preweighed. Two sections from different areas were obtained and digested in 2.0 ml of PROTOSOL® tissue solubilizer at room temperature for at least 48 hours; a few drops of 30% hydrogen peroxide solution were added for discoloration and the radioactivity was measured by scintillation counting. Samples of feces and intestinal contents were homogenized with 10-15 ml of water and the radioactivity was then determined by counting. The urine and plasma samples were analysed by TLC and autoradiography before and after enzymatic hydrolysis. GC/MS was used for final confirmation of the molecular structure of the metabolites. Standard error of the means (S.E.M) was estimated from the range (Mantel, 1951).
動物種	ラット	rat
試験動物:系統		
性別		
細胞株		
年齢		
体重		
試験動物数	雄: 25匹	Males : 25
曝露経路	皮下	s.c.
溶媒(賦刑剤)	水	water
投与量	雄 : 100 mg/kg	Males : 100 mg/kg
統計手法		
実際に投与された量		
排泄経路		
採取体液		
採取組織		
代謝産物		
代謝産物 CAS No.		
結果		
試験結果	注釈: ヒトの血漿及び尿を用いて追加試験が行われた。これらの結果はYeung et al (1981 and 1983)に別々に登録して示されている。	Remark : Additional studies were conducted using human plasma and urine. These results are located in a separate entry Yeung et al (1981 and 1983).
試験結果	結果: 用量選択試験において、55及び88 mg/kg用量レベルでは肉眼的な毒性徴候はみられなかった。中等度から顕著な強直性痙攣へと進行する軽度の振戦が140 mg/kg以上の投与後10分で生じた。投与後1-1.5時間までにそのような影響を受けた動物の全例が完全に回復した。これらの観察所見をもとに、100 mg/kgが薬物動態試験の最大用量として選択された。	Result : In the dose selection studies, no gross toxic signs were observed at 55 and 88 mg/kg dose levels. Slight tremors, which progressed to moderate to marked tonic clonic convulsions, occurred with 10 minutes following doses greater than or equal to 140 mg/kg. Complete recovery occurred in all animals so affected by 1 - 1.5 hours following dosing. On basis of these observations, 100 mg/kg was selected as the maximum dose for the pharmacokinetic studies.
試験結果	この1日の総量を50 mg/kgの2回皮下注射として30日間にわたり与えた結果、明らかな毒性症状はなく、体重増加量、臓器重量(肝臓、腎臓、脳、脾臓及び精巣)、ヘマトクリット、ヘモグロビン、赤血球数及び血清T3及びT4にも有害な変化を示さなかった。追加的な病理組織学的検査では検査した3つの臓器:甲状腺、脊髄及び脳では正常の範囲内であると判断された。	This total daily dose, given as two 50 mg/kg subcutaneous injections over a 30 day period did not result in any overt toxic signs or adverse changes in body weight gain, organ weight (liver, kidney, brain, spleen and testes), hematocrit, hemoglobin, red blood cell count and serum T3 and T4. Additional, histopathology was judged to be within normal limits for the three organs examined: thyroid gland, spinal cord and brain.
試験結果	レゾルシノール水溶液を皮下投与後のラットから得られた薬物動態額的なデータは本剤は組織に生体内蓄積されずに血漿中から速やかに排泄される(投与後2時間以内に尿中に90%)ことを示す。 消失は2相性で、18-21分及び8.6-10.5時間の半減期を示した。10 mg/kg体重投与後24時間以内に適用量の9%が尿を介して、1%が糞を介して主にグルクロン酸抱合体(84%)として排泄された。14C放射活性は生体内蓄積することなく、筋肉、腎臓及び肝臓のような主要な組織に速やかに分布した。	Pharmacokinetic data obtained from the rat following subcutaneous treatment with aqueous solutions of resorcinol show that the drug is rapidly eliminated from plasma without bioaccumulation in tissues (90% in urine within two hours of dosing). The elimination was biphasic with half-lives of 18 - 21 min and 8.6 - 10.5 hrs. Within 24 hrs after dosing with 10 mg/kg bw, 9% of the applied dose was excreted via urine and 1 % via feces, mainly as glucuronide conjugate (84%). The 14C activity was rapidly distributed in major tissues such as muscles, kidneys and liver without indication of bioaccumulation.

試験結果	主な排泄経路は尿 (95%を示し、残りは糞中から回収された)で、ラット(及び恐らくウサギでも)主代謝物はグルクロン酸塩であった。1日最大耐用量の100 mg/kgで30日間反復投与しても薬物動態のパラメータは変化せず、明確な毒性徴候あるいは有害な反応も生じなかった。動物の体重、血液値、血清T3及びT4レベル、甲状腺及び脊髄の肉眼的な顕微鏡観察は正常範囲内であった。 他のいくつかのフェノールでも結論されたように、ラットではレゾルシノールは主に糞中への排泄を示すイヌの他の試験とは対照的に腸肝循環の経路を介して広範には排泄されないと結論された。	The major route of excretion is the urine (95% removal and remaining recovered in the feces), with glucuronide as the major metabolite for rats (and also indicated for rabbits). Repeated dosing for 30 days with maximum tolerated daily doses of 100 mg/kg did not alter pharmacokinetic parameters, nor cause overt toxic signs or adverse reactions. The animals body weight, blood values, levels of serum T3 and T4 and the gross microscopic appearance of the thyroid gland and spinal cord remained within normal limits. It was also concluded as with several other phenols that in the rat, resorcinol is not extensively eliminated via the enterohepatic pathway which is contrasting to other studies in dogs indicated primary excretion in the feces.
結論		
結論	結論 : レゾルシノールによる抗甲状腺活性 (他のロバスト試験サマリーを参照)を示す以前の試験と本試験結果との主な差はコーン油中のレゾルシノール又はレゾルシノールのエステル、レゾルシノール酢酸塩をラットに先に注射したためであると考えられている (Doniach and Fraser, 1950)。ヒトではヒトにおける甲状腺毒性影響は薬剤が軟膏を媒体として開放した足の潰瘍に適用量として異常に大量かつ長期間 (最大2年間)にわたり使用した場合に報告された(Bull and Fraser, 1950)。これらの通常ではない使用条件では、血漿及び組織コンパートメントからの消失の動力学は本実験で用いたようなレゾルシノールの水溶液を注射後に得られる急速な消失よりも恐らく遅延するであろう。 ラットでのこれらのファーマコキネティクスのデータはYeung et al 1982の最近の知見とよく相関している (別のロバスト試験サマリーを参照)。	Conclusion : Main differences in the outcome of this study and previous studies indicating antithyroid activity by resorcinol (see other robust study summaries) are believed to be due to previous injections in rats of resorcinol in oil or an ester of resorcinol, resorcinol acetate (Doniach and Fraser, 1950). In man, thyrotoxic effects in man were reported when the drug was used in an ointment vehicle in abnormally large doses applied to open leg ulcers and over a prolonged time (up to 2 yrs) (Bull and Fraser, 1950). As these unusual conditions of use, the kinetics of elimination from plasma and tissue compartments would probably be more prolonged than the rapid elimination obtained following injection of an aqueous solution of resorcinol as used in this experiment, These pharmacokinetic data from the rat correlate well with the recent findings from Yeung et al 1982 (see separate robust study summary).
信頼性	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	データは信頼性のある二次情報源から得られているので、2の信頼性を割り当てた。	Reliability of 2 assigned because data are taken from a reliable secondary literature source
出典		
引用文献(元文献)	(225)	(225)
備考		

5-2 急性毒性
ACUTE TOXICITY

A. 急性経口毒性
ACUTE ORAL TOXICITY

試験物質名	1.1～1.4で規定	as prescribed by 1.1 – 1.4
CAS番号		
純度等		
注釈		
方法		
方法／ガイドライン	OECDガイドライン401 "急性経口毒性"	OECD Guide-line 401 "Acute Oral Toxicity"
GLP適合	データなし	no data
試験を行った年	1990	1990
試験系(種／系統)	ラット	rat
	Sprague-Dawley	Sprague-Dawley
性別(雄:M、雌:F)	雌雄	male/female
投与量	データなし	no data
各用量群(性別)の動物数	動物数 : 30匹	Number of animals : 30
溶媒(担体)		
投与経路		
観察期間(日)		

その他の試験条件	英文参照	LD50 tests were conducted "blind" and in accordance with OECD TG 401, 1981 rather than the 1987 test guideline in order that information on both sexes would be available for comparision with the fixed dose test results. The only modification in the guideline study was that, where the limit dose studies were indicated, the maximum dose used would be 2000 mg/kg by weight rather than 5000 mg/kg dose prescribed in the 1981 OECD guideline study. One laboratory conducted the classical LD50 test following the OECD guideline as indicated above, while the remaining 31 laboratories conducted the fixed-dose testing (for comparison purposes.) Each substance was tested at least 26 times by different laboratories using identical procedures (not all 31 laboratories were used to test for resorcinol).
その他の試験条件	英文参照	In the fixed dose method one of the following preset doses is to be selected 5, 50, or 500 with an additional dose of 2000 mg/kg bw. These doses were selected as at the time, they matched the EC classification system and would thus allow for appropriate classification. The classic LD50 study was conducted using 30 Sprague Dawley rats while the fixed dose testing used 370 rats (a variety of rats), as laboratories were given the freedom to select the rat strain. This concluded in 21 laboratories performing the study using Sprague Dawley rats, 9 laboratories using Wistar and one laboratory using the Fischer 344 rats. A total of 26 fixed dose studies was conducted using 370 rats for an average of 14.23 rats per study.
その他の試験条件	英文参照	Fixed dose method: Resorcinol was administered orally by gavage. At least 10 animals (5 female and male) are used for each dose level. The dose level to be used by the laboratory should be one of the four levels associated with classification, 5, 50, 500 and 2000 mg/kg/bw. A 14 day observation period. Animals are observed for signs of toxicity including behavioural and clinical abnormalities, gross lesions, body-weight changes, and other toxic effects. All animals are subject to gross necropsy. A vehicle was used in accordance with specified protocols. Vehicle name is not given in the report.
統計学的処理		
結果		
各用量群での死亡数		
臨床所見		
剖検所見		
その他	古典的LD50試験: 雄ではLD50は533 mg/kg bwと決定され、95%信頼限界は(425 - 725 mg/kg bw)であった。雌ではLD50値は489 mg/kg bwであり、95%信頼限界は(397 -650 mg/kg bw)であった。雌雄合わせたLD50は510 mg/kg bwと決定され、95%信頼限界は(439 - 642 mg/kg bw)であった。傾きは8 (s.e. 2.1)と決定された。当時のEC基準に従えばレゾルシノールは有害性ありに分類された。本試験では以下の臨床症状が観察された。眼瞼下垂、姿勢、呼吸への影響、嗜眠、異常歩行、振戦、痙攣及び流涎。 古典的LD50試験では剖検所見はみられなかった。 9匹の動物が死亡発見された (用量レベルは示されていない)。	Classic LD50 study: In males (only)LD50 was determined to be 533 mg/kg bw with the 95% confidence limits being (425 - 725 mg/kg bw). In females (only) the LD50 was determined to be 489 mg/kg/bw with the 95% confidence limits being (397 -650 mg/kg bw). In the males and females the LD50 was determined to be 510 mg/kg bw with the 95% confidence limits being (439 - 642 mg/kg bw). The slope was determined to be 8(s.e. 2.1). In accordance with the EC criteria at the time, resorcinol was classified as harmful. In this test the following clinical signs were observed: Ptosis, posture, respiratory effects, lethargy, abnormal gait, tremors, convulsions and salivation. There were no necropsy findings in the classic LD50 study. 9 animals were found dead (dose level not indicated).

その他	固定用量試験: 固定用量試験の結果は異なるラボで行われた25の固定用量試験において、いずれの試験も当時のEC基準に照らせば有害性ありと分類される一致する結果を示した。1つの例外のみが結果は"分類されない"を示した。これらの試験において26のラボは以下のラボ数が以下の影響を記述したと対応する。眼瞼下垂、2;姿勢、5;呼吸影響、10;下痢及び利尿、1;嗜眠、10;運動失調、2;異常歩行、3;振戦、13;痙攣、9;疲弊昏睡、4;流涎、5;流涙、4;眼球突出、1. 合計146匹の動物が死亡発見され(用量は示されず)、試験当たりの平均死亡数は5.62であった。これらの結果は一般的な用語で記述されているだけで、試験された物質が与えられた影響と関連しているわけではない。 レゾルシノールによる固定用量での剖検所見:肝臓、腎臓、胃及び腸の退色。腺胃粘膜の浮腫。急速な心拍数。	Fixed Dose studies: Results of fixed dose testing indicated that in 25 fixed dose studies conducted in separate laboratories each one of them had consistent results that resulted in a classification as harmful, in accordance with the EC criteria at the time. In only 1 instance did the results indicate "Unclassified." In these studies, 26 laboratories responded in which the following number of "labs" documented the following effects: Ptosis, 2; Posture, 5; Respiratory effects, 10; Diarrhoea and diuresis, 1; Lethargy, 10; Ataxia, 2; Abnormal gait, 3; Tremors, 13; Convulsions, 9; Prostrate Coma, 4; Salivation, 5; Lacrimation, 4; Exopthalmus,1. A total of 146 animals were found dead (dosing not indicated) for an average of 5.62 per test. These results are only stated in general terms and are not associated with any one given chemical that was tested. Autoposy findings in the fixed-dose tests with resorcinol: Liver, kidney, stomach and intestine discoloured. Oedma of glandular gastric mucosa. Rapid heart beat. A classification of harmful is assigned to test substances that have less than 100% survival at 2000 mg/kg bw.
結論		
LD50値又はLC50値	LD50= 489 - 533 mg/kg bw	LD50= 489 - 533 mg/kg bw
雌雄のLD50値又はLC50値の違い等		
注釈	データは以前のOECD TG 401 (1981)の代替として1984年に示された固定用量法を評価した物質から得られている。本記述及び行われた試験 (1988 - 1989)は固定用量法及びOECD TG 401に関して、国際的な検証及びEC、UK及びOECDによる強力作業を提供する必要の結果である。	Data are taken from an article that evaluated the fixed-dose procedure as an alternative to the previous OECD TG 401 (1981) in which a fixed dose procedure was suggested in 1984. This article and testing performed (1988 - 1989) is a result of the need to provide an international validation and comparison exercise by the EC, UK and OECD on the fixed dose procedure and OECD TG 401.
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	基本的なデータを提供する。記述では試験がGLPで行われたかどうかが示されていない。	Provides basic data. Article did not reveal if study was conducted under GLP.
出典		
引用文献(元文献)	(324)	(324)
備考	フラグ : SIDSエンドポイントにとって重要な試験	Flag : Critical study for SIDS endpoint

B. 急性吸入毒性
ACUTE INHALATION TOXICITY

試験物質名	1.1～1.4で規定	as prescribed by 1.1 - 1.4
CAS番号		
純度等		
注釈		
方法		
方法／ガイドライン	その他	other
GLP適合	データなし	no data
試験を行った年	1976	1976
試験系(種／系統)	ラット	rat
	その他: Harlan-Wistar	other: Harlan-Wistar
性別(雄:M、雌:F)	雌	female
投与量	2,130 mg/m3 (473 ppm) 及び 約 7,800 mg/m3 (1732 ppm)	2,130 mg/m3 (473 ppm) and ca. 7,800 mg/m3 (1732 ppm)
各用量群(性別)の動物数	動物数 : 12匹	Number of animals : 12
溶媒(担体)	水	water
投与経路		
観察期間(日)		
その他の試験条件	暴露時間 : 1時間	Exposure time : 1 hour(s)

その他の試験条件	英文参照	The acute toxic effects of catechol-, resorcinol- and phenol-water aerosols were investigated at comparable airborne concentrations. Samples were dissolved in distilled water and the resulting solutions were aerosolized using a D18 Dautrebande aerosol generator operated at 30 psi. At this operating pressure, the D18 generator delivered droplets of 1μ or smaller. The concentration of the sample solutions was adjusted so that the airbourne concentration approximated 2,000 mg/m3 (444 ppm) of the sample in air. Airborne concentrations were determined by measurement of the volume loss of solution following aerosolization. The weight of sample present in that volume was then calculated and related to the total volume of air in generating the aerosol to obtain chamber concentrations. In groups of 6, rats, weighing between 87 and 126 g, were subjected to a single 1 hour inhalation period of the aerosolized sample.
その他の試験条件	英文参照	At the 1 hour time interval, rats were exposed to concentrations of 7800 mg/m3 (57.4% weight/unit volume)(1732 ppm) and 2130 mg/mg3 (18.2% weight/unit volume) (473 ppm). It should be noted that in the study conducted at a concentration of 7800 mg/m3, the solution turned milky. And some precipitate was noted. It is likely that flow concentrations were less than the concentration indicated. The animals were held for 14 days following exposure and were then weighed and sacrificed for gross necropsy.
統計学的処理		
結果		
各用量群での死亡数		
臨床所見		
剖検所見		
その他	ラットにレゾルシノール-水エアロゾルを2,130 mg/M3 (473 ppm) 及び 約 7,800 mg/M3 (1732 ppm)の濃度で約1時間吸入させたが、死亡例は生じなかった。全ての動物が14日間正常な体重増加を示した。エアロゾルの吸入による傷害は剖検時にはみられなかった。	No deaths resulted when rats inhaled resorcinol-water aerosols for one-hour at concentrations of 2,130 mg/M3 (473 ppm) and approx 7,800 mg/M3 (1732 ppm) for a 1 hour period. All animals had normal 14-day weight gains, and no lesions attributable to inhalation of the aerosol were seen at gross necropsy.
結論		
LD50値又はLC50値	LC0 > 7800 mg/m³	LC0 > 7800 mg/m³
雌雄のLD50値又はLC50値の違い等		
注釈	結論 : およそ7,800 mg/m3 (1732 ppm) のエアロゾル濃度で1時間レゾルシノールに急性暴露しても毒性影響は何ら期待されない。	Conclusion : No toxic effects are anticipated from acute exposures to resorcinol at aerosol concentrations approximating 7,800 mg/m3 (1732 ppm) for one hour.
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	基本的なデータを提供する	Provides basic data
出典		
引用文献(元文献)	(102) (190)	(102) (190)
備考	フラグ : SIDSエンドポイントにとって重要な試験	Flag : Critical study for SIDS endpoint

C. 急性経皮毒性
ACUTE DERMAL TOXICITY

試験物質名	1.1～1.4で規定	as prescribed by 1.1 - 1.4
CAS番号		
純度等		
注釈	レゾルシノールのフレーク	Flaked Resorcinol
方法		
方法／ガイドライン	その他: Federal Register of August 12 1961, pages 7333-7341	other: Federal Register of August 12 1961, pages 7333-7341
GLP適合	いいえ	no
試験を行った年	1962	1962
試験系(種／系統)	ウサギ	rabbit
	系統 : データなし	Strain : no data
性別(雄:M、雌:F)	雄	male
投与量	1000, 2000, 3980 及び7950 mg/kg	1000, 2000, 3980 and 7950 mg/kg
各用量群(性別)の動物数	動物数 : 16匹	Number of animals : 16
溶媒(担体)	生理食塩水	physiol. Saline
投与経路		
観察期間(日)		

その他の試験条件	英文参照	The study was conducted in accordance with Federal Hazardous Substances Labeling Act (FHSLA), Federal Register Aug. 12, 1961, p 7333-7341, Part 191 "Hazardous Substances Definitions and Procedural and Interpretative Regulations, Final Order" Four groups of male albino rabbits (4/dose group) were used, weighing between 2.3-3.0 kg after undergoing a seven day laboratory observation and acclimatization period.
その他の試験条件	英文参照	The rabbits were administered the following doses of flaked resorcinol: 1000, 2000, 3980 and 7950 mg/kg. Prior to exposure, the animals were prepared by clipping the skin of the trunk, approximately 10% of the body surface, free of hair. One-half of each group was further prepared by making epidermal abrasions every two or three centimeters longitudinally over the area of future exposure. The abrasions were sufficiently deep to penetrate the stratum corneum but not to disturb the derma and cause bleeding. The skin and the material, which was evenly distributed on cotton gauze in an amount calculated to yield the desired dosage level, were moistened with physiological saline. The gauze and material were applied to the skin of the rabbits and the entire trunk was wrapped in an impervious plastic film. The maximum justifiable dosage level for solids in this procedure is approximately 4. 0 gm/kg. which is twice the upper limit for the "toxic substance" category as defined in the regulations pursuant to the FHSLA. Following dosing, the rabbits were immobilized in stocks for 24 hours after which the dam and any excess chemical were removed and the skin was examined for gross changes.
その他の試験条件	英文参照	Mortality due to the effect of the chemical was considered complete after 14 days. All fatalities were subjected to necropsy to exclude extraneous causes of death while some survivors were sacrificed and examined for the existence of gross lesions. The skin penetration LD50, based upon mortality attributable to the material during the 14-day observation period, was estimated employing Thompson's method of moving averages using the tables of Weil.
統計学的処理		
結果		
各用量群での死亡数		
臨床所見		
剖検所見		
その他	フレーク品: 用量 mg/kg　死亡数/投与数　死亡が生じた投与後の日数 1000　0/4　- 2000　1/4　1 (1) 3980　2/4　1 (2) 7950　4/4　1 (4) 95%信頼限界: 1980-5710 mg/kg.	Flaked Grade: Dosage mg/kg No. Died/No. Dosed Days after dosing on which death occurred 1000　0/4　- 2000　1/4　1 (1) 3980　2/4　1 (2) 7950　4/4　1 (4) 95% confidence limits: 1980-5710 mg/kg.
	レゾルシノールは3980 mg/kg以上に暴露したウサギの全例及び2000 mg/kgに暴露した4匹のうち3匹に皮膚の壊死を生じた。フレーク品は24時間接触後に中等度ないし重度の刺激症状に続いて軽度の過角化のみを示した。14日間の観察期間を生存したウサギの大部分が対照群のウサギよりも有意に低値の体重増加を示した。剖検時には内部の肉眼損傷はみられなかった。	Resorcinol produced necrosis of the skin in all rabbits exposed to 3980 mg/kg and above and in 3 out of 4 rabbits exposed to 2000 mg/kg. The rabbits exposed to 1000 mg/kg Flaked Grade showed only slight hyperkeratosis following signs of moderate to severe irritation after 24 hours contact. The majority of the rabbits that survived the 14-day observation period exhibited body weight gains significantly less than those of control rabbits. No internal gross lesions were observed at necropsy.
結論		
LD50値又はLC50値	LD50= 3360　mg/kg bw	LD50= 3360　mg/kg bw
雌雄のLD50値又はLC50値の違い等		
注釈	投与量は 1.0, 2.0, 3.98 及び 7.95 g/kg からmg/kgに変換された。	Dosage has been converted from 1.0, 2.0, 3.98 and 7.95 g/kg to mg/kg.
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	ガイドライン試験; 非GLP	Guideline Study; Not GLP
出典		
引用文献(元文献)	(102) (187)	(102) (187)

備考	フラグ ： SIDSエンドポイントにとって重要な試験	Flag : Critical study for SIDS endpoint

D. 急性毒性（その他の投与経路）
ACUTE TOXICITY、OTHER ROUTES

5-3 腐食性／刺激性
CORROSIVENESS/IRRITATION

A. 皮膚刺激／腐食
SKIN IRRITATION/CORROSION

試験物質名	1.1～1.4で規定	as prescribed by 1.1 - 1.4
CAS番号		
純度等		
注釈		
pH		
方法		
方法／ガイドライン	OECDガイドライン404 "急性皮膚刺激性/腐食性"	OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
GLP適合	はい	yes
試験を行った年	2006	2006
試験系（種／系統）	ウサギ	rabbit
性別（雄：M、雌：F）		
投与量	濃度 ： 2.5% 暴露 ： 半閉塞 暴露時間 ： 72時間	Concentration : 2.5 % Exposure : Semiocclusive Exposure time : 72 hour(s)
各用量群（性別）の動物数	動物数 ： 3匹	Number of animals : 3
溶媒（担体）	水	water
投与経路		
観察期間（日）		
その他の試験条件	英文参照	Based on OECD Guideline 404 and EC Directive No 92/69/EEC.B.4 The test item was prepared at the concentration of 2.5% (w/w) in the vehicle. Application: The dosage was first evaluated in a single animal. The duration of exposure was 3 minutes in the anterior left flank, 1 hour in the anterior right flank, and four hours on the posterior right flank. Since the dosage was not an irritant on this first animal, it was applied for 4 hours to two other animals. Doses of 0.5 mL of the dosage from preparations were placed on a dry gauze pad which was then applied to the anterior and posterior right flanks (application for 1 and 4 hours, respectively) on the left flank (application 3 minutes) of the animals. The gauze pad was held in contact with the skin by means of a hypoallergenic adhesive aerated semi-occlusive dressing and a restraining bandage.
その他の試験条件	英文参照	Untreated skin served as the control. No residual test substance was observed on removal of the dressing. Evaluation at 1, 24, 48 and 72 hours post treatment. The study was ended on day 4 in the absence of persistent irritation reactions.
統計学的処理		
結果		
一次刺激スコア		
皮膚反応等		
その他	試験中に皮膚反応はみられなかった。 各動物に対する24、48及び72時間での紅斑及び浮腫に対する平均スコアは0.0、0.0、0.0であった。 純水中2.5%の濃度でウサギに局所適用しても刺激性を示さなかった。	No cutaneous reactions were observed during the study. Mean scores over 24, 48 and 72 hours for each animal were 0.0, 0.0, 0.0 for erythema and oedema. Not irritating when applied topically to rabbits at a concentration of 2.5% in purified water.
結論		
皮膚刺激性	刺激性なし	not irritating
皮膚腐食性		
注釈		
信頼性	(1) 制限付きで信頼性あり	(1) valid without restriction
信頼性の判断根拠	ガイドライン及びGLP試験	Guideline and GLP study
出典		
引用文献（元文献）	(57)	(57)
備考		

B. 眼刺激／腐食
EYE IRRITATION/CORROSION

試験物質名	1.1～1.4で規定	as prescribed by 1.1 - 1.4
CAS番号		
純度等		
注釈	フレーク及び工業等級のレゾルシノール	Flaked and Industrial Grade Resorcinol
方法		
方法／ガイドライン	その他: Federal Hazardous Substance Labeling Act (FHSLA), Federal Register Aug 12, 1961, p 7333-7341, Part 191 "Hazardous Substances Definitions and Procedural and Interpretative Regulations, Final Order"	other: Federal Hazardous Substance Labeling Act (FHSLA), Federal Register Aug 12, 1961, p 7333-7341, Part 191 "Hazardous Substances Definitions and Procedural and Interpretative Regulations, Final Order"
試験のタイプ		
GLP適合	いいえ	no
試験を行った年	1962	1962
試験系(種／系統)	ウサギ	rabbit
性別(雄:M、雌:F)		
投与量	用量 : 1 gm 暴露時間 : 72時間	Dose : .1 other: gm Exposure time : 72 hour(s)
各用量群(性別)の動物数	動物数 : 6匹	Number of animals : 6
溶媒(担体)	なし	none
投与経路		
観察期間(日)		
その他の試験条件	英文参照	The study was conducted in accordance with Federal Hazardous Substance Labeling Act (FHSLA), Federal Register Aug 12, 1961, p 7333-7341, Part 191 "Hazardous Substances Definitions and Procedural and Interpretative Regulations, Final Order". Flaked Grade (deep, ivory colored solid) and Industrial Grade (dark brown-colored solid), no purity data available
その他の試験条件	英文参照	Six male albino rabbits were treated in determining the extent of injury that might be expected following accidental contamination of the eyes with each material. Two to four hours prior to the application of the material upon the cornea and into the conjunctival sac, the eyes were stained with fluorescein to assure the use of undamaged eyes. Since the material was water soluble, the standard test procedure was modified to test both the dissolved material and the semi-solid in its usual state. One tenth of a gram of the material was applied to one eye of each of six rabbits, the six untreated eyes serving as controls. The exposed eyes were not washed following application of the material. The eyes were examined and evaluated at 24 hours, 48 hours, and 72 hours after treatment for gross damage to the palpebral and bulbar conjunctivae, to the iris, and to the cornea. All damaged eyes were examined periodically thereafter for a maximum period of two weeks to evaluate the permanence of the damage and the rate and degree of repair.
その他の試験条件	英文参照	In many of the older studies, a distinction is made between the two forms of resorcinol commercial products: flaked and industrial. This distinction is no longer made, as in the 1950's and 1960's Koppers made a lower purity grade resorcinol which was referred to as "industrial grade resorcinol". Industrial grade resorcinol is no longer produced. "Flaked resorcinol" is still in production along with a USP flaked product and powder forms. (INDSPEC (2007) personal communication)
統計学的処理		
結果		
腐食		
刺激点数: 角膜		
刺激点数: 虹彩		
刺激点数: 結膜		

その他	フレーク又は工業等級のレゾルシノールに対するウサギの眼の反応には有意な差はみられなかった。雄のアルビノウサギの眼にいずれかの試験物質を0.1 gm適用した際に、結膜は赤くなり、角膜は混濁し、ウサギは顕著な苦痛の証拠を示した。暴露後24時間の検査では重度の結膜炎、虹彩炎、角膜の混濁、虹彩の大半の閉塞及び角膜の潰瘍が示された。観察期間中及び14日までに眼の状態はほとんど回復せず、暴露した眼は全て円錐角膜及びパンヌス形成を示した。従って、試験物質はFHSLAに準じた規制では眼刺激物質と定義される。	There was no significant difference in the response of the eyes of rabbits to Flaked or Industrial Resorcinol. Upon the application of 0.1 gm of either of the test materials into the eyes of male, albino rabbits, the conjunctivae became inflamed, the corneas opaque, and the rabbits gave evidence of marked discomfort. Examination at 24 hours post exposure showed severe conjunctivitis, iritis, corneal opacities occluding most of the iris, and corneal ulcerations. There was almost no perceptible improvement in the condition of the eyes during the observation period and by the 14th-day, all of the exposed eyes revealed keratoconus and pannus formation. The test substance, therefore, is an eye irritant as defined in the regulations pursuant to the FHSLA.
	Draize法を用いて24、48及び72時間での眼の傷害の多くの評価はそれぞれの時間に対して得られる最大110のスコアのうち、それぞれ105、105及び105の眼刺激の総スコアを与えた。 眼刺激物質として分類された。	Using Draize methods, a numerical evaluation of the eye injuries at 24, 48 and 72 hours gave a resultant total eye irritation scores of 105, 105 and 105, respectively, with a maximum obtainable score of 110 for each time period. Classified as an eye irritant.
結論		
眼刺激性		
眼腐食性	腐食性あり	corrosive
注釈	分類 : 刺激性あり	Classification : irritating
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	ガイドライン試験; 非GLP	Guideline Study; Not GLP
出典		
引用文献(元文献)	(102) (114) (187) (236) (288)	(102) (114) (187) (236) (288)
備考		

5-4 皮膚感作
SKIN SENSITISATION

試験物質名	1.1～1.4で規定	as prescribed by 1.1 – 1.4
CAS番号		
純度等	レゾルシノル、純度99.9% (白色フレーク)	Resorcinol, purity 99.9% (white flakes)
注釈		
方法		
方法／ガイドライン	OECDガイドライン406 "皮膚感作性"	OECD Guide-line 406 "Skin Sensitization"
試験のタイプ	モルモットマキシマイゼーション試験	Guinea pig maximization test
GLP適合	1989	1989
試験を行った年	はい	yes
試験系(種／系統)	モルモット	guinea pig
性別(雄:M、雌:F)		
投与量	濃度: 1回目: 誘導 2%皮内注射 2回目: 誘導 25%閉塞塗布 3回目: 惹起 25%閉塞塗布	Concentration : 1st: Induction 2 % intracutaneous 2nd: Induction 25 % occlusive epicutaneous 3rd: Challenge 25 % occlusive epicutaneous
各用量群(性別)の動物数	動物数 : 20匹	Number of animals : 20
溶媒(担体)		other: sodium chloride
投与経路		
観察期間(日)		
その他の試験条件	英文参照	Twenty Pirbright White guinea pigs were used to determine the potential for sensitization: treatment group: 10; control group: 5; accompanying group: 20 Vehicles used were 50% Freund's complete adjuvant and 0.9% isotonic saline solution. The Freund's adjuvant was mixed
その他の試験条件	英文参照	immediately prior to use with an equal volume of 0.9% NaCl solution. This 50% Freund's adjuvant was injected intradermally into the test animals. For the dermal applications and intradermal injections, resorcinol was diluted with 0.9% NaCl solution. For intradermal injections of the test substance in Freund's adjuvant, resorcinol was diluted with 0.9% NaCl solution and this dilution was then mixed with an equal volume of the original Freund's adjuvant. The intradermal induction exposure was conducted with 2% test substance in 0.9% NaCl solution; dermal induction exposure and the dermal challenge exposure with 25% test substance in 0.9% NaCl solution.

その他の試験条件	英文参照	Exposure Groups: Position Volume Applied (ml) Conc. % Substance vehicle 1 2 x 0.1 – 50% Freund's adjuvant 2 2 x 0.1 2.0 0.9% Nacl solution 3 2 x 0.1 2.0 50% Freund's adjuvant Control and Accompanying groups received only the vehicle without the test substance. 0.5 ml of the test substance preparation or the vehicle was applied to a 2 x 4 cm cellulose pad during the dermal induction exposure which was conducted on Day 8. The pad covered the area of the intradermal injection sites. An occlusive bandage with impermeable film and elastic binding sealed the application site for 48 hours. The exposure group received 25.0% test substance in 0.9% NaCl solution. Control and accompanying group received only 0.9% NaCl solution.
その他の試験条件	英文参照	On Day 10 the occlusive bandage was removed, any irritating effect was recorded. The test animal were observed up to Day 21. On Day 22 dermal challenge exposure was performed. The fur was removed mechanically from a 5 x 5 cm area on the left flank of the test animals. 0.5 ml of the test substance preparation was applied to a 2 x 2 cm cellulose pad. An occlusive bandage with impermeable film and elastic adhesive binding sealed the application site for 24 hours. Exposure and control Group (left flank) received 25.0% test substance in 0.9% NaCl solution. On Day 23 the occlusive bandage was removed. Day 24 and 25, evaluation of the skin was conducted. The repeat dermal challenge exposure was conducted on Day 29. Exposure and control group (right flank) were exposed to 25.0% test substance in 0.9%Nacl solution.
統計学的処理		
結果		
試験結果	暴露された動物は全試験期間を通して毒性症状を示さなかった。 Freundのアジュバント(試験物質を含む及び含まない)での皮内注射は注射部位に明らかな発赤と腫脹を生じた。投与後3日から注射部位も硬化した。	The exposed animals showed no signs of intoxication throughout the entire test period. The intradermal injections with Freund's adjuvant (with and without test substance) led to a clear reddening and swelling of the injection sites. As of Day 3 post-administration, the injection sites were also hardened.
試験結果	投与後5日には痂皮も観察された。50%のFreundのアジュバント中で試験物質を処置した注射部位も投与後1及び2日には褐色を帯び、投与5日後には部分的な壊死が観察された。0.9%塩化ナトリウム溶液中試験物質の皮内注射後には1及び2日に軽度の発赤及び腫脹が現れた。10日に閉塞包帯を除去後にFreundのアジュバントに暴露した注射部位は対照群及び暴露群ともに赤くなり、腫れて硬化した。壊死及び部分的に開いた傷口も出現した。(Freundのアジュバントなしの)第2部位では適用部位に刺激症状はみられなかった。暴露した動物の体重が低下する傾向はなかった。最初の惹起暴露後にごく軽度から明らかな境界を示す紅斑が閉塞帯除去24及び48時間後に暴露群の2ないし3匹の動物の皮膚にみられた。対照動物の皮膚は明らかな刺激の徴候えお示した。	Five days postadministration, scabbing was also observed. The injection sites treated with the test substance in 50% Freund's adjuvant were also brown-colored on Days 1 and 2 after administration; after 5 days post-administration, partial necrosis was observed. After intradermal injection of the test substance in 0.9% NaCl solution, minor reddening and swelling appeared on Days 1 and 2. After removal of the occlusive bandage on Day 10, the application sites exposed to Freund's adjuvant were reddened, swollen and hardened in animals in the control, accompanying and exposure groups. Necrosis and in part, open wounds, appeared as well. No signs of irritation were observed at the application sites in Position 2 (without Freund's adjuvant). The trend in body weight of the exposed animals was not impaired. After the first challenge exposure, very slight to clearly circumscribed erythema was observed on the skin of two or three animals in the exposure group 24 and 48 hours after removal of the occlusive bandage. The skin of the control animals was clear of signs of irritation.
試験結果	2回目の惹起暴露後、閉塞帯除去後24時間の暴露群の7匹及び48時間の暴露群の7匹の皮膚にごく軽度から明瞭な境界を持つ紅斑がみられた。閉塞帯除去後24時間の暴露群の1匹には軽度の腫脹も観察された。 暴露群の7匹が惹起暴露後に陽性反応を示した。このように、陽性反応動物の相対頻度は限界値の30%を上回った。すなわち、試験物質は感作性ありと示される。	After the second challenge exposure, very slight to clearly circumscribed erythema was observed on the skin of 7 animals in the exposure group 24 hours and on 5 animals in the exposure group 48 hours after removal of the occlusive bandage. Minor swelling was also observed in one animal in the exposure group 24 hours after removal of the occlusive bandage. The skin of the control animals was clear of signs of irritation. Seven animals in the exposure group presented with a positive reaction after the challenge exposure. The relative frequency of the positively reacting animals is thus over the limit value of 30%. Therefore, the test substance is designated as sensitising.
その他		

結論		
感作性	感作性あり	sensitizing
注釈	分類 : 感作性あり	Classification : sensitizing
信頼性	(1) 制限なく信頼性あり	(1) valid without restriction
信頼性の判断根拠	ガイドライン試験	Guideline Study
出典		
引用文献(元文献)	(147)	(147)
備考		

5-5 反復投与毒性
REPEATED DOSE TOXICITY

試験物質名	1.1 - 1.4に規定	as prescribed by 1.1 - 1.4
CAS番号		
純度等	純度>99%	purity >99%
注釈		
方法		
方法／ガイドライン	OECD 408と同等	other: comparable to OECD 408
GLP適合	はい	yes
試験を行った年	1981	1981
試験系(種／系統)	rat/Fischer 344	rat/Fischer 344
性別(雄:M、雌:F)	雌雄	male/female
投与量	0, 27.5, 55, 110, 225, 450 mg/kg/bw	0, 27.5, 55, 110, 225, 450 mg/kg/bw
各用量群(性別)の動物数		
溶媒(担体)		
投与経路	強制経口	gavage
対照群に対する処理	処理なし	no treatment
投与期間(日)(OECD422等で、投与期間のデータ等がある場合、最長投与期間)	17日間	17 days
投与頻度	1回/日、5日/週(12回投与)	Once daily for 5 days a week (12 doses dispensed over 17 days)
回復期間(日)		
試験条件		
統計学的処理		
結果		
体重、体重増加量		
摂餌量、飲水量		
臨床所見(重篤度、所見の発現時期と持続時間)		
眼科学的所見(発生率、重篤度)		
血液学的所見(発生率、重篤度)		
血液生化学的所見(発生率、重篤度)		
尿検査所見(発生率、重篤度)		
死亡数(率)、死亡時間		
剖検所見(発生率、重篤度)		
臓器重量		
病理組織学的所見(発生率、重篤度)		
実際に摂取された量		
用量反応性		
注釈		
結論		
NOAEL (NOEL)	NOAEL (雌) = 27.5 mg/kg bw (55 mg/kg bw 以上の用量での過剰興奮、110 及び450 mg/kg bwでの頻呼吸に基づく。絶対及び相対胸腺重量の減少が450 mg/kg bwで観察された。 NOAEL (雄) = 110 mg/kg bw 225 mg/kg bwでの過剰興奮及び頻呼吸に基づく。	NOAEL (females) = 27.5 mg/kg bw (based on hyperexcitability at doses at and greater than 55 mg/kg bw along with tachypnea at 110 and 450 mg/kg bw. Decreased absolute and relative thymus weights were observed at 450 mg/kg bw. NOAEL (males) = 110 mg/kg bw based on hyperexcitability and tachypnea at 225 mg/kg bw.
LOAEL (LOEL)		
NOAEL/LOAELの推定根拠		
雌雄のNOAEL(LOAEL)の違い等		
注釈	全ての動物が試験終了まで生存した。体重の伸びは対照群と同じ程度で生じた。毒性の臨床症状は投与の30分以内に発現し、1-2時間持続した。過剰興奮及び頻呼吸が225～450 mg/kgを投与した雄で観察された。55 mg/kg以上の投与量を与えれた雌は過剰興奮を示し、110及び450 mg/kgを投与した雌は頻呼吸を示した。高用量の雌では胸腺の絶対及び相対重量の減少が示された。物質に関連した肉眼的変化も病理組織学的変化もみられなかった。レゾルシノールに起因する肉眼病変も顕微鏡的病変もみられなかった。	All rats survived to the end of the study. Body weight development lay in same range as that of control. Clinical signs of toxicity appeared within half an hour of dosing and lasted 1 to 2 hours. Hyperexcitability and tachypnea were observed in males receiving 225 to 450 mg/kg. Females receiving doses of 55 mg/kg and greater showed hyperexcitability and those receiving 110 and 450 mg/kg showed tachypnea. High dose females had significantly decreased absolute and relative thymus weights. There were no substance-related macroscopic or histopathological changes. No gross or microscopic lesions attributable to resorcinol were observed.
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions

信頼性の判断根拠	基本的なデータを提供する。後に続く13週間及び2年間の生物試験はGLPで行われたが、その前の2週間の用量設定試験。	Provides basic data. Two week range finding study in which the subsquent 13 week and 2 yr bioassay were conducted under GLP.
出典		
引用文献(元文献)	(233) (234)	(233) (234)
備考		

試験物質名	1.1 - 1.4の記述どおり	as prescribed by 1.1 - 1.4
CAS番号		
純度等	純度>99%	purity >99%
注釈		
方法		
方法／ガイドライン	OECD 408と同等	other: comparable to OECD 408
GLP適合	はい	yes
試験を行った年	1981	1981
試験系(種／系統)	rat/Fischer 344	rat/Fischer 344
性別(雄:M、雌:F)	雌雄	male/female
投与量	0, 32, 65, 130, 260, 520 mg/kg/bw	0, 32, 65, 130, 260, 520 mg/kg/bw
各用量群(性別)の動物数		
溶媒(担体)		
投与経路	強制経口	gavage
対照群に対する処理		
投与期間(日)(OECD422等で、投与期間のデータ等がある場合、最長投与期間)	13週間	13 weeks
投与頻度	1回/日、5日/週	Once a day 5 days a week
回復期間(日)		
試験条件		
統計学的処理		
結果		
体重、体重増加量		
摂餌量、飲水量		
臨床所見(重篤度、所見の発現時期と持続時間)		
眼科学的所見(発生率、重篤度)		
血液学的所見(発生率、重篤度)		
血液生化学的所見(発生率、重篤度)		
尿検査所見(発生率、重篤度)		
死亡数(率)、死亡時間		
剖検所見(発生率、重篤度)		
臓器重量		
病理組織学的所見(発生率、重篤度)		
実際に摂取された量		
用量反応性		
注釈		
結論		
NOAEL (NOEL)	NOAEL は報告書の中では判明しなかった。入手可能な情報に基づき、また、NTPレビューパネルの結論を考慮してNOAELは以下の通り: NOAEL (雌) = 65 mg/kg/bwでの肝臓の絶対及び相対重量の増加に基づき、32 mg/kg/bw。520 mg/kg bwで振戦がみられた。 NOAEL (雄) = 130 及び260 mg/kg/bwでの肝臓絶対重量の増加に基づき、65 mg/kg bw。520 mg/kg bwで振戦がみられた。副腎の絶対及び相対重量は雄の生存全投与群で有意に増加した。	A NOAEL was not identified within the report. Based on available information and taking into consideration the conclusions of the NTP review panel the NOAEL's appear to be as follows: NOAEL (females) = 32 mg/kg/bw based on increased absolute and relative liver weights at 65 mg/kg/bw. Tremors were observed at 520 mg/kg bw. NOAEL (males) = 65 mg/kg bw based on increased absolute liver weights at 130 and 260 mg/kg/bw. Tremors were observed at 520 mg/kg bw. Absolute and relative adrenal gland weights were significantly increased in all surviving male doses groups.
LOAEL (LOEL)		
NOAEL/LOAELの推定根拠		
雌雄のNOAEL(LOAEL)の違い等		

注釈	雌の全ラット及び520 mg/kg群の2匹を除く雄全例が試験の最初の4週間の間に化合物に関連した毒性で死亡した。第2日に260 mg/kg投与群のラットに誤って520 mg/kgが投与された。この群の雄2匹及び雌5匹が5日以内に死亡した。この用量を投与されたラットでは更なる死亡が生じなかったことからこれらの死亡は投与の過誤によるものであった。ラットの最終体重及び平均体重増加量の変化は対照群と同程度であった。 高用量の雌雄のラットで振戦がみられた。130または260 mg/kgを投与された雄及び65、130または260 mg/kgを投与された雌では肝臓の絶対及び相対重量は有意に増加した。副腎の絶対及び相対重量は生存した雄の全投与群で有意に増加した。血液検査または臨床化学検査では生物学的に有意な差はみられなかった。様々なパラメータにおけるいくつかの有意差が群間で散見されたが、生物学的に意義があると考えられるものはなかった。投与に起因する肉眼的病変あるいは顕微鏡的病変はいずれもなかった。	All female rats and all but 2 males receiving 520 mg/kg died from compound related toxicity during first 4 weeks of the study. On day 2 rats receiving 260 mg/kg were given 520 mg/kg in error. Within 5 days 2 males and 5 females died from this group. These deaths were attributed to error in dosing since no further deaths occurred from rats receiving this dose. The final body weight and changes in mean body weight weight of rats were similar to that of controls. Tremors were observed in high-dose rats of both sexes. Males receiving 130 or 260 mg/kg and females receiving 65, 130 or 260 mg/kg had significantly increased absolute and relative liver weights. Absolute and relative adrenal gland weights were significantly increased in all surviving male dosed groups. No biologically significant differences in hematology or clinical chemistry were observed. A few significant differences in various parameters scattered among the groups were seen, but none were considered biologically significant. There were no gross or microscopic lesions attributable to treatment.
信頼性	(1) 制限なく信頼性あり	(1) valid without restriction
信頼性の判断根拠		
出典		
引用文献(元文献)	(233) (234)	(233) (234)
備考		

試験物質名	1.1 - 1.4の記述どおり	as prescribed by 1.1 - 1.4
CAS番号		
純度等	純度>99%	purity >99%
注釈		
方法		
方法／ガイドライン		
GLP適合	記載なし	no data
試験を行った年	1981	1981
試験系(種／系統)	mouse/B6C3F1	mouse/B6C3F1
性別(雄:M、雌:F)	雌雄	male/female
投与量	0、37.5、75、150、300、600 mg/kg/bw	0、37.5、75、150、300、600 mg/kg/bw
各用量群(性別)の動物数		
溶媒(担体)		
投与経路	強制経口	gavage
対照群に対する処理		
投与期間(日)(OECD422等で、投与期間のデータ等がある場合、最長投与期間)	17日間	17 days
投与頻度	1回/日、5日/週(12回投与)	Once a day 5 days a week (12 doses over 17 days)
回復期間(日)		
試験条件		
統計学的処理		
結果		
体重、体重増加量		
摂餌量、飲水量		
臨床所見(重篤度、所見の発現時期と持続時間)		
眼科学的所見(発生率、重篤度)		
血液学的所見(発生率、重篤度)		
血液生化学的所見(発生率、重篤度)		
尿検査所見(発生率、重篤度)		
死亡数(率)、死亡時間		
剖検所見(発生率、重篤度)		
臓器重量		
病理組織学的所見(発生率、重篤度)		
実際に摂取された量		
用量反応性		
注釈		
結論		

NOAEL (NOEL)	NOAELは報告書の中では判明しなかった。入手可能な情報及びNTPレビューパネルの結論に基づいて、NOAELは以下の通りである: NOAEL(雄) = 150 mg/kg bwでの疲憊及び振戦に基づき、75 mg/kg/bw。600 mg/kg bwで80%の死亡率、300 mg/kg bwで20%の死亡率で、対照群と比べてその他に有意差なし。 NOAEL(雌) = 300 mg/kg bwでの疲憊及び振戦に基づき、150 mg/kg bw。600 mg/kg bwで100%の死亡率。その他に有意な所見なし。	A NOAEL was not identified within the report. Based on available information and the conclusions of the NTP review panel the NOAEL's appear to be as follows: NOAEL(males) = 75 mg/kg/bw based on prostration and tremors at 150 mg/kg bw. 80% mortality at 600 mg/kg bw, 20% mortality at 300 mg/kg bw and absence of any other significant differences when compared to controls. NOAEL(females) = 150 mg/kg bw based on prostration and tremors at 300 mg/kg bw. Complete mortality at 600 mg/kg bw; no other significant findings.
LOAEL (LOEL)		
NOAEL/LOAELの推定根拠		
雌雄のNOAEL(LOAEL)の違い等		
注釈	体重の伸びは対照群の伸びと同程度であった。600 mg/kg体重投与群では雄5匹中4匹、及び雌5匹中5匹が死亡した。300 mg/kg体重群では雄5匹中1匹が死亡した。対照群の雄の死亡は誤投与によるものであった。疲憊及び振戦を含む臨床所見が150 mg/kg以上の雄及び300 mg/kg以上の雌の間で記録された。これらの所見は通常投与後1時間以内に発現し、1-2時間持続した。臓器重量には生物学的に有意な変化はみられなかった。物質に関連した肉眼的あるいは病理組織学的変化はなかった。レゾルシノール投与に起因する肉眼的病変も顕微鏡的病変もみられなかった。	Body weight development lay in same range as that of control; in the 600 mg/kg body weight dose group, 4 out of 5 males and 5 out of 5 females died; in the 300 mg/kg body weight group, 1 out of 5 males died. The death of a control male was due to a gavage accident. Clinical findings, including prostration and tremors, were recorded among males receiving 150 mg/kg and greater and females receiving 300 mg/kg or greater. these findings usually appeared within an hour of dosing and lasted 1 to 2 hours. No biologically significant changes in organ weight were observed. No substance related macroscopic or histopathological changes. No gross or microscopic lesions attributable to resorcinol adminsteration were observed.
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	許容できる良好に文書化され、科学的原理を満たす試験	Acceptable, well-documented study which meets scientific principles
出典		
引用文献(元文献)	(233) (234)	(233) (234)
備考	基本的なデータを提供する。後に続く13週間及び2年間の生物試験はGLPで行われたが、その前の2週間の用量設定試験。	Provides basic data. Two week range finding study in which the subsquent 13 week and 2 yr bioassay were conducted under

試験物質名	1.1 - 1.4の記述どおり	as prescribed by 1.1 - 1.4
CAS番号		
純度等	純度>99%	purity >99%
注釈		
方法		
方法/ガイドライン	OECD 408と同等	other: comparable to OECD 408
GLP適合	はい	yes
試験を行った年	1981	1981
試験系(種/系統)	mouse/B6C3F1	mouse/B6C3F1
性別(雄:M、雌:F)	雌雄	male/female
投与量	0, 28, 56, 112, 225, 420 mg/kg/bw	0, 28, 56, 112, 225, 420 mg/kg/bw
各用量群(性別)の動物数		
溶媒(担体)		
投与経路	強制経口	gavage
対照群に対する処理		
投与期間(日)(OECD422等で、投与期間のデータ等がある場合、最長投与期間)	13週間	13 weeks
投与頻度	1回/日、5日/週	Once a day 5 days a week
回復期間(日)		
試験条件		
統計学的処理		
結果		
体重、体重増加量		
摂餌量、飲水量		
臨床所見(重篤度、所見の発現時期と持続時間)		
眼科学的所見(発生率、重篤度)		
血液学的所見(発生率、重篤度)		
血液生化学的所見(発生率、重篤度)		
尿検査所見(発生率、重篤度)		
死亡数(率)、死亡時間		
剖検所見(発生率、重篤度)		
臓器重量		
病理組織学的所見(発生率、重篤度)		
実際に摂取された量		

用量反応性		
注釈		
結論		
NOAEL (NOEL)	NOAEL は報告書の中では判明しなかった。入手可能な情報及びNTPレビューパネルの結論に基づき、NOAELは以下の通りと判断される: NOAEL(雄) = 最高用量の420 mg/kg bwで生じた呼吸困難、疲憊、及び振戦に基づき、225 mg/kg bw。420 mg/kg bwでは死亡例の発現。 NOAEL(雌) = 最高用量の420 mg/kg bwで生じた呼吸困難、疲憊、及び振戦に基づき、225 mg/kg bw。420 mg/kg bwでは死亡例の発現。	A NOAEL was not identified within the report. Based on available information and the conclusions of the NTP review panel, the NOAEL's appear to be as follows: NOAEL(males) = 225 mg/kg bw based on dyspnea, prostration, and tremors occuring at the highest dose of 420 mg/kg bw. Mortality at 420 mg/kg bw. NOAEL(Females) = 225 mg/kg bw based on dyspnea, prostration, and tremors occuring at the highest dose of 420 mg/kg bw. Mortality at 420 mg/kg bw.
LOAEL (LOEL)		
NOAEL/LOAELの推定根拠		
雌雄のNOAEL(LOAEL)の違い等		
注釈	420 mg/kgを投与された雌雄のマウスの8匹が試験4週までに化合物に関連した毒性により死亡した。これらの死亡例のうち2例を除く全例が第1週の間に死亡した。112 mg/kgを投与された雄1例の死亡は投与過誤によるものであった。高用量の生存雄マウス2例の最終平均体重は対照群よりも有意に低値であった。他の全ての投与したマウスの最終平均体重及び平均体重の変化量は対照群の値と同程度であった。高用量の動物で記録された毒性の臨床症状は呼吸困難、疲憊、及び振戦であった。臨床症状は全般的に投与後30分以内に出現した。28、56、112及び225 mg/kgを投与された雄では副腎の絶対及び相対重量に有意な減少が認められた。様々な臓器重量におけるその他のいくつかの差が試験群間に散見されたが、生物学的に意義があると考えられるものはなかった。血液検査、または臨床化学パラメータにおける物質に関連した生物学的に有意な変化はみられなかった。物質に関連した肉眼的ないし顕微鏡的病変はいずれも観察されなかった。	Eight mice of each sex receiving 420 mg/kg died by week 4 of the studies from compound-related toxicity. All except two of these deaths occurred during the first week. The death of one male receiving 112 mg/kg was due to improper gavage. The final mean body weight of the two surviving high-dose male mice was significantly less than controls. The final mean body weights and changes in mean body weights in all other dosed mice were similar to those of the controls. Clinical signs of toxicity recorded for the high-dose animals included dyspnea, prostration, and tremors. Clinical signs generally appeared within one-half hour of dosing. Significant decreases were noted in absolute and relative adrenal gland weights for males receiving 28, 56, 112 and 225 mg/kg. A few other differences in various organ weights were scattered among the study groups, but none were considered biologically significant. No chemical-related, biologically significant changes in hematology or clinical chemistry parameters were seen. No chemical related gross or microscopic lesions were observed.
信頼性	(1) 制限なく信頼性あり	(1) valid without restriction
信頼性の判断根拠	ガイドライン試験に類似	Similar to a guideline study
出典		
引用文献(元文献)	(233) (234)	(233) (234)
備考		

5-6 *in vitro*遺伝毒性
GENETIC TOXICITY IN VITRO

A. 遺伝子突然変異
GENE MUTATION

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈	Resorcinol >95%	Resorcinol >95%
方法		
方法／ガイドライン	エームス試験	Ames test
	OECDガイドライン471	OECD Guide-line 471
GLP適合	適合	Yes
試験を行った年	2005年	2005
細胞株又は検定菌	Salmonella typhimrium TA98, TA100, TA1535, TA1537, TA102	Salmonella typhimrium TA98, TA100, TA1535, TA1537, TA102
代謝活性化(S9)の有無	有及び無	with and without
試験条件	原文参照	Test concentration : up to 5000 ug/plate. OECD Guideline 471 (adopted 1997), EEC Annex 4D Test B13/14 (2000), UKEMS Guidelines (1990) and ICH Harmonised Tripartite Guideline (1997). This study was performed according to the protocol, with the exception of minor deviations detailed below, none of which in any way prejudiced the validity of this study. Deviations from Protocol: Subject Deviation Analysis of Results Acceptance criteria Following Experiment 2, the mean solvent control value for TA1537 in the presence of S-9 was above the laboratory's historical range. However, counts were considered comparable to the range and data was accepted as valid. Materials Test Article The crude test compound was not stored under nitrogen as stated in the protocol. Following discussions with the sponsor this deviation was not considered to affect stability of the test compound and therefore the study integrity was not affected.

試験条件	原文参照	An initial toxicity range-finder experiment was carried out in strain TA100 only in the absence and presence of S-9, using final concentrations of Resorcinol (AO11) at 1.6, 8, 40, 200, 1000 and 5000 mg/plate, plus negative (solvent) and positive controls. In experiment 2, treatments of all the test strains were performed up to 5000 µg/plate. In each case narrowed dose intervals were used to comprise the remaining test doses (dose ranges of 3.2768 to 5000 µg/plate for strain TA102 in the absence of S-9 only and 51.2 to 5000 µg/plate for all other treatments), in order to more closely investigate those doses of Resorcinol (AO11) approaching the limit dose levels, and therefore considered most likely to provide evidence of any mutagenic activity. In addition, treatments in the presence of metabolic activation were further modified by the inclusion of a pre-incubation step, and in this way the range of mutagenic chemicals that can be detected in this assay system was increased.
結果		
細胞毒性		
代謝活性ありの場合	5000 ug/plate	5000 ug/plate
代謝活性なしの場合	5000 ug/plate	5000 ug/plate
変異原性		
代謝活性ありの場合	陰性	negative
代謝活性なしの場合	陰性	negative
注釈	原文参照	In the range finding study, TA100, evidence of toxicity was observed at the highest dose level in the absence and presence of S-9 and was manifest as a marked decrease in revertant numbers. These results were considered to be acceptable for mutation assessment and are used to comprise the TA100 mutagenicity data for Experiment 1. Treatments of the remaining test strains (TA98, TA1535 and TA102) in Experiment 1 retained the same test doses employed for the range-finder experiment treatments. Following these treatments, no evidence of toxicity was observed. In experiment 2, evidence of toxicity in the form of a marked decrease in revertant numbers and/or a thinning of the background lawn was observed at the highest test dose for strains TA98 and TA1535 in the absence of S-9 and strains TA98 and TA102 in the presence of S-9.
注釈	原文参照	Stastical significance: Following Experiment 1 a statistically significant increase in revertants was observed at a single dose level for strains TA1537 and TA102 in the absence of S-9 when data were analysed at the 1% level using Dunnett's test. However, these increases showed no evidence of a dose response, and were not reproducible in Experiment 2. Therefore it is considered that the increases in revertant numbers were due to a chance event and not indicative of Resorcinol (AO11) mutagenic activity. No statistically significant, dose-related and reproducible increases in revertant numbers were observed following any other strain treatments in the absence or presence of metabolic activation, and therefore this study was considered to have provided no clear evidence of any Resorcinol (AO11) mutagenic activity. Controls: Negative (solvent) and positive control treatments were included for all strains in both experiments. The mean numbers of revertant colonies on negative control plates all fell within acceptable ranges, and were significantly elevated by positive control treatments.
結論		
遺伝子突然変異	陰性	negative
注釈	この試験条件下で、Resorcinol (AO11)はヒスチジン要求性のネズミチフス菌5菌株(TA98, TA100, TA1535, TA1537 and TA102)に突然変異を誘発しなかった。本試験条件はラット肝代謝活性化の有無で5000 mg/plate以下の用量での処理を含んだ。	It was concluded that Resorcinol (AO11) did not induce mutation in five histidine-requiring strains (TA98, TA100, TA1535, TA1537 and TA102) of Salmonella typhimurium when tested under the conditions of this study. These conditions included treatments at concentrations up to 5000 mg/plate, in the absence and in the presence of a rat liver metabolic activation system (S-9).
信頼性	(1)制限なしに有効	(1) valid without restriction
信頼性の判断根拠	ガイドライン試験	Guideline Study
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	Covance Laboratories (2005) Resorcinol (AO11) Reverse mutation in five histidine-requiring strains of Salmonella typhimurium. Study number 413/67-D6171. Study Sponsor: L'Oreal.	Covance Laboratories (2005) Resorcinol (AO11) Reverse mutation in five histidine-requiring strains of Salmonella typhimurium. Study number 413/67-D6171. Study Sponsor: L'Oreal.
備考	フラグ : SIDSエンドポイントの重要な試験	Flag : Critical study for SIDS endpoint

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈		
方法		
方法／ガイドライン	エームス試験	Ames test
	他	other
GLP適合	情報無し	no data
試験を行った年	1981年	1981
細胞株又は検定菌	Salmonella typhimurium TA 98, TA 100, TA 1535, TA 1537, TA 1538	Salmonella typhimurium TA 98, TA 100, TA 1535, TA 1537, TA 1538
代謝活性化(S9)の有無	有及び無	with and without
試験条件	原文参照	Test concentration : up to 5500 ug/plate. Experiments with Salmonella Strains TA98, TA100, TA1535, TA1537 and TA1538 were conducted at concentrations up to 5.5mg/plate in the presence and absence of Aroclor-1254 induced rat-liver microsomes (S9 mix).
結果		
細胞毒性		
代謝活性ありの場合	情報無し	no data
代謝活性なしの場合	情報無し	no data
変異原性		
代謝活性ありの場合	陰性	negative
代謝活性なしの場合	陰性	negative
注釈		
結論		
遺伝子突然変異	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	データは信頼できる二次情報からのものである。	Data are from reliable secondary literature.
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	Bracher M, Wisak J, Noser F (1981) Studies on the potential in vivo inducation of sister chromatid exchanges in rat bone marrow by resorcinol. Mutation Research 91:363-369.	Bracher M, Wisak J, Noser F (1981) Studies on the potential in vivo inducation of sister chromatid exchanges in rat bone marrow by resorcinol. Mutation Research 91:363-369.
備考	前に未公開のBracher et al.からのデータであり、Resorcinolによるラット骨髄のSCEに関する資料に含まれている。	Previously unpublished results from Bracher et al, that are located within the article on SCE in rat bone marrow by Resorcinol.

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈	ResorcinolはRadian Corporation (Austin, TX)からコード分割品として送られた。	Resorcinol sent as a coded aliquot from Radian Corporation (Austin, TX)
方法		
方法／ガイドライン	エームス試験	Ames test
	他	other
GLP適合	情報無し	no data
試験を行った年	1981年	1981
細胞株又は検定菌	Salmonella typhimrium TA98, TA100, TA1535, TA1537	Salmonella typhimrium TA98, TA100, TA1535, TA1537
代謝活性化(S9)の有無	有及び無	with and without
試験条件	原文参照	Test concentration : 0, 33, 100, 333, 1000, 3333 µg/plate. The chemical was tested using the pre-incubation procedure of the Salmonella Assay as described by Yangi et al (1975). At least five doses of test chemical, in addition to the concurrent solvent and positive controls. were tested on each strain in the presence of S-9 mix or buffer. Three plates were used, and the experiment was repeated no less than 1 week after completion of the initial test. To select the dose range for the mutagenicity assay, the test chemicals were checked for toxicity to TA100 up to a concentration of 10 mg/plate or the limit of solubility, both in the presence and absence of S-9 mix. One or more parameters were used as an indication of toxicity: viability on complete medium (EGG) and reduced numbers of revertant colonies per plate and/or thinning or absence of the bacterial lawn If toxicity was not apparent in the preliminary toxicity determination, the highest dose tested was 10 mg/plate: otherwise the upper limit of solubility was used. If toxicity was observed, the doses of test chemical were chosen so that the high dose exhibited some degree of toxicity. Occasionally, in the earlier tests the high dose was greater than 10 mg/plate.

		S9 was prepared from Sprague-Dawley rats (RL1) and Syrian Hamsters (HL1) that were injected (i.p.) with Aroclor 1254 (200 mg/L in corn oil) at 500 mg/kg. Five days after injection the animals were sacrificed by cervical dislocation. The solvent of choice was distilled water unless the substance was insoluble, in this case, DMSO was selected. Ethanol or actetone was used in case the substance was not soluble in DMSO.
結果		
細胞毒性		
代謝活性ありの場合	情報無し	no data
代謝活性なしの場合	情報無し	no data
変異原性		
代謝活性ありの場合	陰性	negative
代謝活性なしの場合	陰性	negative
注釈	Resorcinolは、Aroclor 1254で誘導した雄SDラットあるいはシリアンハムスターの肝S9の有無で、プレインキュベーション法によりネズミチフス菌4菌株で試験した場合、33 から3,333 μg/plateの用量範囲で、そのいずれにおいても遺伝子突然変異を誘発しなかった。	Resorcinol at doses from 33 to 3,333 µg/plate did not induce gene mutations in any of the four strains of Salmonella typhimurium when tested with a preincubation protocol in the presence and absence of Aroclor 1254-induced male Sprague-Dawley rat or Syrian hamster liver S9.
結論		
遺伝子突然変異	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	ガイドライン試験に類似、GLPについては情報無し。ネズミチフス菌の試験はCase Western Reserve University (CWR)で実施された。	Similar to a guideline study, no data regarding GLP. The salmonella test was conducted by Case Western Reserve University (CWR).
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	National Toxicology Program (NTP) (1992) Technical Report on the Toxicology and Carcinogenesis Studies of Resorcinol (CAS No. 108-46-3) in F344/N Rats and B6C3F1 Mice (Gavage Studies) NIH Publication No. 91-2858 Technical report TR403.	National Toxicology Program (NTP) (1992) Technical Report on the Toxicology and Carcinogenesis Studies of Resorcinol (CAS No. 108-46-3) in F344/N Rats and B6C3F1 Mice (Gavage Studies) NIH Publication No. 91-2858 Technical report TR403.
備考	フラグ:SIDSエンドポイントの重要な試験	Flag : Critical study for SIDS endpoint

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈		
方法		
方法／ガイドライン	エームス試験	Ames test
	他:ガイドライン試験に類似	other: Similar to a guideline study
GLP適合	情報無し	no data
試験を行った年	1980年	1980
細胞株又は検定菌	Salmonella typhimrium TA 98, TA 100, TA 1535, TA 1537, TA 1538	Salmonella typhimrium TA 98, TA 100, TA 1535, TA 1537, TA 1538
代謝活性化(S9)の有無	有及び無	with and without
試験条件	原文参照	Test concentration : 5-1000 ug/plate. 5-1000 µg/plate, 3 plates/concentration, independent repetition.
結果		
細胞毒性		
代謝活性ありの場合	情報無し	no data
代謝活性なしの場合	情報無し	no data
変異原性		
代謝活性ありの場合	陰性	negative
代謝活性なしの場合	陰性	negative
注釈	細胞毒性の範囲では代謝活性化の有無に関わらず陰性を含まない。	Cytotoxic range not included negative for both with and without metabolic activation.
結論		
遺伝子突然変異	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	ガイドライン試験に類似、GLPについては情報無し。	Similar to a guideline study, no data regarding GLP
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	Shahin MM, Bugaut A, Gilard P, Kalopissis G (1980) Studies n the mutagenicity of resorcinol and hydroxy-3-(p-amino)anilino-6,N-[9p-amino)phenol] benzoquinone-monoimine-1,4 in Salmonella typhimurium. Mutation Research 78:213-218.	Shahin MM, Bugaut A, Gilard P, Kalopissis G (1980) Studies n the mutagenicity of resorcinol and hydroxy-3-(p-amino)anilino-6,N-[9p-amino)phenol] benzoquinone-monoimine-1,4 in Salmonella typhimurium. Mutation Research 78:213-218.
備考		

試験物質名	resorcinol	resorcinol

CAS番号	108-46-3	108-46-3
純度等		
注釈	Resorcinol はMerck Co. (Germany)から入手した。	Resorcinol was obtained from the Merck Co. (Germany)
方法		
方法／ガイドライン	エームス試験	Ames test
	他:ガイドライン試験に類似	other: Similar to a guideline study
GLP適合	情報無し	no data
試験を行った年	1981年	1981
細胞株又は検定菌	Salmonella typhimrium TA98, TA100, TA1535, TA1537, TA1538	Salmonella typhimrium TA98, TA100, TA1535, TA1537, TA1538
代謝活性化(S9)の有無	有及び無	with and without
試験条件	原文参照	Test concentration : up to 3600 ug/plate. Concentration up to 3600 µg/plate; in ZLM medium: Tests were done following standard procedures. In the Ames Assay, at least 5 doses usually up to 3600 ug/plate for non toxic and soluble compounds were tested in all five strains with and without activation using the S9 liver fraction from Aroclor-pretreated rats. All compounds were treated on 2 slightly different different minimal media, one (in the following named ZLM medium) is a modified minimal medium for e.coli and the other is the Vogel-Bonner (VB) medium. ZLM contained (in g/L): tri-Nacitrate. 2H2O tri-Nacitrate-2H2O (0.82),K2HPO4.3H20 (4.60),KH2PO4 (1.50),(NH4)2SO4(1.00), MgSO4.7H2O (0.10) and glucose(17.0).The concentration of citrate was 3.5 times higher in VB medium than in ZLM medium. The concentrations of the other ions are up to 2-fold higher in VB medium.
結果		
細胞毒性		
代謝活性ありの場合	情報無し	no data
代謝活性なしの場合	情報無し	no data
変異原性		
代謝活性ありの場合	陽性	positive
代謝活性なしの場合	陽性	positive
注釈	個別の試験結果は原文参照。	Positive in TA 100 (without activation) and TA1535 (with activation) TA100: (-)S9 positive, (+)S9 ambiguous on the ZLM medium TA1535: -S9 negative, (+)S9 positive on the ZLM medium In other strains: negative
結論		
遺伝子突然変異	陽性	positive
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	ガイドライン試験に類似、GLPについては情報無し。	Similar to a guideline study, no data regarding GLP
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	Gocke E, King MT, Eckhardt K, Wild D (1981) Mutagenicity of cosmetics ingredients. Mutation Research 90:91-109.	Gocke E, King MT, Eckhardt K, Wild D (1981) Mutagenicity of cosmetics ingredients. Mutation Research 90:91-109.
備考		

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等	純度: 99%	Purity: 99%
注釈		
方法		
方法／ガイドライン	エームス試験	Ames test
	other: no data	other: no data
GLP適合	情報無し	no data
試験を行った年	1984年	1984
細胞株又は検定菌	Salmonella typhimurium TA 98, TA 100, TA 1535, TA 1537	Salmonella typhimurium TA 98, TA 100, TA 1535, TA 1537
代謝活性化(S9)の有無	有	with
試験条件	原文参照	Test concentration : 200-5000 ug/plate. 200 - 5000 ug/Plate; 3 Plates/concentration; 1 independent repetition A urinary mutagenic assay was conducted in conjunction with standard plate incorporation assay with raw materials. Each of the S. typhimurium strains (TA 98, 100, 1535 and 1537) were assayed in the plate incorporation assay in the presence of S9 from Aroclor induced male Sprague Dawley rats. Resorcinol was evaluated at a range of concentrations up to the maximum tolerated dose. Each determination was made in triplicate and repeated at least once. 2-aminoanthracene, sodium azide and 4-nitro-o-phenylenediamine were used as positive controls. DMSO was used as a solvent.
結果		

細胞毒性		
代謝活性ありの場合	情報無し	no data
代謝活性なしの場合		
変異原性		
代謝活性ありの場合	陰性	negative
代謝活性なしの場合		
注釈	陰性(プレート法) 陽性対照は正常範囲内の値	Negative (raw material plate incorporation assay). Postive controls were within normal ranges.
結論		
遺伝子突然変異	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	基本的なデータを与える。標準法が使用されている(resorcinolの部分のみ)	Provides basic data. Standard method used. (resorcinol raw material portion only).
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	・Crebelli R, Falcone E, Aquilina G, Carere A (1984) Mutagenicity studies in a tyre plant: in vitro activity of workers' urinary concentrates and rubber chemicals. IARC Scientific Publications 59:289-295. ・Crebelli R, Paoletti A, Falcone E, Aquilina G, Fabri G, Carere A (1985) Mutagenicity studies in a type plant: in vitro activity of workers' urinary concentrates and raw materials. British Journal of Industrial Medicine 42:481-487.	・Crebelli R, Falcone E, Aquilina G, Carere A (1984) Mutagenicity studies in a tyre plant: in vitro activity of workers' urinary concentrates and rubber chemicals. IARC Scientific Publications 59:289-295. ・Crebelli R, Paoletti A, Falcone E, Aquilina G, Fabri G, Carere A (1985) Mutagenicity studies in a type plant: in vitro activity of workers' urinary concentrates and raw materials. British Journal of Industrial Medicine 42:481-487.
備考		

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈	ResorcinolはRadian Corporation (Austin, TX)からコード分割品として送られた。	Resorcinol sent as a coded aliquot from Radian Corporation (Austin, TX)
方法		
方法/ガイドライン	マウスリンフォーマ試験	Mouse lymphoma assay
	他法: McGregor et al (1988) and Clive et al (1979)	other: McGregor et al (1988) and Clive et al (1979)
GLP適合	情報無し	no data
試験を行った年	1988年	1988
細胞株又は検定菌	L 5178Y TK +/-	L 5178Y TK +/-
代謝活性化(S9)の有無	無	without
試験条件	原文参照	Test concentration : 0, 156.25, 312.5, 625, 1250, 2500, 5000 μg/ml. The experiment consisted of the following groups: a vehicle control, four cultures; positive control, two cultures; at least five test compound concentations, two cultures per concentration. The first experiment was a toxicity test in which cell population expansion was measured. The toxicity test was followed by at least two experiments in the absence of S9 mix. Test compound concentrations were primarily two-fold dilutions form the highest testable concentration, as estimated from the toxicity test. Trial 1 had the following concentrations: 0, 125, 250, 500, 1000 and 2000 ug/ml. Trial 2 had the following concentrations: 0, 156.2, 312.5, 625, 1250 2500 and 5000 ug/ml. Trial 3 had the following concentrations: 0, 156.2, 312.5, 625, 1250, 2500and 5000 ug/ml. The highest concentration of the study compound was determined by solubility or toxicity, and did not exceed 5 mg/mL. Mouse lymphoma L5178Y cells were maintained at 37° C as suspension cultures in Fischer's medium supplemented with 2 mM 1-glutamine, 110 μg/mL sodium pyruvate, 0.05% pluronic F68, antibiotics, and heat-inactivated horse serum; normal cycling time was about 10 hours.
		To reduce the number of spontaneously occurring trifluorothymidine (TFT) resistant cells, subcultures were exposed once to medium containing THMG (thymidine, hypoxanthine, methotrexate, glycine) for one day, to THG for one day, and to normal medium for 3 to 5 days. For cloning, horse serum content was increased and Noble agar was added. All treatment levels within an experiment, including concurrent positive and solvent controls, were replicated. Treated cultures contained 6 x 10+6 cells in a 10 mL volume of medium. This volume included the S9 fraction in those experiments performed with metabolic activation. Incubation with study chemical continued for 4 hours, at which time the medium plus chemical was removed and the cells were resuspended in 20 ml of fresh medium and incubated for an additional 2 days to express the mutant phenotype.

試験条件	原文参照	Cell density was monitored so that log phase growth was maintained. After the 48 hour expression period, 3 x 10+6 cells were plated in medium and soft agar supplemented with TFT for selection of TFT-resistant cells (TK), and 600 cells were plated in nonselective medium and soft agar to determine cloning efficiency. Plates were incubated at 37° C in 5% CO2, for 10 to 12 days. All data were evaluated statistically for both trend and peak response. Both responses had to be significant (P<0.05) for a chemical to be considered capable of inducing TFT-resistance; a single significant response led to a "questionable" conclusion, and the absence of both a trend and a peak response resulted in a "negative" call. Controls: EMS at a concentration of 250 ug/ml was used in the resorcinol trials. Vehicle controls: Distilled water was used in the resorcinol trials. Statistical Analysis was based upon the mathematical model proposed for this system and consisted of a dose-trend test and a variance analysis of pair-wise comparisons of each dose against the vehicle control.
結果		
細胞毒性		
代謝活性ありの場合		
代謝活性なしの場合	5000	5000
変異原性		
代謝活性ありの場合		
代謝活性なしの場合	陽性	positive
注釈	原文参照	Significant mutagenic activity was demonstrated in three experiments in the absence of S9. There was a reproducible tendency for the mutant fraction to fall at high concentrations, an effect that is not normally observed in this assay. In the first trial resorcinol was positive at concentrations of 250, 500 and 1000 ug/ml. In the second trial resorcinol was positive at concentrations of 312.5, 625 and 1250 ug/ml and cytotoxic at 5000 ug/ml. In the third trial resorcinol was positive at concentrations of 156.2, 312.5, 625, 1250 and 2500 ug/ml and cytotoxic at 5000 ug/ml. Resorcinol was not tested with S9.
結論		
遺伝子突然変異	陽性	positive
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	ガイドライン試験、GLPに関し情報無し。	Guideline study; No data regarding GLP
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	・McGregor DB Brown A, Cattanach P, Edwards I, McBride D, Caspary WJ (1988) Responses of the L5178Y TK+/TK- mouse lymphoma cell forward mutation assay. II: 18 coded chemicals. Environmental and Molecular Mutagenesis 11:91-118. ・McGregor DB et al (1988) Environmental and Molecular Mutagenesis 11:523-544. ・National Toxicology Program (NTP) (1991) Toxicology and Carcinogenesis Studies of Resorcinol (CAS No. 108-46-3) in F344/N Rats and B6C3F1 Mice. (Gavage Studies). Draft TR403. ・National Toxicology Program (NTP) (1992) Technical Report on the Toxicology and Carcinogenesis Studies of Resorcinol (CAS No. 108-46-3) in F344/N Rats and B6C3F1 Mice (Gavage Studies) NIH Publication No. 91-2858 Technical report TR403.	・McGregor DB Brown A, Cattanach P, Edwards I, McBride D, Caspary WJ (1988) Responses of the L5178Y TK+/TK- mouse lymphoma cell forward mutation assay. II: 18 coded chemicals. Environmental and Molecular Mutagenesis 11:91-118. ・McGregor DB et al (1988) Environmental and Molecular Mutagenesis 11:523-544. ・National Toxicology Program (NTP) (1991) Toxicology and Carcinogenesis Studies of Resorcinol (CAS No. 108-46-3) in F344/N Rats and B6C3F1 Mice. (Gavage Studies). Draft TR403. ・National Toxicology Program (NTP) (1992) Technical Report on the Toxicology and Carcinogenesis Studies of Resorcinol (CAS No. 108-46-3) in F344/N Rats and B6C3F1 Mice (Gavage Studies) NIH Publication No. 91-2858 Technical report TR403.
備考	フラグ:SIDSエンドポイントの重要な試験	Flag : Critical study for SIDS endpoint

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等	純度>95%	>95% purity
注釈	Resorcinol (AO11)	Resorcinol (AO11)
方法		
方法／ガイドライン	他:チミジンキナーゼ遺伝子座	other: thymidine kinase locus
	OECDガイドライン476	OECD Guide-line 476
GLP適合	適合	Yes
試験を行った年	2004年	2004
細胞株又は検定菌	L5178Y マウスリンフォーマ細胞	L5178Y mouse lymphoma cells
代謝活性化(S9)の有無	有及び無	with and without

試験条件	原文参照	Test concentrations: 5, 6, 7, 8, 9, and 10 mM (with out S9, Experiments 1 and 2) 0.313, 0.625, 1.25, 2.5, 5 and 10 mM (with S9 Experiment 1) 5, 6, 7, 8, 9 and 10 mM (with S9 Experiment 2) In the Preliminary Toxicity test: The test item was freely soluble in the vehicle (DMSO) at 220 mg/mL. In the culture medium, the dose-level of 10 mM (corresponding to 1100 µg/mL) showed no precipitate. At this dose-level, the pH was 7.1 (as for the vehicle control) and the osmolality equal to 386 mOsm/kg H2O (389 for the vehicle control). Consequently, with a dose volume of 100 µL/20 mL culture medium, the treatment-levels for the preliminary toxicity test were: 0.02, 0.2, 1, 2, 5 and 10 mM. No precipitate was observed at the end of the treatment period at any dose-level. First Experiment: Since the test item was not severely toxic and freely soluble in the preliminary test, the highest dose-level was 10 mM, according to the criteria specified in the international guidelines. Experiments without S9 mix: First Experiment: 5, 6, 7, 8, 9 and 10 mM Second Experiment: 5, 6, 7, 8, 9 and 10 mM.
試験条件	原文参照	Experiment with S9 mix: First experiment: 0.313, 0.625, 1.25, 2.5, 5 and 10 mM. Second experiment: 5, 6, 7, 8, 9 and 10 mM. Cytotoxicity was measured by assessment of adjusted relative total growth (Adj. RTG) and relative suspension growth (Adj. RSG) as well as cloning efficiency following the expression time (CE2). The number of mutant clones (differentiating small and large colonies) were checked after the expression of the mutant phenotype. Vehicle: The test item was dissolved in dimethylsulfoxide (DMSO). Positive Controls: The dose-levels for the positive controls were as follows: Without S9 mix: methylmethane sulfonate (MMS), used at a final concentration of 25 µg/mL, With S9 mix: cyclophosphamide (CPA), used at a final concentration of 3 µg/mL.
結果		
細胞毒性		
代謝活性ありの場合		
代謝活性なしの場合		
変異原性		
代謝活性ありの場合	陽性	positive
代謝活性なしの場合	陽性	positive
注釈	原文参照	Preliminary Toxicity Study: Without S9: Following the 3-hour treatment without S9 mix, a moderate to marked toxicity was noted at dose-levels = 1 mM (50-75% decrease in adjusted relative suspension growth (Adj. RSG) and up to 50-69% decrease in adjusted relative total growth (Adj. RTG)). Main study: Without S9: In both experiments, a moderate to marked toxicity was noted at all dose-levels as shown by 54-76% decrease in Adj. RSG and 46-83% decrease in Adj. RTG. Noteworthy increases in the mutation frequency (up to 4.8-fold the vehicle control value) were observed following the 3-hour treatment in both experiments. With S9: A slight to marked toxicity was observed at dose-levels = 5mM, as shown by 30-78% decrease in Adj. RSG and 28-65% decrease in Adj. RTG In the First experiment: a slight increase in the mutation frequency was noted at the dose-level of 10 mM. Since this very slight increase which did not reach the 2-fold level was neither dose-related nor reproducible in the second experiment, it was not considered as biologically relevant.
結論		
遺伝子突然変異	陽性	positive
注釈	マウスリンフォーマ試験の条件下で、代謝活性化無しの場合、Resorcinol (A011) は変異原性を誘発した。	Under these experimental conditions, Resorcinol (A011) induced mutagenic activity in the mouse lymphoma assay, without metabolic activation (S9 mix)
信頼性	(1)制限なしに有効	(1) valid without restriction
信頼性の判断根拠	ガイドライン試験	Guideline study
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	CIT (2004) In Vitro Mammalian Cell Gene Mutation Test in L5178Y TK+/- Mouse Lymphoma Cells. Study number 27065 MLY RCS, Evreux, France. Study sponsor: L'Oreal.	CIT (2004) In Vitro Mammalian Cell Gene Mutation Test in L5178Y TK+/- Mouse Lymphoma Cells. Study number 27065 MLY RCS, Evreux, France. Study sponsor: L'Oreal.
備考	フラグ:SIDSエンドポイントの重要な試験	Flag : Critical study for SIDS endpoint

B. 染色体異常
CHROMOSOMAL ABBERATION

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈	被験物質はSigma Chemical Co.から入手した。	Test substance was obtained from Sigma Chemical Co.
方法		
方法／ガイドライン	染色体異常試験、 他法	Cytogenetic assay, other
GLP適合	情報無し	no data
試験を行った年	1981年	1981
細胞株	チャイニーズハムスター卵巣細胞(CHO)	Chinese hamster ovary cells (CHO)
代謝活性化(S9)の有無	有及び無	with and without
試験条件	原文参照	Test concentration : 1600 ug/ml. Resorcinol was assesed with other simple phenols to determine its clastogenic activity in Chinese hamster ovary (CHO) cells with and without the addition of an S9 mixture, Cu2+ (10-4M) and Mn2+ (10-4 M). This was part of a study assessing the genotoxic activity of naturally occuring food components (in plants.) Solutions were prepared by dissolving the compounds in 2.5% MEM at 37C and adjusting the pH to 7.4. Preparation of metal solutions: Solutions of cupric sulfate (0.1M), manganese chloride (0.1M) and glycine (0.5 M) were prepared in distilled water. Stock solutions of the chelated metals were then made by mixing glycine with the metal stock at a 10:1 molar ratio, followed by dilution with 2.5% MEM.
試験条件	原文参照	Approximately 140,000 CHO cells were seeded on 22-mm2 coverslips in 3.5-cm plastic dishes and kept in MEM with 10% fetal calf serum at 37C for 2-3 days. Experiments were begun when cells were 40 - 60% confluent. The tissue culture medium was removed from the petri dishes and replaced with 1ml of the phenolic acid solution. For tests involving the influence of the S9 preparation or metal solutions on the clastogenic activity of the phenolic acid, 0.5-ml aliquots of these mixtures were added to each petri dish prior to addition of 0.5 ml of the phenolic acid. The S9 preparation was prepared with livers (300 ul/ml S9 mix) from Aroclor 1254-pretreated Fischer male rats. Following a 3-h exposure time, this medium was removed, the coverslips washed with MEM, and fresh MEM, with 10% fetal calf serum added to the petri sidhes. For estimating the frequency of chromosome aberrations, 0.1 ml of colchiicine (0.01% in 2.5% MEM) was added at 16 h post-exposure to the chemicals and left for 4 h. Cells were then treated with 1% sodium citrate solution for 20 min, followed immediately with fixation in ethanol/acetic acid (3:1) for 20 min. Air dried slides were stained with 2% orcein in 50% acetic acid/water, dehydrated and mounted. For each sample 200 metaphase plates were analyzed for chromosome aberrations. The frequency of 2 types of chromosome aberrations were estimated: (a) chromatid breaks; (b) chromatid exchanges. Chromatid exchanges occurred between homologous and non-homologous chromosomes and between 2 or more chromosomes.
結果		
細胞毒性		
代謝活性ありの場合	情報無し	no data
代謝活性なしの場合	情報無し	no data
染色体異常		
代謝活性ありの場合	陽性	positive
代謝活性なしの場合	陽性	positive

注釈	原文参照	All dihydroxylated (resorcinol) and trihydroxylated phenolics induced chromatid breaks and exchanges. The introduction of a methyl group seems to reduce the clastogenic capacity. The addition of an S9 mixture or the transition metals Cu2+ and Mn2+ enhanced the chromosome-damaging activity in some phenolics and suppressed it in others. Results with Resorcinol: Clastogenic Activity in CHO cells: At a concentration of 1.6 mg/ml, % metaphases with chromosome aberrations: (-) S9 is 14.4 and (+) S9 is 13.5; chromatid breaks per cell: (-) S9 is 0.08 and (+) S9 is 0.05; and chromatid exchange per cell: (-) S9 is 0.95 and (+) S9 is 0.52 Effect of Transition Metals on the Clastogenic Activity: At a concentration of 0.8 mg/ml % metaphases with chromsome aberrations No metals: 4.3 (0.08) Cu2+: 4.3 (0.03) Mn2+: 3.2 (0.03)
結論		
染色体異常	陽性	positive
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	基本データを与える。	Provides basic data
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	Stich HF, Rosin MP, Wu CH, Powrie WD (1981) The action of transition metals on the genotoxicity of simple phenols, phenolic acids and cinnamic acids. Cancer Letters 14:251-260.	Stich HF, Rosin MP, Wu CH, Powrie WD (1981) The action of transition metals on the genotoxicity of simple phenols, phenolic acids and cinnamic acids. Cancer Letters 14:251-260.
備考		

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈	Resorcinol は純度99.5%以上でL'Oreal Parisから供給された。試験結果は純化されたresorcinol 試料からのものである。	Resorcinol was supplied by L'Oreal Paris with a purity of at least 99.5% or greater. These results are from a purified resorcinol sample.
方法		
方法／ガイドライン	染色体異常試験、 他法	Cytogenetic assay, other
GLP適合	情報無し	no data
試験を行った年	1983年	1983
細胞株	ヒト末梢血リンパ球	Peripheral human lymphocytes
代謝活性化(S9)の有無	無	without
試験条件	原文参照	Test concentration : 0, 20, 60 and 100 µg/ml (0, 0.002, 0.006 and 0.01%). 200 metaphases assessed/concentration (pooled data from 2 experiments (repeats). 100/metaphases assessed/concentration/experiment. This is a repeat of the previous experiment with the following exceptions: A new purified sample of resorcinol was used, along with whole blood and isolated cultures of lymphocytes. Previous protocol: Samples of blood (0.5 ml) were cultured in screw-capped bottles containing 5 ml medium (Ham's F10, inactivated calf serum, PHA, L-glutamine 200 mM, hparin and penicillin (100 U/ml) + streptomycin (100 ug/ml)). The mixtures were incubated at 37C for 48 and 72 h for evaluating the frequencies of chromosomal aberrations. Resorcinol was dissolved in sterile water and then added to the medium to give final concentrations of 0, 0.01, 0.006 and 0.002%. In the chromosomal aberrations study, slides were stained with 2% aqueous Giemsa solution for 6 - 7 minutes. All studies were repeated twice. Data were pooled from the two replicate studies. In a single test, the isolated lymphocytes were treated with resorcinol for 24h. The isolation was performed by Histopaque-1077 and the isolated lymphocytes were fixed at 48 hours after the start of the culture.
結果		
細胞毒性		
代謝活性ありの場合		
代謝活性なしの場合	情報無し	no data
染色体異常		
代謝活性ありの場合		
代謝活性なしの場合	陽性	positive

注釈	2つの繰り返し試験でいずれも明らかなresorcinol の染色体切断の能力が観察された。	In both studies (pooled data from 2 experiments (repeats)) a clear chromosome-breaking ability of resorcinol was observed.
結論		
染色体異常	陽性	positive
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	基本データを与える。データは信頼できる二次情報からのものである。	Provides basic data. Data are from reliable secondary literature.
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	Darroundi F, Natarajan AT (1983) Cytogenetic analysis of uman peripheral blood lymphocytes (in vitro) treated with resorcinol. Mutation Research 124:179-189.	Darroundi F, Natarajan AT (1983) Cytogenetic analysis of uman peripheral blood lymphocytes (in vitro) treated with resorcinol. Mutation Research 124:179-189.
備考		

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈	Resorcinol はRadian Corporation (Austin, TX)からコード分割品として送られた。	Resorcinol sent as a coded aliquot from Radian Corporation (Austin, TX)
方法		
方法／ガイドライン	染色体異常試験、 他法：Galloway et al (1985, 1987)	Cytogenetic assay, other: Galloway et al (1985, 1987)
GLP適合	情報無し	no data
試験を行った年	1981年	1981
細胞株	チャイニーズハムスター卵巣細胞(CHO)	Chinese hamster ovary cells (CHO)
代謝活性化(S9)の有無	有及び無	with and without
試験条件	原文参照	Test concentration : 750, 1000, 1500 and 2000 µg/ml in the absence of S9 mix and 4000, 4500 and 5000 in the presence of S9 mix. In the test without S9, cells were incubated in McCoy's 5A medium with the study chemical for 21 hours; Colcemid was added and incubation continued for 2 to 3 hours. The cells were then harvested by mitotic shake-off, fixed, and stained with Giemsa. For the test with S9, cells were treated with the study chemical and S9 for 2 hours, after which the treatment medium was removed and the cells incubated for 21.8 hours in fresh medium, with Colcemid present for the final 2 hours. Cells were harvested in the same manner as for the treatment without S9. Cells were selected for scoring on the basis of good morphology and completeness of karyotype (21 ± 2 chromosomes). All slides were scored blind and those from a single test were read by the same person. 100 first-division metaphase cells were scored at each dose level. Classes of aberrations included simple (breaks and terminal deletions), complex (rearrangements and translocations), and other (pulverized cells, despiralized chromosomes, and cells containing 10 or more aberrations). Statistical analyses were conducted on both the slopes of the dose response curves and the individual dose points. Data presented as a percentage of the cells with aberrations. Both the dose response curve and individual dose points were statistically analyzed. A statistically significant ($P<0.05$) difference for one dose point was considered weak evidence for a positive response (+w); significant differences for two or more doses indicated the trial was positive (+) (Galloway et al., 1987).
結果		
細胞毒性		
代謝活性ありの場合	情報無し	no data
代謝活性なしの場合	情報無し	no data
染色体異常		
代謝活性ありの場合	陽性	positive
代謝活性なしの場合	あいまいな結果	Equivocal
注釈	ResorcinolはS9無しの場合、染色体異常を誘発したが、その反応は 1000 µg/mlでのみ異常の有意な増加を示しており、equivocal(あいまいな結果)とした。一方、S9有の場合は、3用量全て(4,00, 4,500 and 5000 µg/ml)において、染色体異常の有意な増加が観察された。	Resorcinol induced chromosome aberrations without S-9, the response was equivocal with a significant increase in aberrations only at 1000 µg/ml. With S-9 a signifiacnt increase in aberrations was observed at all three doses (4,00, 4,500 and 5000 µg/ml).
結論		
染色体異常	陽性	positive
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	ガイドライン試験に類似。GLPについては情報無し。	Similar to a guideline study, no data regarding GLP
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009

引用文献(元文献)	・National Toxicology Program (NTP) (1991) Toxicology and Carcinogenesis Studies of Resorcinol (CAS No. 108-46-3) in F344/N Rats and B6C3F1 Mice. (Gavage Studies). Draft TR403. ・National Toxicology Program (NTP) (1992) Technical Report on the Toxicology and Carcinogenesis Studies of Resorcinol (CAS No. 108-46-3) in F344/N Rats and B6C3F1 Mice (Gavage Studies) NIH Publication No. 91-2858 Technical report TR403.	・National Toxicology Program (NTP) (1991) Toxicology and Carcinogenesis Studies of Resorcinol (CAS No. 108-46-3) in F344/N Rats and B6C3F1 Mice. (Gavage Studies). Draft TR403. ・National Toxicology Program (NTP) (1992) Technical Report on the Toxicology and Carcinogenesis Studies of Resorcinol (CAS No. 108-46-3) in F344/N Rats and B6C3F1 Mice (Gavage Studies) NIH Publication No. 91-2858 Technical report TR403.
備考		

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈	Resorcinolは純度99.5%以上でL'Oreal Parisにより供給された。	Resorcinol was supplied by L'Oreal Paris with a purity of at least 99.5% or greater.
方法		
方法／ガイドライン	染色体異常試験、 他法：情報無し	Cytogenetic assay, other: no data
GLP適合	情報無し	no data
試験を行った年	1983年	1983
細胞株	チャイニーズハムスター卵巣細胞(CHO)	Chinese hamster ovary cells (CHO)
代謝活性化(S9)の有無	有及び無	with and without
試験条件	原文参照	Test concentration : 0, 400, 800 and-1600 ug/ml (0, 0.04, 0.08 and 0.16%). 100 metaphases/concentration assessed. Concentrations of 0, 0.04, 0.08 and 0.16% resorcinol were evaluated with and without activation (S9) at 12 and 16 hours post treatment. The S9 homogenate was prepared from livers of male rats pretreated with Aroclor 1254. CHO cells were prelabelled with BrdUrd (5 uM) for one cycle (chromosomes are TB) and then treated for 1 h with resorcinol in the presence of S9 mix. The cells were washed with PBS (phosphate-buffered saline) and allowed to recover in the medium containing BrdUrd (chromosomes will be BB-BT) or thymidine (4 uM) (chromosomes will be TT-TB) for 12 and 16 hours. SCE were scored in the first mitosis after treatment. 2-h colcemid treatment was followed by trypsinization, hypotonic shock (1% sodium citrate) for 10 min at 37C and fixation with methanol:acetic acid (3:1). Air dried preparations were made on ice cold wet slides. Staining was performed with 2% Giemsa solution.
結果		
細胞毒性		
代謝活性ありの場合	情報無し	no data
代謝活性なしの場合	情報無し	no data
染色体異常		
代謝活性ありの場合	陰性	negative
代謝活性なしの場合	陰性	negative
注釈	陰性。ラット肝ホモジェネート(S9 mix)の有無で被験物質用量0.16% (1600 ug/ml)以下のresorcinolで処理したCHO細胞は、染色体異常頻度で判定される変異原性を発現しなかった。	Negative. Treatment of CHO cells with resorcinol up to a concentration of 0.16% (1600 ug/ml) in the presence and absence of rat liver homogenate (S9 mix) did not reveal any mutagenic activity as judged by the frequencies of chromosomal aberrations.
結論		
染色体異常	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	基本データを与える。データは信頼できる二次情報からのものである。	Provides basic data. Data are from reliable secondary literature.
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	Darroundi F, Natarajan AT (1983) Cytogenetic analysis of uman peripheral blood lymphocytes (in vitro) treated with resorcinol. Mutation Research 124:179-189.	Darroundi F, Natarajan AT (1983) Cytogenetic analysis of uman peripheral blood lymphocytes (in vitro) treated with resorcinol. Mutation Research 124:179-189.
備考		

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈	Resorcinolは純度99.5%以上でL'Oreal Parisにより供給された。	Resorcinol was supplied by L'Oreal Paris with a purity of at least 99.5% or greater.
方法		
方法／ガイドライン	染色体異常試験、 他法：情報無し	Cytogenetic assay, other: no data

GLP適合	情報無し	no data
試験を行った年	1983年	1983
細胞株	ヒト線維芽細胞	Human fibroblasts
代謝活性化(S9)の有無	無	without
試験条件	原文参照	Test concentration : 0,12, 25 and- 50 ug/ml (0, 0.0012, 0.0025 and 0.0050%). 100 metaphases/concentration assessed. Blood from 4 donors, 2 females and 2 males, were used. Normal human diploid fibroblasts were grown in MEM supplemented with foetal calf serum and antibiotics. After 2 days of culture, cells were treated with concentrations of 0, 0.0012, 0.0025 and 0.0050 % resorcinol for 24 h and a 2-h colcemid treatment preceded the fixation. Cultures were grown at 37C and 2.5% CO2. After trypsinization, cells received a hypotonic shock (1% sodium citrate) and were fixed in methanol: acetic acid (3:1). Air-dried preparations were made on ice cold wet slides. 100 metaphases/concentration were assessed to determine chromosomal aberrations.
結果		
細胞毒性		
代謝活性ありの場合		
代謝活性なしの場合	情報無し	no data
染色体異常		
代謝活性ありの場合		
代謝活性なしの場合	陰性	negative
注釈	対照群の値を上回る染色体異常を誘発せず陰性。	Negative for inducing chromosomal aberrations above the control level.
結論		
染色体異常	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	基本データを与える。データは信頼できる二次情報からのものである。	Provides basic data. Data are from reliable secondary literature.
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	Darroundi F, Natarajan AT (1983) Cytogenetic analysis of uman peripheral blood lymphocytes (in vitro) treated with resorcinol. Mutation Research 124:179-189.	Darroundi F, Natarajan AT (1983) Cytogenetic analysis of uman peripheral blood lymphocytes (in vitro) treated with resorcinol. Mutation Research 124:179-189.
備考		

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈	Resorcinol はRadian Corporation (Austin, TX)からコード分割品として送られた。	Resorcinol sent as a coded aliquot from Radian Corporation (Austin, TX)
方法		
方法／ガイドライン	姉妹染色分体交換試験、 他法:Galloway et al (1985, 1987)	Sister chromatid exchange assay, other: Galloway et al (1985, 1987)
GLP適合	情報無し	no data
試験を行った年	1991年	1991
細胞株	チャイニーズハムスター卵巣細胞(CHO)	Chinese hamster ovary cells (CHO)
代謝活性化(S9)の有無	有及び無	with and without
試験条件	原文参照	Test concentration : 50, 167, 500 and 1670 µg/ml in the absence of S9 mix and 500, 1670 and 5000 in the presence of S9 mix. CHO cells were incubated for 26 hours with the study chemical in McCoy's 5A medium supplemented with 10% fetal bovine serum, 1-glutamine (2 mM), and antibiotics. Bromodeoxyuridine (BrdU) was added 2 hours after culture initiation. After 26 hours, the medium containing the test chemical was removed and replaced with fresh medium plus BrdU and Colcemid, and incubation was continued for 2 hours. Cells were then harvested by mitotic shake-off, fixed, and stained with Hoechst 33258 and Giemsa. In the SCE test with S9 (metabolic activation), cells were incubated with the chemical, serum-free medium, and S9 for 2 hours. The medium was then removed and replaced with medium containing BrdU and no test chemical and incubation proceeded for an additional 26 hours, with Colcemid present for the final 2 hours.

		Harvesting and staining was the same as for cells treated without S9. If significant chemical-induced cell cycle delay was seen, incubation time was lengthened to ensure a sufficient number of scorable cells. 50 second-division metaphase cells were scored for frequency of SCE per cell from each dose level. Statistical analyses were conducted on both the slopes of the dose-response curves and the individual dose points. An SCE frequency 20% above the concurrent solvent control value was chosen as a statistically conservative positive response. The probability of this level of difference occurring by chance at one dose point is less than 0.01; the probability for such a chance occurrence at two dose points is less than 0.001.
結果		
細胞毒性		
代謝活性ありの場合		
代謝活性なしの場合	1670 μg/ml	1670 μg/ml
姉妹染色分体交換		
代謝活性ありの場合	陽性	positive
代謝活性なしの場合	陽性	positive
注釈	ResorcinolはS9無しの場合、167及び500 μg/mL で、S9 (Aroclor 1254誘導雄SDラット肝S9)有の場合、1,670 及び5,000 μg/mLでいずれもSCEを誘発した。	Resorcinol induced SCE at doses of 167 and 500 μg/mL in the absence of S9 and at 1,670 and 5,000 μg/mL in the presence of Aroclor 1254-induced male Sprague-Dawley rat liver S9.
結論		
姉妹染色分体交換	陽性	positive
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	ガイドライン試験、GLPに関する情報なし。	Guideline study; No data regarding GLP
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	National Toxicology Program (NTP) (1992) Technical Report on the Toxicology and Carcinogenesis Studies of Resorcinol (CAS No. 108-46-3) in F344/N Rats and B6C3F1 Mice (Gavage Studies) NIH Publication No. 91-2858 Technical report TR403.	National Toxicology Program (NTP) (1992) Technical Report on the Toxicology and Carcinogenesis Studies of Resorcinol (CAS No. 108-46-3) in F344/N Rats and B6C3F1 Mice (Gavage Studies) NIH Publication No. 91-2858 Technical report TR403.
備考	フラグ：SIDSエンドポイントの重要な試験	Flag : Critical study for SIDS endpoint

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈	Resorcinolは純度99.5%以上でL'Oreal Parisにより供給された。	Resorcinol was supplied by L'Oreal Paris with a purity of at least 99.5% or greater.
方法		
方法／ガイドライン	姉妹染色分体交換試験、 他	Sister chromatid exchange assay, other
GLP適合	情報無し	no data
試験を行った年	1983年	1983
細胞株	ヒト末梢血リンパ球	peripheral human lymphocytes
代謝活性化(S9)の有無	無	without
試験条件	原文参照	Test concentration :0, 20, 60 and 100 ug/ml （ 0, 0.002, 0.006 and 0.01%). Blood from 4 donors, 2 females and 2 males, were used. Separate experiments were carried out by growing the cells in a medium containing 10 uM BrdUrd from the start and incubating them for 72 h. Resorcinol was dissolved in sterile water and then added to the medium to give final concentrations of 0, 0.01, 0.006 and 0.002%. Treatment was done 24h after initiation of cultures. Mitotic arrest was achieved by 2-h treatment with colcemid (0.0028%). The lmphocytes were further treated with a hypotonic solution of KCl (5.6 g/l) for 10 min at 37C and finally fixed with a solution of methanol: acetice acid (3:1). Air dried preparations were made by standard procedures. For determing the frequencies of SCE's, the slides were stained by the FPG technique. All experiments were repeated twice. 50 cells were scored in the SCE study. In a single test, the isolated lymphocytes were treated with resorcinol for 24h. The isolation was performed by Histopaque-1077 and the isolated lymphocytes were fixed at 48 hours after the start of the culture.
結果		
細胞毒性		
代謝活性ありの場合		
代謝活性なしの場合	情報無し	no data
姉妹染色分体交換		
代謝活性ありの場合		
代謝活性なしの場合	陰性	negative

注釈	resorcinolの処理によりSCEの頻度は増加しなかった。ドナー1（SCEのかなり高い頻度を有している）は、resorcinolの処理によりSCE頻度の増加反応を示さなかった。	The frequencies of SCEs did not increase after treatment with resorcinol. Donor 1, who had a rather high based-line frequency of SCEs, did not respond with an increased frequency of SCEs after treatment with resorcinol.
結論		
姉妹染色分体交換	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	基本データを与える。データは信頼できる二次情報からのものである。	Provides basic data. Data are from reliable secondary literature.
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献（元文献）	Darroundi F, Natarajan AT (1983) Cytogenetic analysis of uman peripheral blood lymphocytes (in vitro) treated with resorcinol. Mutation Research 124:179-189.	Darroundi F, Natarajan AT (1983) Cytogenetic analysis of uman peripheral blood lymphocytes (in vitro) treated with resorcinol. Mutation Research 124:179-189.
備考		

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈	Resorcinolは純度99.5%以上でL'Oreal Parisにより供給された。	Resorcinol was supplied by L'Oreal Paris with a purity of at least 99.5% or greater.
方法		
方法／ガイドライン	姉妹染色分体交換試験、 他	Sister chromatid exchange assay, other
GLP適合	情報無し	no data
試験を行った年	1983年	1983
細胞株	チャイニーズハムスター卵巣細胞（CHO）	Chinese Hamster ovary cells (CHO)
代謝活性化（S9）の有無	無	without
試験条件	原文参照	Test concentration :ml0, 200, 400, 800 and 1600 ug/ml (0, 0.02, 0.04, 0.08 and 0.16%). The cells were treated for 1 h (the highest concentration being 0.16%) and allowed to recover for 24 h before fixation. 0, 200, 400, 800 and 1600 ug/ml (0, 0.02, 0.04, 0.08 and 0.16%) The medium is the same as above but containing 5 uM BrdUrd at 37C and 5% CO2. 2-h colcemid treatment was followed by trypsinization, hypotonic shock (1% sodium citrate) for 10 min at 37C and fixation with methanol:acetic acid (3:1). Air dried preparations were made on ice cold wet slides. Staining was performed via the FPG technique. The fequencies of SCE's were analysed in 50 -75 metaphases.
結果		
細胞毒性		
代謝活性ありの場合		
代謝活性なしの場合	情報無し	no data
姉妹染色分体交換		
代謝活性ありの場合		
代謝活性なしの場合	陰性	negative
注釈	SCEの頻度増加は観察されなかった。	No increase in the frequencies of SCE's were observed.
結論		
姉妹染色分体交換	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	基本データを与える。データは信頼できる二次情報からのものである。	Provides basic data. Data are from reliable secondary literature.
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献（元文献）	Darroundi F, Natarajan AT (1983) Cytogenetic analysis of uman peripheral blood lymphocytes (in vitro) treated with resorcinol. Mutation Research 124:179-189.	Darroundi F, Natarajan AT (1983) Cytogenetic analysis of uman peripheral blood lymphocytes (in vitro) treated with resorcinol. Mutation Research 124:179-189.
備考		

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈		
方法		
方法／ガイドライン	姉妹染色分体交換試験、 他	Sister chromatid exchange assay, other
GLP適合	情報無し	no data
試験を行った年	1986年	1986
細胞株	ヒトリンパ球	Human lymphocytes
代謝活性化（S9）の有無	情報無し	no data

試験条件	原文参照	Test concentration :0 – 0.25 mM. Blood was collected from health non-smoking donors, it was centrifuged (250 x g) to remove the erythrocytes and the supernate was collected. The lymphocyte fraction was grown in Medium 199 with Earles salt. After 24h incubation at 37C the fractions or compounds to be tested were added to the cultures. For biological testing purposes,stock solutions were made up in dimethyl sulfoxide(DMSO) ethanol (EtOH) or DMSO/EtOH (1:1) and stored at -800C until used. Final concentrations of DMSO, EtOH or DMSO/EtOH (1:1) did not exceed 0.66, 1.0 and 5.0 %, respectively. After 88-90 h, the cells were treated consecutively with colchicine (50 ng/ml,2 h) and hypotonic KCI (0.075 M, 5-10 min) and they were then fixed in methanol/acetic acid (3:1) for 1 hour. After the culture time used, the portion of cells that have divided more than 2 times is about 20-30%. Chromosome preparations were made by applying the cell suspension to wet cooled slides. The staining procedure was mainly according to Wolff and Perry (J9'74).The slides were stained with Hoechst dye (0.5 µg/ml) for 12 min and then rinsed in McIlvaines buffer (pH 7.0). They were then exposed to UV-light (Philips TUV 30W G30T8, 10 cm) for 10 min, incubated in 0.3 M NaCl/O.3 M sodium citrare for 2 h at 60oC and stained with Giemsa dye (4%,pH 6.8) for 20 min. Well-spread metaphases were scored on coded slides and 25 metaphases from one culture were analysed for each concentration tested. Analytical Methods: Analytical GC was conducted with a Hewlett Packard 5790. GC-MS was carried out using a Kratos MS-50 instrument operatered at 70eV and connected to a Kratos 55 computer system. All compounds used for testing were obtained commercially and their purity evaluatedby GC or HNMR before testing. In the case of Resorcinol, it was deemed a purity of 99%. The structures of the compounds studied were confirmed by H- and C-NMR. Positive controls: Since resorcinol was considered a pure substance, the potent SCE inducer styrene-7,8-oxide was used as a positive control. Statistical Analysis were performed.
結果		
細胞毒性		
代謝活性ありの場合	情報無し	no data
代謝活性なしの場合	情報無し	no data
姉妹染色分体交換		
代謝活性ありの場合		
代謝活性なしの場合		
注釈	原文参照	Concentration range was from 0 – 0.25 mM , a regression coefficient (SCE/cell/mM) of 1.3, a correlation coefficient of 0.25, the significance level was not determined to be significant, and the degrees of freedom were 5.
結論		
姉妹染色分体交換	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	基本データを与える。データは信頼できる二次情報からのものである。	Provides basic data. Data are from reliable secondary literature.
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	Jansson T, Curvalli M, Hedin A, Enzel CR (1986) In vitro studies of biological effects of cigarette smoke condensate. II, Induction of sister chromatid exchanges in human lymphjocytes by weakly acidic, semivolatile constituents. Mutation Research 169:129-139.	Jansson T, Curvalli M, Hedin A, Enzel CR (1986) In vitro studies of biological effects of cigarette smoke condensate. II, Induction of sister chromatid exchanges in human lymphjocytes by weakly acidic, semivolatile constituents. Mutation Research 169:129-139.
備考		

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈	被験物質はSigma Chemical Co.から入手。	Test substance was obtained from Sigma Chemical Co.
方法		
方法／ガイドライン	姉妹染色分体交換試験、 他	Sister chromatid exchange assay, other
GLP適合	情報無し	no data
試験を行った年	1981年	1981
細胞株	チャイニーズハムスター卵巣細胞(CHO)	Chinese Hamster ovary cells (CHO)
代謝活性化(S9)の有無	有及び無	with and without

試験条件	原文参照	Test concentration :1600 µg/ml. Resorcinol was assesed with other simple phenols to determine its clastogenic activity in Chinese hamster ovary (CHO) cells with and without the addition of an S9 mixture, Cu2+ (10-4M) and Mn2+ (10-4 M). This was part of a study assessing the genotoxic activity of naturally occuring food components (in plants.) This includes chromatid exchanges. Solutions were prepared by dissolving the compounds in 2.5% MEM at 37C and adjusting the pH to 7.4. Preparation of metal solutions: Solutions of cupric sulfate (0.1M), manganese chloride (0.1M) and glycine (0.5 M) were prepared in distilled water. Stock solutions of the chelated metals were then made by mixing glycine with the metal stock at a 10:1 molar ratio, followed by dilution with 2.5% MEM.
試験条件	原文参照	Approximately 140,000 CHO cells were seeded on 22-mm2 coverslips in 3.5-cm plastic dishes and kept in MEM with 10% fetal calf serum at 37 ° C for 2-3 days. Experiments were begun when cells were 40 - 60% confluent. The tissue culture medium was removed from the petri dishes and replaced with 1ml of the phenolic acid solution. For tests involving the influence of the S9 preparation or metal solutions on the clastogenic activity of the phenolic acid, 0.5-ml aliquots of these mixtures were added to each petri dish prior to addition of 0.5 ml of the phenolic acid. The S9 preparation was prepared with livers (300 ul/ml S9 mix) from Aroclor 1254-pretreated Fischer male rats. Following a 3-h exposure time, this medium was removed, the coverslips washed with MEM, and fresh MEM, with 10% fetal calf serum added to the petri dishes. For estimating the frequency of chromosome aberrations, 0.1 ml of colchiicine (0.01% in 2.5% MEM) was added at 16 h post-exposure to the chemicals and left for 4 h. Cells were then treated with 1% sodium citrate solution for 20 min, followed immediately with fixation in ethanol/acetic acid (3:1) for 20 min. Air dried slides were stained with 2% orcein in 50% acetic acid/water, dehydrated and mounted. For each sample 200 metaphase plates were analyzed for chromosome aberrations. The frequency of 2 types of chromosome aberrations were estimated: (a) chromatid breaks; (b) chromatid exchanges. Chromatid exchanges occurred between homologous and non-homologous chromosomes and between 2 or more chromosomes.
結果		
細胞毒性		
代謝活性ありの場合	情報無し	no data
代謝活性なしの場合	情報無し	no data
姉妹染色分体交換		
代謝活性ありの場合	陽性	positive
代謝活性なしの場合	陽性	positive
注釈	原文参照	All dihydroxylated (resorcinol) and trihydroxylated phenolics induced chromatid breaks and exchanges. The introduction of a methyl group seems to reduce the clastogenic capacity. The addition of an S9 mixture or the transition metals Cu2+ and Mn2+ enhanced the chromosome-damaging activity in some phenolics and suppressed it in others. Results with Resorcinol: chromatid exchange per cell: (-) S9 is 0.95 and (+) S9 is 0.52
結論		
姉妹染色分体交換	陽性	positive
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	基本データを与える。	Provides basic data
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	Stich HF, Rosin MP, Wu CH, Powrie WD (1981) The action of transition metals on the genotoxicity of simple phenols, phenolic acids and cinnamic acids. Cancer Letters 14:251-260.	Stich HF, Rosin MP, Wu CH, Powrie WD (1981) The action of transition metals on the genotoxicity of simple phenols, phenolic acids and cinnamic acids. Cancer Letters 14:251-260.
備考		

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈	Resorcinolは純度99.5%以上でL'Oreal Parisにより供給された。	Resorcinol was supplied by L'Oreal Paris with a purity of at least 99.5% or greater.
方法		
方法／ガイドライン	姉妹染色分体交換試験、 他	Sister chromatid exchange assay, other
GLP適合	情報無し	no data

試験を行った年	1983年	1983
細胞株	チャイニーズハムスター卵巣細胞(CHO)	Chinese Hamster ovary cells (CHO)
代謝活性化(S9)の有無	無	without
試験条件	原文参照	Test concentration :0, 50, 100, 200 and 400 ug/ml (0, 0.005, 0.01, 0.02 and 0.04%). 50 - 75 Metaphases assessed/concentration The cells were continuously grown in the presence of resorcinol for 24 h to 0, 50, 100, 200 and 400 ug/ml (0, 0.005, 0.01, 0.02 and 0.04%) resorcinol. The medium is the same as above but containing 5 uM BrdUrd at 37C and 5% CO2. 2-h colcemid treatment was followed by trypsinization, hypotonic shock (1% sodium citrate) for 10 min at 37C and fixation with methanol:acetic acid (3:1). Air dried preparations were made on ice cold wet slides. Staining was performed via the FPG technique. The fequencies of SCE's were analysed in 50 -75 metaphases.
結果		
細胞毒性		
代謝活性ありの場合	情報無し	no data
代謝活性なしの場合	情報無し	no data
姉妹染色分体交換		
代謝活性ありの場合		
代謝活性なしの場合	陰性	negative
注釈	SCE頻度の増加は観察されなかった。	No increase in the frequencies of SCE's were observed.
結論		
姉妹染色分体交換	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	基本データを与える。データは信頼できる二次情報からのものである。	Provides basic data. Data are from reliable secondary literature.
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	Darroundi F, Natarajan AT (1983) Cytogenetic analysis of uman peripheral blood lymphocytes (in vitro) treated with resorcinol. Mutation Research 124:179-189.	Darroundi F, Natarajan AT (1983) Cytogenetic analysis of uman peripheral blood lymphocytes (in vitro) treated with resorcinol. Mutation Research 124:179-189.
備考		

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈	Resorcinolは純度99.5%以上でL'Oreal Parisにより供給された。	Resorcinol was supplied by L'Oreal Paris with a purity of at least 99.5% or greater.
方法		
方法／ガイドライン	染色体異常試験	Chromosomal aberration test
GLP適合	情報無し	no data
試験を行った年	1983年	1983
細胞株	ヒト末梢血リンパ球	Peripheral human lymphocytes
代謝活性化(S9)の有無	無	without
試験条件	原文参照	Test concentration :0, 20, 60 and 100 µg/ml (0, 0.002, 0.006 and 0.01%). 100 metaphases assessed/concentration Samples of blood (0.5 ml) were cultured in screw-capped bottles containing 5 ml medium (Ham's F10, inactivated calf serum, PHA, L-glutamine 200 mM, hparin and penicillin (100 U/ml) + streptomycin (100 ug/ml)). The mixtures were incubated at 37C for 48 and 72 h for evaluating the frequencies of chromosomal aberrations. Resorcinol was dissolved in sterile water and then added to the medium to give final concentrations of 0, 0.01, 0.006 and 0.002%. In the chromosomal aberrations study, slides were stained with 2% aqueous Giemsa solution for 6 - 7 minutes. All studies were repeated twice. Data were pooled from the two replicate studies. 100 cells were scored in the chromosomal aberration study. In a single test, the isolated lymphocytes were treated with resorcinol for 24h. The isolation was performed by Histopaque-1077 and the isolated lymphocytes were fixed at 48 hours after the start of the culture.
結果		
細胞毒性		
代謝活性ありの場合		
代謝活性なしの場合	情報無し	no data
染色体異常		
代謝活性ありの場合		
代謝活性なしの場合	陽性	positive

注釈	48時間及び72時間では染色体切断及びギャップである染色体異常頻度の有意な増加が見られた。細胞回収時間48時間の結果は、0.01%の被験物質に暴露された両女性ドナーの試料は染色体交換が観察されたことを示した。データは各々の細胞回収時間（48時間、72時間）あたり2回の繰り返し試験から収集された。	At 48 and 72 hours a significant elevation in the frequencies of chromosomal aberrations of the type breaks and gaps were found. At the 48 h harvest time results indicated that both female donor samples exposed to 0.01% noted that exchanges were observed. Data were pooled from the two replicate studies for each harvest time (48 and 72h).
結論		
染色体異常	陽性	positive
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	基本データを与える。データは信頼できる二次情報からのものである。	Provides basic data. Data are from reliable secondary literature.
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献（元文献）	Darroundi F, Natarajan AT (1983) Cytogenetic analysis of uman peripheral blood lymphocytes (in vitro) treated with resorcinol. Mutation Research 124:179-189.	Darroundi F, Natarajan AT (1983) Cytogenetic analysis of uman peripheral blood lymphocytes (in vitro) treated with resorcinol. Mutation Research 124:179-189.
備考		

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈	Resorcinolは純度99.5%以上でL'Oreal Parisにより供給された。	Resorcinol was supplied by L'Oreal Paris with a purity of at least 99.5% or greater.
方法		
方法／ガイドライン	染色体異常試験	Chromosomal aberration test
GLP適合	情報無し	no data
試験を行った年	1983年	1983
細胞株	チャイニーズハムスター卵巣細胞（CHO）	Chinese Hamster ovary cells (CHO)
代謝活性化（S9）の有無	無	without
試験条件	原文参照	Test concentration :0, 40, 100, 200 and 400 µg/ml (0, 0.004, 0.01, 0.02 and 0.04%). In an in vitro experiment a CHO cell line was used. The cells were grown in Ham's F10 medium, supplemented with 15% newborn calf serum and penicillin (100 U/,l) + streptomycin (100 ug/ml) at 37C with 5% CO2. Resorcinol was dissolved in sterile water and added to the medium to give final concentrations of 0, 0.04, 0.02, 0.01 and 0.004%. Fixations were done at 6, 12 and 16 h after the start of the treatment. For the determination of chromsomal aberrations, at least 100 metaphases were scored for each concentration and results from 3 experiments were pooled. From 3 experiments a total of 400 metaphases were scored. 2-h colcemid treatment was followed by trypsinization, hypotonic shock (1% sodium citrate) for 10 min at 37C and fixation with methanol:acetic acid (3:1). Air dried preparations were made on ice cold wet slides. Staining was performed with 2% aqueous Giemsa solution.
結果		
細胞毒性		
代謝活性ありの場合		
代謝活性なしの場合	情報無し	no data
染色体異常		
代謝活性ありの場合		
代謝活性なしの場合	陰性	negative
注釈	染色体異常頻度の増加は観察されなかった。	No increase in the frequencies of chromosol aberrations were observed.
結論		
染色体異常	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	基本データを与える。データは信頼できる二次情報からのものである。	Provides basic data. Data are from reliable secondary literature.
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献（元文献）	Darroundi F, Natarajan AT (1983) Cytogenetic analysis of uman peripheral blood lymphocytes (in vitro) treated with resorcinol. Mutation Research 124:179-189.	Darroundi F, Natarajan AT (1983) Cytogenetic analysis of uman peripheral blood lymphocytes (in vitro) treated with resorcinol. Mutation Research 124:179-189.
備考		

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈		
方法		

方法／ガイドライン	小核試験、 他：OECDガイドライン487（ドラフト）	Micronucleus test in vitro, other: OECD TG 487 (draft)
GLP適合	適合	Yes
試験を行った年	2004年	2004
細胞株	ヒト（女性）培養リンパ球	Human lymphocyte cultures prepared (female)
代謝活性化（S9）の有無	有及び無	with and without
試験条件	原文参照	Test concentration :3+45 hours With S-9, 94.49, 184.5, 704.0 ug/ml; 20+28 hours without S-9, 704.0, 880.0, and 1100 µg/mL.. Resorcinol (A011) was tested in an in vitro micronucleus assay using duplicate human lymphocyte cultures prepared from the pooled blood of two female donors in two independent experiments. Treatments covering a broad range of doses, separated by narrow intervals, were performed both in the absence and presence of metabolic activation (S-9). The test article was dissolved in water for injection (purified water) and the highest dose level used, 1100 µg/mL, (equivalent to 10 mM), an acceptable maximum concentration for in vitro cytogenetic studies according to current regulatory guidelines. In Experiment 1, treatment of cells commenced approximately 24 hours following mitogen (PHA) stimulation. In the absence of S-9 this was for 20 hours followed by a 28-hour recovery period prior to harvest (20+28). Treatment in the presence of S-9 was for 3 hours followed by a 45-hour recovery period prior to harvest (3+45). The S-9 used was prepared from a rat liver post-mitochondrial fraction (S-9) from Aroclor 1254 induced animals. The test article dose levels for micronucleus analysis were selected by evaluating the effect of Resorcinol (A011) on the replication index (RI). Micronuclei were analysed at three dose levels (see below). The highest concentrations chosen for analysis, 704.0 µg/mL in the absence of S-9 and 94.49 µg/mL in the presence of S-9, induced approximately 55% and 60% reduction in RI respectively.
試験条件	原文参照	In Experiment 2, treatment of cells commenced approximately 48 hours following mitogen stimulation. In the absence of S-9 this was for 20 hours followed by a 28-hour recovery period prior to harvest (20+28). Treatment in the presence of S-9 was for 3 hours followed by a 45-hour recovery period prior to harvest (3+45). Micronuclei were analysed at three dose levels (see below). The highest concentration chosen for analysis, 1100 µg/mL (10 mM) in the absence of S-9 and 704.0 µg/mL in the presence of S-9, induced approximately 11% and 57% reduction in RI respectively. Negative controls: Appropriate negative (solvent) control cultures were included in the test system under each treatment condition. The proportion of binucleate cells with micronuclei in these cultures fell within historical solvent control ranges in the majority of cases. The one exception to this was observed in the 'A' replicate culture for the 20+28 hour -S-9 treatment in Experiment 1. This culture exhibited a micronucleated binucleate (MNBN) cell frequency that marginally exceeded the normal range. However, further analysis of the 'C' and 'D' vehicle cultures resulted in MNBN cell frequencies that were within normal values. As such, 3 of the 4 vehicle cultures analysed exhibited normal MNBN cell frequencies. It was therefore considered that this increase was spurious. As the group mean vehicle data fell with historical values, the data were considered acceptable and valid.
試験条件	原文参照	Positive Controls: 4-Nitroquinoline 1-oxide (NQO) and Vinblastine (VIN) were employed as clastogenic and aneugenic positive control chemicals respectively in the absence of liver S-9. Cyclophosphamide (CPA) was employed as a clastogenic positive control chemical in the presence of liver S-9. Cells receiving these were sampled at 48 after the start of treatment; all compounds induced statistically significant increases in the proportion of cells with micronuclei. The one exception to this was observed following treatment in Experiment 1 (24 hour PHA stimulation) for the Vinblastine treatments. However, Vinblastine is an aneugenic agent whose target area of effect is the mitotic spindle apparatus. This positive control is therefore most suited to a treatment regime where the cells are in active proliferation at the time of addition (Experiment 2, 48 hour PHA stimulation). As such, and in consideration of the fact that the NQO positive control exhibited a clear positive increase in MNBN cells (thereby illustrating sensitivity of the assay system to clastogenic agents), the failure of the Vinblastine treatment in Experiment 1 was not thought to affect the validity of the study. With the exception of the minor deviations detailed below, none of which in any way prejudices the validity of the study, this study was performed according to the protocol.

試験条件	原文参照	Protocol Deviations: Materials Controls: The protocol stated that all positive controls would be dissolved in DMSO prior to use. This was in error as sterile water was used as the vehicle for Vinblastine. This had no impact on the validity of the study. Methods Treatment of Cytochalasin B The protocol stated that Cytochalasin B (Cyto-B) would be present in all cell cultures for the last 28 hours prior to harvest. However, practically this is not accurate. Cyto-B was added to both the 20+28 hour -S-9 and 3+45 hour +S-9 treatments at the same time (where treatments were conducted concurrently). This was immediately following the test article wash-off for the 20+28 hour -S-9 treatment. As such, the actual time of Cyto-B addition was often approximately 1 hour later than would be required. This may have resulted in an actual Cyto-B exposure period of approximately 27 hours rather than 28 hours. Nevertheless, this was considered suitably sufficient for the generation of adequate numbers of binucleate cells for analysis and as such had no adverse affect on the validity of the study. Protocol Deviations: Positive Controls: It should be noted that positive control slides were not assessed prior to analysis in Experiment 2 in error. This constituted a minor deviation to protocol. However, as suitable concentrations were analysed that provided a suitable positive control response, this omission did not affect the validity of the study data.
結果		
細胞毒性		
代謝活性ありの場合	94.49 ug/ml	94.49 ug/ml
代謝活性なしの場合	704 ug/ml	704 ug/ml
染色体異常		
代謝活性ありの場合	陽性	positive
代謝活性なしの場合	陽性	positive
注釈	原文参照	Positive with and without activation. Treatment in the presence of S-9, Experiment 1 (24 hour PHA stimulation prior to treatment): Treatment of cells with Resorcinol (A011) in the presence of metabolic activation (S-9) resulted in frequencies of micronucleated binucleate (MNBN) cells, which were significantly elevated as compared to concurrent vehicle controls for all concentrations analysed. A dose dependent increase in numbers of MNBN cells was noted with both replicate cultures at the highest concentration analysed (94.49 mg/mL) exhibiting frequencies of MNBN cells that exceeded the historical negative control (normal) range. This result was therefore considered of biological importance. Treatment in the presence of S-9, Experiment 2 (48 hour PHA stimulation prior to treatment): Treatment of cells with Resorcinol (A011) in the presence of metabolic activation (S-9) resulted in frequencies of micronucleated binucleate (MNBN) cells, which were similar to and not significantly different from those observed in concurrent vehicle controls for all concentrations analysed. The MNBN cell frequencies of all Resorcinol (A011) treated cultures fell within normal values.
注釈	原文参照	Treatment in the absence of S-9 (Experiments 1 and 2): Treatment of cells with Resorcinol (A011) in the absence of S-9 in Experiments 1 and 2 (following 24 or 48 hour mitogen (PHA) stimulation), resulted in frequencies of MNBN cells, which were significantly elevated compared to those in concurrent vehicle controls for the majority of all concentrations analysed. Both replicate cultures at the highest two concentrations analysed in Experiment 1 (536.2 and 704.0 mg/mL) or the highest concentration analysed in Experiment 2 (1100 mg/mL) exhibited MNBN cell frequencies that exceeded the historical negative control (normal) range. These increases were therefore considered of biological importance. It is concluded that Resorcinol (A011) induced micronuclei in cultured human peripheral blood lymphocytes following 20+28 hour treatment in the absence of a rat liver metabolic activation system (S-9), where treatment commenced either 24 or 48 hours following PHA (mitogen) stimulation. Increased frequencies of micronucleated cells were also observed following 3+45 hour treatment in the presence of S-9 where treatment commenced 24 hours post mitogen stimulation. No such increases in micronucleated cells were apparent following 3+45 hour treatment in the presence of S-9 where treatment commenced 48 hours post mitogen stimulation at concentrations up to its limit of cytotoxicity.
結論		
染色体異常	陽性	positive
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	ガイドライン試験、試験逸脱参照。	Guideline study; see study deviations

出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	Covance Laboratories (2004) Resorcinol (A011): Induction of micronuclei in cultured human peripheral blood lymphocytes. Report number 413/68-D6172. Sponsor L'OREAL.	Covance Laboratories (2004) Resorcinol (A011): Induction of micronuclei in cultured human peripheral blood lymphocytes. Report number 413/68-D6172. Sponsor L'OREAL.
備考	フラグ:SIDSエンドポイントの重要な試験	Flag : Critical study for SIDS endpoint

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈		
方法		
方法／ガイドライン	不定期DNA合成、 他法	Unscheduled DNA synthesis, other
GLP適合	情報無し	no data
試験を行った年	1981年	1981
細胞株	ラット初代肝細胞	primary rat hepatocytes
代謝活性化(S9)の有無	情報無し	no data
試験条件	原文参照	Test concentration :0.5, 1, 5, 10, 50, 100, 500 and 1,000 nmoles/ml. Multi-substance test (over 200 compounds): Resorcinol obtained from Aldrich Chemical Co, Milwaukee, Wisconsin. Resorcinol was tested up to its highest nontoxic concentration (1000 nmoles/ml). This concentration is used for quantification purposes. The following concentrations are documented as being tested: 0.5, 1, 5, 10, 50, 100, 500 and 1,000 nmoles/ml. Primary cultures of adult rat hepatocytes were prepared in situ perfusion of the livers of 150 - 170 gm male Fischer 344 rats as described by Williams. Yields of 1.2 - 2.5 x 10E8 hepatocytes/liver wth 86% to 92% viability were routinely obtained. Autoradiographic Assay: The HPC-DNA repair test was conducted as described by Williams with minor modifications: Freshly prepared hepatocytes were plated at a density of 3.5 x 10E4 cells/cm2 in 26- x 33-mm Lux-Mulitiples® containing 10.5 x 22-mm plastic coverslips in Williams' medium E buffered to pH 7.2 with 0.05 M HEPES (WMEH) containing 10% fetal bovine serum (FBS), 50 units/ml gentamicin and 100 units/ml each of penicillin and streptomcin. Incubation was conducted at 37 ° C in a humidified 95%/5% air/CO2 environment. Following an attachment period of 90 minutes, the cells were washed once with EMEH, and then 1.6 ml of serum-free WMEH containing 10 µCi/ml 3H-TdR (methyl-3H-thymidine, specific activity, 18-25 Ci/mmole) and the appropriate test compound dilution was added to each culture.
試験条件	原文参照	After 5 hrs incubation the medium was replaced with WMEH containing 10% FBS and incubation was conducted for an additional 18 - 20 hours (Chase Period). Compounds showing negative response for UDS following the above method were then retested, except that the exposure period was increased to 20 hours and the Chase Period was deleted. Washing and fixing operations were conducted at 4 ° C in the Multiplate chambers. Each culture was rinsed once with Hank's balanced salt solution (HBSS), allowed to stand for 10 minutes in 1% sodium citrate, fixed by 3 - 1 hr washes with ethanol acetic acid (3:1, v/v) and then rinsed once with absolute ethanol. Air dried coverslips were glued to glass slides and then stained with 1% aceto-orcein for three to five minutes. The slides were individually dipped into undiluted NTB-2 liquid emulsion thoroughly dried, sealed in light-tight desiccated boxes, incubated 12 to 14 days at 4 ° C, developed with Kodak D-19 developer and fixed with Kodak fixer. Autoradiograms were examined by oil immersion microscopy without coverslips.

試験条件	原文参照	UDS was quantified by counting the number of silver grains over the nucleus using a Biotran II automated colony counter adapted for oil immersion microscopy. Cytoplasmic background counts were determined by counting three nuclear-sized areas adjacent to the nucleus and subtracting the mean from the nuclear count. Under these conditions, a negative value for UDS was obtained when the mean cytoplasmic count exceeded the nuclear count. Under standard assay conditions the background count varied between five and 24 grains depending on the preparation and chemical treatment. Nuclei of 20 morphologically unaltered cells, judged to be representative of the UDS responsiveness of the cell population and containing at least four grains, were counted for the selected chemical concentration. Test chemical concentrations selected for quantification were not necessarily those producing the maximum response but rather those in which the nuclear silver grains were adequately dispersed for accurate counting. In many cases the maximal response for UDS could not be quantified since the nuclear silver grains were either too clustered or so exclusively dense that individual grains could not be resolved by the counter. In the case of resorcinol, the highest dose not producing cytotoxicity was selected for quantification.
試験条件	原文参照	A positive response is indicated when at least two successive concentrations produced nuclear grain counts which exceeded those of the control by at least two standard deviations of the control value. Positive control: The positive controls 2-acetylaminofluorene (AAF) and N-methyl-N'-nitro-N-nitrosoguanidine (MNNG) were used. In general the highest level of UDS occurred at the highest chemical concentration that did not produce pronounced cytotoxicity. 2-AAF was always more active than MNNG. A non-treated negative control group and 1% DMSO control group was used. Controls were within normal limits.
結果		
細胞毒性		
代謝活性ありの場合	情報無し	no data
代謝活性なしの場合	情報無し	no data
不定期DNA合成		
代謝活性ありの場合		
代謝活性なしの場合		
注釈	原文参照	Cycotoxic concentr. : >1000 nmoles/ml. Negative Concentration (nmoles/ml) Nuclear Silver grain counts Active Range Conc Counted Treated Control None 1,000 0.6 + 1.4 -0.2 + 1.4
結論		
不定期DNA合成	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	基本データを与える。	Provides basic data
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	Probst GS, McMahon R., Hill L, Thompson C, Epp J, Neal S (1981) Chemically induced unscheduled DNA synthesis in primary rat hepatocyte cultures: a comparison with bacterial mutagenicity using 318 compounds. Environmental Mutagenesis 3:11-32.	Probst GS, McMahon R., Hill L, Thompson C, Epp J, Neal S (1981) Chemically induced unscheduled DNA synthesis in primary rat hepatocyte cultures: a comparison with bacterial mutagenicity using 318 compounds. Environmental Mutagenesis 3:11-32.
備考		

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈		
方法		
方法／ガイドライン	他:SHE細胞形質転換、 他:OECD、FDA、MHLWの方法	other: SHE Cell transformation, other: OECD, FDA and MHLW methods
GLP適合	適合	Yes
試験を行った年	2005年	2005
細胞株	シリアンハムスター胚細胞	Syrian hamster embryo cells
代謝活性化(S9)の有無	無	without

試験条件	原文参照	Test concentration :0, 28, 55, 83, 110 and 138 μg/ml. The SHE assay was conducted on five coded compounds. Methods and results presented are relevant for resorcinol. The SHE assay was conducted at Covance Laboratories in compliance with OECD, FDA and MHLW GLP Regulatons. The SHE assays were performed at pH 6.7 were based upon procedures described previously (Kerckaert et al., 1996.) All compounds were coded and tested blind using the standard 7 day continuous treatment version of the assay. Initial dose range finding studies were conducted to determine cytotoxicity in SHE cells. Ten cultures were prepared for each concentration of each test article and each concurrent vehicle control. The SHE cell colonies were counted to determine the average number of colonies per culture dish for the vehicle control and each treatment group. This information was used to calculate the relative plating efficiency to provide a measure of cytotoxicity. The results the dose range finding studies were used to selecte the appropriate range of test concentrations for each of the compounds in the SHE assay. In the case of resorcinol, the following doses were used: 0, 28, 55, 83, 110 and 138 μg/ml.
試験条件	原文参照	The SHE assay was conducted as described above with the exception that 45 culture dishes were prepared for each treatment group and the target SHE cell population was adjusted to maintain around 35 +/− 10 colonies per dish per concentration. The SHE assay was considered acceptable if at least one concentration of the test article caused a 50% decrease in relative plating efficiency or relative colony density. If the test article was non-cytotoxic, then the substance was tested up to a maximum of 10 mM. At least 5 treatment groups were selected for SHE cell morphological transformation evaluation. Morphologically transformed colonies were identified by light microscopy using the criteria outlined in previous studies (Kerckaert et al., 1996.) Vehicle control: Dimethyl sulfoxid or culture media. Positive control: benzo[a]pyrene. A Fisher's exact test was conducted to determine whether treatment groups were considered significantly different ($P < 0.05$) from the vehicle control. In addition, if one dose group was positive, a Cochran-Armitage trend test was performed to determine if there was a statistically significant ($P < 0.05$) positive dose-related response.
試験条件	原文参照	The test article was defined as positive if it induced a statistically significant increase in the morphological transformation frequency at two or more concentrations compared with the concurrent vehicle control. In addition, the test article ws considered positive if one concentration showed a statistically significant increase and there was a statistically significant positive dose-related response. A compound was considered negative if it failed to match either of the criteria defined for a positive result.
結果		
細胞毒性		
代謝活性ありの場合	情報無し	no data
代謝活性なしの場合	情報無し	no data
不定期DNA合成		
代謝活性ありの場合		
代謝活性なしの場合	陰性	negative

注釈	原文参照	Negative at all doses. Morphological transformation in SHE cells following 7 days treatment with: Dose µg/ml / morp trans freq (%) / # of trans colonies / Total # colonies / Rel Plating efficiency Resorcinol 0 0.168 3 1788 100 28 0.404 7 1731 97 55 0.132 2 1516 87 83 0.059 1 1700 66 110 0.000 0 1689 57 138 0.000 0 1755 44 B[a]P 5 1.402* 25 1783 100 * statistically different from the vehicle control (P< 0.05, one-sided Fisher's exact test). Maximum concentration tested was limited by cytotoxicity.
結論		
不定期DNA合成	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	データは信頼できるピアレビューを受けた二次情報からのものである。	Data are from reliable peer reviewed secondary literature.
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	Harvey JS, Howe JR, Lynch AM, Rees RW (2005) The results of five coded compounds: genistein, metaproterenol, rotenone, p-anisidine and resorcinol tested in the pH 6.7 Syrian hamster embryo cell morphological transformation assay. Mutagenesis 20(1):51-56.	Harvey JS, Howe JR, Lynch AM, Rees RW (2005) The results of five coded compounds: genistein, metaproterenol, rotenone, p-anisidine and resorcinol tested in the pH 6.7 Syrian hamster embryo cell morphological transformation assay. Mutagenesis 20(1):51-56.
備考		

5-7 *in vivo*遺伝毒性
GENETIC TOXICITY IN VIVO

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈		
方法		
方法／ガイドライン	OECDガイドライン474「遺伝毒性：小核試験」	OECD Guide-line 474 "Genetic Toxicology: Micronucleus
試験のタイプ	小核試験	Micronucleus assay
GLP適合	適合	Yes
試験を行った年	2005年	2005
試験系(種／系統)	ラット	rat
	Sprague-Dawley	Sprague-Dawley
性別(雄：M、雌：F)	雌雄	male/female
投与量	0, 125, 250 and 500 mg/kg	0, 125, 250 and 500 mg/kg
投与経路	強制経口	gavage
試験期間	48時間	48 hours
試験条件	原文参照	A dose ranging finding assay was conducted using 3 male and female SD rats per dose to doses of 100, 200, 400, 500 and 750 mg/kg and observed for up to 2 days after dosing to observe toxic signs and/or mortality. In the assay, the test article was formulated in water for cell culture application. In the main study, 5 male and female SD rats per dose of 125, 250 and 500 mg/kg. Bone marrow was extracted and at least 2000 PCEs per animal were analyzed for the frequency of micronuclei. Cytotoxicity was assessed by scoring the number of PCEs and normochromatic erythrocytes (NCEs) in at least the first 500 total erythrocytes of each animal. Plasma analysis: In order to confirm the systemic exposure of the test substance, a plasma analysis was done with a satellite group using 3 animals/sex at doses of 80 mg/kg and 500 mg/kg.
統計学的処理		
結果		
性別及び投与量別の結果		
遺伝毒性効果	陰性	negative
NOAEL (NOEL)		
LOAEL (LOEL)		
統計的結果		

注釈	原文参照	Range finding assay: The maximum tolerated dose level was determined to be 500 mg/kg. Main study: Resorcinol caused mortality to one female at 500 mg/kg and signs of clinical toxicity included: tremors, rapid respiration, salivation, and/or squinted eyes. Resorcinol did not induce statistically significant increases in micronucleated PCEs at any test article dose. However, resorcinol was cytotoxic to bone marrow (i.e. a statistically significant decreases in PCEs:NCEs ratios) in females at 500 mg/kg at the 48 hour harvest timepoint, indicating that the bone marrow was exposed to the test substance. Plasma Analysis: Results of the plasma analysis confirmed the systemic exposure of the test animals after oral administration to doses of 80 and 500 mg/kg. Vehicle Control Group: All mean group values for micronucleated PCEs were within the Covance-Vienna 2003 historical control range.
結論		
*in vivo*遺伝毒性	陰性	negative
注釈	ラット骨髄の小核試験で、最大耐量の500mg/kg以下で試験を行った結果、resorcinol (A011)は陰性である。	When tested up to the maximum tolerated dose of 500 mg/kg under the conditions of this rat bone marrow micronucleus assay, resorcinol (A011) is negative.
信頼性	(1)制限なしで有効	(1) valid without restriction
信頼性の判断根拠	ガイドライン試験	Guideline Study
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	Covance Laboratories (2005) In vivo rat micronucleus assay in Resorcinol (AO11). Study number 6182-114. Genetic toxicology assay number 26557-0-454 OECD. Study sponsor: L'Oreal.	Covance Laboratories (2005) In vivo rat micronucleus assay in Resorcinol (AO11). Study number 6182-114. Genetic toxicology assay number 26557-0-454 OECD. Study sponsor: L'Oreal.
備考	フラグ:SIDSエンドポイントの重要な試験	Flag : Critical study for SIDS endpoint

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈	ALIQUOT A90027	ALIQUOT A90027
方法		
方法／ガイドライン	OECDガイドライン474「遺伝毒性:小核試験」	OECD Guide-line 474 "Genetic Toxicology: Micronucleus
	他	other
試験のタイプ	小核試験	Micronucleus assay
GLP適合	情報なし	no data
試験を行った年	1994年	1994
試験系(種／系統)	マウス	mouse
	B6C3F1	B6C3F1
性別(雄:M、雌:F)	雄	male
投与量	0, 18.75, 37.50, 75, 150, 300, 400 and 500 mg/kg	0, 18.75, 37.50, 75, 150, 300, 400 and 500 mg/kg
投与経路	腹腔内	i.p.
試験期間	24時間	24hours
試験条件	原文参照	Three interperitoneal injections (i.p)/24 hour post-treatment method (post injection harvest) was utilized with the following doses: 0, 18.75, 37.50, 75, 150, 300, 400 and 500 mg/kg. These dose levels were determined based on discussions between appropriate individuals that had performed previous studies using the test substance (knowledge of test substance prior performance). The solvent used for administration was Phosphate Buffered Saline (PBS). Maximum solubility was determined to be 36.8 mg/l (500 mg/kg) solublized in phosphate buffered saline. An analysis of variance (ANOVA) was performed. Positive Controls: Cyclophosphamide (CPA, 25 mg/kg) was used as the concurrent positive control.
統計学的処理		
結果		
性別及び投与量別の結果		
遺伝毒性効果	陽性	positive
NOAEL (NOEL)		
LOAEL (LOEL)		
統計的結果		

注釈	原文参照	At 300, 400 and 500 mg/kg there was 100% mortality. At 500 and 400 mg/kg 100% mortality occurred within 15 and 30 minutes, respectively. At 300 mg/kg, 80% mortality was observed within 45 minutes following the first i.p. injection and 20% within 15 minutes following the second i.p. injection. At the time of the scheduled harvest, there was no significant effect on the %PCEs in the remaining dose groups when compared to the solvent controls. The number of MN-PCEs/1000 PCEs was significantly increased in the surviving highest dose group (150 mg/kg) compared to the current solvent control solvent. Therefore, the test substance is considered positive in this study.
結論		
*in vivo*遺伝毒性	陽性	positive
注釈	被験物質はこの試験で陽性と考えられた。本試験の結果に基づき、プロジェクトオフィサーは第二回目の試験の実施を決定した。この第二回目の試験は別の要約でサマライズされている。 オリジナル報告書では、影響が300mg/kgで見られていると述べている。しかし、この用量では全動物が死亡しているため、被験物質の影響が150mg/kgの用量の動物とした。	The test substance is considered positive in this study. Based on the results of this study, the project officer made the determination to conduct a second study. The second study is summarized in a separate summary. Note that the original report said that the effects were seen at 300 mg/kg, but since all of the animals died at that dose, the effects were attributed to animals dosed at 150 mg/kg.
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	ガイドライン試験に類似。GLPについては情報なし。	Similar to a guideline study, no data regarding GLP
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	National Toxicology Program (NTP) (1995) In vivo Bone Marrow Micronucleus Assay Tests 1 and Repeat In vivo Bone Marrow Micronucleus Assay Test 2. Contract Number: N-01-ES-15312 submitted by Novel Pharamceutical, Inc. Durham, NC.	National Toxicology Program (NTP) (1995) In vivo Bone Marrow Micronucleus Assay Tests 1 and Repeat In vivo Bone Marrow Micronucleus Assay Test 2. Contract Number: N-01-ES-15312 submitted by Novel Pharamceutical, Inc. Durham, NC.
備考	フラグ:SIDSエンドポイントの重要な試験	Flag : Critical study for SIDS endpoint

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈	ALIQUOT A90027	ALIQUOT A90027
方法		
方法／ガイドライン		
	他	other
試験のタイプ	小核試験	Micronucleus assay
GLP適合	情報なし	no data
試験を行った年	1994年	1994
試験系(種／系統)	マウス	mouse
	B6C3F1	B6C3F1
性別(雄:M、雌:F)	雄	male
投与量	0, 75, 100, 150 and 200 mg/kg	0, 75, 100, 150 and 200 mg/kg
投与経路	腹腔内	i.p.
試験期間	24時間	24hours
試験条件	原文参照	Three interperitoneal injections (i.p)/24 hour post-treatment method (post injection harvest) was utilized with the following doses: 0, 75, 150, 200 and 18.75, 37.50, 75, 150, and 200 mg/kg. These dose levels were determined based on discussions between appropriate individuals that had performed previous studies using the test substance (knowledge of test substance prior performance). The solvent used for administration was Phosphate Buffered Saline (PBS). An analysis of variance (ANOVA) was performed. Positive Controls: Cyclophosphamide (CPA, 15 mg/kg) was used as the concurrent positive control.
統計学的処理		
結果		
性別及び投与量別の結果		
遺伝毒性効果	陰性	negative
NOAEL (NOEL)		
LOAEL (LOEL)		
統計的結果		

注釈	原文参照	One hundred percent survival was observed at the time of harvest in all the dose groups. An analysis of variance (ANOVA) and a multi-comparision test revealed no statistically significant effect in % PCEs. Aliquot A90027 demonstrated a slight but non-statistically significant increase in MN-PCEs/1000 PCEs. There was an increasing trend observed in MN-PCEs.
結論		
*in vivo*遺伝毒性	陰性	negative
注釈	被験物質は本試験では陰性と考えられた。その理由は、MN-PCEs/1000 PCEs の僅かな増加が観察されたものの、統計学的に有意でなかったことによる。本試験の結果に基づき、プロジェクトオフィサーはA90027は陽性にも見えるが再試験の検討が必要であると決定している。なお、第一回目の試験は別の要約でサマライズされている。 本試験は、NTPにより行われた第二回目の試験である。	The test substance is considered negative in this study as the a slight increase in MN-PCEs/1000 PCEs were observed however, it was not statisticially significant. Based on the results of this study, the project officer made the determination that A90027 is likely positive but warrants consideration for possible retest. The first study is summarized in a separate summary. This is the second test run conducted by NTP.
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	ガイドライン試験に類似。GLPについては情報なし。	Similar to a guideline study, no data regarding GLP
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	National Toxicology Program (NTP) (1995) In vivo Bone Marrow Micronucleus Assay Tests 1 and Repeat In vivo Bone Marrow Micronucleus Assay Test 2. Contract Number: N-01-ES-15312 submitted by Novel Pharamceutical, Inc. Durham, NC.	National Toxicology Program (NTP) (1995) In vivo Bone Marrow Micronucleus Assay Tests 1 and Repeat In vivo Bone Marrow Micronucleus Assay Test 2. Contract Number: N-01-ES-15312 submitted by Novel Pharamceutical, Inc. Durham, NC.
備考		

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈		
方法		
方法／ガイドライン		
	他:情報なし	other: no data
試験のタイプ	小核試験	Micronucleus assay
GLP適合	非適合	no
試験を行った年	1977年	1977
試験系(種／系統)	ラット	rat
	other: CFY	other: CFY
性別(雄:M、雌:F)	雌雄	male/female
投与量	250 mg/kg bw	250 mg/kg bw
投与経路	経口(特定されていない)	oral unspecified
試験期間	2日間	2 days
試験条件	原文参照	The effects of 12 hair dye components on the genetic material of mammalian somatic cells were studied. Rats were administered a total dose of 500mg/kg resorcinol (108463). Treatments were given by gastric intubation as two equal doses separated by 24 hours. The animals were sacrificed 6 hours after the final dose and bone marrow smears were prepared from the femur. 5 animals/sex/dose; time of preparation: 30h; 2000 polychomatic erythrocytes per animal assessed.
統計学的処理		
結果		
性別及び投与量別の結果		
遺伝毒性効果	陰性	negative
NOAEL (NOEL)		
LOAEL (LOEL)		
統計的結果		
注釈		
結論		
*in vivo*遺伝毒性	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	基本データを与える。	Provides basic data
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	・Hossack DJN, Richardson JC (1976) Examination of the Potential Mutagenicity of Hair Dye Constituents Using the Micronucleus Test. Experientia 33:377-378 (as cited in BiblioLine(c) 1997-2006, NISC International, Inc. All Rights Reserved. www.nisc.com). ・Pedersen et al. (1973) J.Chem.Soc. Perkin II, 424-431.	・Hossack DJN, Richardson JC (1976) Examination of the Potential Mutagenicity of Hair Dye Constituents Using the Micronucleus Test. Experientia 33:377-378 (as cited in BiblioLine(c) 1997-2006, NISC International, Inc. All Rights Reserved. www.nisc.com). ・Pedersen et al. (1973) J.Chem.Soc. Perkin II, 424-431.
備考		

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈	Resorcinolは純度99.5%以上でL'Oreal Parisにより供給された。	Resorcinol was supplied by L'Oreal Paris with a purity of at least 99.5% or greater.
方法		
方法／ガイドライン		
	他	other
試験のタイプ	小核試験	Micronucleus assay
GLP適合	情報なし	no data
試験を行った年	1983年	1983
試験系（種／系統）	マウス	mouse
	情報なし	no data
性別（雄：M、雌：F）	雄	male
投与量	0, 37.5, 75, 150 and 300 mg/kg bw	0, 37.5, 75, 150 and 300 mg/kg bw
投与経路	腹腔内	i.p.
試験期間	情報なし	no data
試験条件	原文参照	The protocol assigned by Schmid (1975) was used. Study was conducted to evaluate the frequencies of micronuclei. 4 male CBA mice received i.p. single doses of resorcinol calculated at 0, 37.5, 5, 150 and 300 mg/kg/bw. The bone marrow was sampled after 24 and 48 h. An equivalent amount of sterile water was injected into the control mice. 1000 polychromatic eryhrocytes were analyzed per animal assessed (for a total of 4000 per dose).
統計学的処理		
結果		
性別及び投与量別の結果		
遺伝毒性効果	陰性	negative
NOAEL (NOEL)		
LOAEL (LOEL)		
統計的結果		
注釈	300mg/kg/bwの被験物質で単回腹腔内投与し、24時間及び48時間後に小核の誘発を調べた試験で、被験物質は小核の頻度を増加させなかった。 このin vivoでの陰性結果は、被験物質の解毒メカニズムによるものとし得る。	No increase in the frequencies of micronuclei could be detected after one i.p. injection up to a concentration of 300 mg/kg/bw and studied after 24 and 48 hrs. The negative effect in vivo can be due to the detoxication mechanism operating in the animal body.
結論		
*in vivo*遺伝毒性	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	基本データを与える。データは信頼できる二次情報からのものである。	Provides basic data. Data are from reliable secondary literature.
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献（元文献）	Darroundi F, Natarajan AT (1983) Cytogenetic analysis of uman peripheral blood lymphocytes (in vitro) treated with resorcinol. Mutation Research 124:179-189.	Darroundi F, Natarajan AT (1983) Cytogenetic analysis of uman peripheral blood lymphocytes (in vitro) treated with resorcinol. Mutation Research 124:179-189.
備考		

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈	ResorcinolはMerck Co. (Germany)から入手。	Resorcinol was obtained from the Merck Co. (Germany)
方法		
方法／ガイドライン		
	他：情報なし	other: no data
試験のタイプ	小核試験	Micronucleus assay
GLP適合	情報なし	no data
試験を行った年	1981年	1981
試験系（種／系統）	マウス	mouse
	NMRI	NMRI
性別（雄：M、雌：F）	雌雄	male/female
投与量	0, 55, 110, 220 mg/kg bw	0, 55, 110, 220 mg/kg bw
投与経路	腹腔内	i.p.
試験期間	30時間	30 hours

試験条件	原文参照	2 animals/sex/dose for a total of 4 animals per dose; time of preparation: 30h; 1000 polychromatic erythrocytes per animal assessed The micronucleus test was performed according to Schmid.The animals were treated at 0 and 24h, and, bone-marrow smears were prepared at 30h. Usually, 4 mice (2 male, 2 female) were used for each of 3 doses and 1 control. Doses were at 0, 55, 110 and 220 mg/kg bw (0.5, 1.0, 2.2 mM). Slides were coded, and 1000 polychromatic erythrocytes were scored per mouse. Significance was calculated according to the Kastenbaum-Bowman tables. [Kastenbaum, M.A., and K.O. Bowman, Tables for determining the statistical significance of mutation frequencies, Mutation Res., 9 (1970) 527-549]
統計学的処理		
結果		
性別及び投与量別の結果		
遺伝毒性効果	陰性	negative
NOAEL (NOEL)		
LOAEL (LOEL)		
統計的結果		
注釈	原文参照	Negative Dose Micronucleated PE % 0 1.5 55 1.7 110 2.0 220 2.4 Dose: 2 x 220 mg/kg Surviving/treated mice: 4/4 Micronucleated PE (%): 2.4 Dose: 2 x 110 mg/kg Surviving/treated mice: 4/4 Micronucleated PE (%): 2.0 Dose: 2 x 55 mg/kg Surviving/treated mice: 4/4 Micronucleated PE (%): 1.7 Dose: 0 mg/kg Surviving/treated mice: 4/4 Micronucleated PE (%): 1.5 All four treated animals survived each dosing concentration.
結論		
*in vivo*遺伝毒性	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	基本データを与える。データは信頼できる二次情報からのものである。	Provides basic data. Data are from reliable secondary literature.
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	・Gocke E, King MT, Eckhardt K, Wild D (1981) Mutagenicity of cosmetics ingredients. Mutation Research 90:91-109. ・Wild D, King MT, Eckhardt K, Gocke E (1981) Mutagenic activity of aminophenols and diphenols, and relations with chemical structures. Mutation Research 85:456.	・Gocke E, King MT, Eckhardt K, Wild D (1981) Mutagenicity of cosmetics ingredients. Mutation Research 90:91-109. ・Wild D, King MT, Eckhardt K, Gocke E (1981) Mutagenic activity of aminophenols and diphenols, and relations with chemical structures. Mutation Research 85:456.
備考		

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈		
方法		
方法／ガイドライン		
	他	other
試験のタイプ	姉妹染色分体交換試験	Sister chromatid exchange assay
GLP適合	情報なし	no data
試験を行った年	1981年	1981
試験系(種／系統)	ラット	rat
	Sprague-Dawley	Sprague-Dawley
性別(雄:M、雌:F)	雌雄	male/female
投与量	0.8, 4, 20, 100 mg/kg	0.8, 4, 20, 100 mg/kg
投与経路	強制経口	gavage
試験期間	24時間	24 hours

試験条件	原文参照	3 animals/dose; treatment time: 24 h; 12 – 54 metaphases analyzed per animal SCE in bone marrow cells. Female, Sprague-Dawley rats, 10 -15 weeks old were administered doses of 0.8, 4, 20 and 100 mg/kg via gavage. Control, (0.5 ml water), negative control values from the laboratory (13 independent experiments, representing 2 animals each): 3.55 SCE/cell (+ 0.25 s.e.m. indicating variability among experiments) BrdU tablets (1 g/kg pressed with 5 ton/cm2) were subcutaneously implanted into the lower back region of mildly etherized animals 2 h before application of the test or control substances. Drugs were administered perorally by gavage Bone marrow cells were prepared and stained by the procedure of Renner and Munzner (1978) with the following modifications: Bone marrow was directly brought into 1% trisodium citrate. Fixation solution was ethanol/acetic acid (2.5:1). First staining in 5 ul/ml bisbenzimid-H33258. 2 x SSC treatment for 60 min at 60C. Second staining for 7 min in 3% Giemsa.
統計学的処理		
結果		
性別及び投与量別の結果		
遺伝毒性効果	陰性	negative
NOAEL (NOEL)		
LOAEL (LOEL)		
統計的結果		
注釈	陰性(resorcinol) 結果は、各用量ごとに、全動物の平均SCE+(平均の標準誤差)(s.e.m)の値が収集された。	Negative (resorcinol) Results were pooled to establish a mean SCE + (standard error of the mean) (s.e.m) for all animals at each dose.
結論		
*in vivo*遺伝毒性	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	基本データを与える。データは信頼できる二次情報(ピアレビューされた雑誌)からのものである。	Provides basic data. Data are from reliable secondary literature (peer reviewed journal).
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	Bracher M, Wisak J, Noser F (1981) Studies on the potential in vivo inducation of sister chromatid exchanges in rat bone marrow by resorcinol. Mutation Research 91:363-369.	Bracher M, Wisak J, Noser F (1981) Studies on the potential in vivo inducation of sister chromatid exchanges in rat bone marrow by resorcinol. Mutation Research 91:363-369.
備考	フラグ:SIDSエンドポイントの重要な試験	Flag : Critical study for SIDS endpoint

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈		
方法		
方法/ガイドライン		
	他	other
試験のタイプ	姉妹染色分体交換試験	Sister chromatid exchange assay
GLP適合	情報なし	no data
試験を行った年	1981年	1981
試験系(種/系統)	ラット	rat
	Sprague-Dawley	Sprague-Dawley
性別(雄:M、雌:F)	雌雄	male/female
投与量	1, 5, 15, 50 and 100 mg/kg bw	1, 5, 15, 50 and 100 mg/kg bw
投与経路	腹腔内	i.p.
試験期間	24時間	24 hours

試験条件	原文参照	1 – 3 animals/dose; treatment time: 24 h; 13 – 36 metaphases analyzed per animal Male and female Sprague–Dawley rats, 10 –15 weeks old were administered doses of. 1, 5, 15, 50 and 100 mg/kg via i.p. injection. Specifically dosing occurred in the following manner: At 1 mg/kg (one male/female) 5 mg/kg (2 females and one male) 15 mg/kg (2 males and one female) 50 mg/kg (2 females and one male) 100 mg/kg (one male) two SCE/cell counts were performed Control, (0.5 ml water), negative control values from our laboratory (13 independent experiments, representing 2 animals each): 3.55 SCE/cell (+ 0.25 s.e.m. indicating variability among experiments) BrdU tablets (1 g/kg pressed with 5 ton/cm2) were subcutaneously implanted into the lower back region of mildly etherized animals 2 h before application of the test or control substances. Drugs were administered intraperitoneally. 24 h after drug administration the animals were sacrificed. Mitotic arrest was achieved by an interperitoneal injection of 10 mg/kg colchicine 2 h before sacrifice. Bone marrow cells were prepared and stained by the procedure of Renner and Munzner (1978) with the following modifications: Bone marrow was direclty brought into 1% trisodium citrate. Fixation solution was ethanol/acetic acid (2.5:1). First staining in 5 ul/ml bisbenzimid–H33258. 2 x SSC treatment for 60 min at 60C. Second staining for 7min in 3% Giemsa.
統計学的処理		
結果		
性別及び投与量別の結果		
遺伝毒性効果	陰性	negative
NOAEL (NOEL)		
LOAEL (LOEL)		
統計的結果		
注釈	陰性(resorcinol) 結果は、各用量ごとに、全動物の平均SCE+(平均の標準誤差)(s.e.m)の値が収集された。	Negative (resorcinol). Results were pooled to establish a mean SCE + (standard error of the mean) (s.e.m) for all animals at each dose.
結論		
*in vivo*遺伝毒性	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	基本データを与える。データは信頼できる二次情報(ピアレビューされた雑誌)からのものである。	Provides basic data. Data are from reliable secondary literature (peer reviewed journal).
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	Bracher M, Wisak J, Noser F (1981) Studies on the potential in vivo inducation of sister chromatid exchanges in rat bone marrow by resorcinol. Mutation Research 91:363–369.	Bracher M, Wisak J, Noser F (1981) Studies on the potential in vivo inducation of sister chromatid exchanges in rat bone marrow by resorcinol. Mutation Research 91:363–369.
備考	フラグ:SIDSエンドポイントの重要な試験	Flag : Critical study for SIDS endpoint

試験物質名	resorcinol	resorcinol
CAS番号	108–46–3	108–46–3
純度等		
注釈		
方法		
方法／ガイドライン		
	他	other
試験のタイプ	姉妹染色分体交換試験	Sister chromatid exchange assay
GLP適合	情報なし	no data
試験を行った年	1981年	1981
試験系(種／系統)	ラット	rat
	Sprague–Dawley	Sprague–Dawley
性別(雄:M、雌:F)	雌雄	male/female
投与量	0.2, 2, 20, 100, 200, 300 mg/kg	0.2, 2, 20, 100, 200, 300 mg/kg
投与経路	経皮	dermal
試験期間	24時間	24 hours

試験条件	原文参照	2 – 3 animals/dose; treatment time: 24 h; 20–54 metaphases analyzed per animal SCE in Bone Marrow Cells. Male and female Sprague–Dawley rats, 10 –15 weeks old were administered doses of 0.2, 2, 20, 100, 200 and 300 mg/kg via the dermal route. Specifically dosing occurred in the following manner: 0.2 mg/kg (2 females) 2 mg/kg (3 females) 20 mg/kg (3 females) 100 mg/kg (one male and one female) 200 mg/kg (2 females) 200 mg/kg (one male and one female rat were administered 200 mg/kg in 2 doses of 100 mg/kg each, 17 h before, and 2 hr after BrdU implanation) 300 mg/kg (one male and one female were administered 300 mg/kg in 3 doses of 100 mg/kg each, 24h and 17 h before and 2 h after BrdU implantation Control, (0.2 ml water) (one male and one female), negative control values from our laboratory (13 independent experiments, representig 2 animals each): 3.55 SCE/cell (+ 0.25 s.e.m. indicating variability among experiments)
試験条件	原文参照	BrdU tablets (1 g/kg pressed with 5 ton/cm2) were subcutaneously implanted into the lower back region of mildly etherized animals 2 h before application of the test or control substances (unless otherwise noted). Drugs were administered topically on a shaved area (7–8 cm2 leaving behind 3 mm of hair) on the neck region. During 20 minutes after topical drug administration, the animals were not allowed to lick the treated skin or to ingest the drug material indirectly by cleaning their necks with their paws, and then the drugs were washed off with a mild shampoo. Mitotic arrest was achieved by an interperitoneal injection of 10 mg/kg colchicine 2 h before sacrifice. Bone marrow cells were prepared and stained by the procedure of Renner and Munzner (1978) with the following modifications: Bone marrow was direclty brought into 1% trisodium citrate. Fixation solution was ethanol/acetic acid (2.5:1). First staining in 5 ul/ml bisbenzimid–H33258. 2 x SSC treatment for 60 min at 60C. Second staining for 7 min in 3% Giemsa.
統計学的処理		
結果		
性別及び投与量別の結果		
遺伝毒性効果	陰性	negative
NOAEL (NOEL)		
LOAEL (LOEL)		
統計的結果		
注釈	陰性(resorcinol) 結果は、各用量ごとに、全動物の平均SCE+(平均の標準誤差)(s.e.m)の値が収集された。	Negative (resorcinol) Results were pooled to establish a mean SCE + (standard error of the mean) (s.e.m) for all animals at each dose.
結論		
*in vivo*遺伝毒性	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	基本データを与える。データは信頼できる二次情報(ピアレビューされた雑誌)からのものである。	Provides basic data. Data are from reliable secondary literature (peer reviewed journal).
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	Bracher M, Wisak J, Noser F (1981) Studies on the potential in vivo induction of sister chromatid exchanges in rat bone marrow by resorcinol. Mutation Research 91:363–369.	Bracher M, Wisak J, Noser F (1981) Studies on the potential in vivo induction of sister chromatid exchanges in rat bone marrow by resorcinol. Mutation Research 91:363–369.
備考	フラグ:SIDSエンドポイントの重要な試験	Flag : Critical study for SIDS endpoint

試験物質名	resorcinol	resorcinol
CAS番号	108–46–3	108–46–3
純度等		
注釈	ResorcinolはMerck Co. (Germany)から入手。	Resorcinol was obtained from the Merck Co. (Germany).
方法		
方法／ガイドライン		
	他	other
試験のタイプ	Drosophila SLRL test	Drosophila SLRL test
GLP適合	情報なし	no data
試験を行った年	1981年	1981
試験系(種／系統)	Drosophila melanogaster	Drosophila melanogaster
	other: Basc	other: Basc
性別(雄:M、雌:F)	雌雄	male/female
投与量	50mM	50mM
投与経路	混餌	oral feed

試験期間	情報なし	no data
試験条件	原文参照	The Basc test was performed on Drosophila to detect sex linked recessive lethal mutations. The Berlin K and Basc strains were used. Concentration tested was 50mM. In Drosophila one dose close to the LD50 was applied by the adult feeding method in 5% saccharose. About 1200 X-chromosomes were tested per experiment in each of 3 successive broods (3-3-4 days). In repeat experiments, sometimes only single broods were tested. F2, progeny cultures with 2 or fewer wild-type males were routinely retested in the F3, generation to confirm X-linked recessive lethal mutations (RLs). Mosaics were not counted. "Clusters" of 2 were included because their occurrence was compatible with statistical expectation of independent origin.
統計学的処理		
結果		
性別及び投与量別の結果		
遺伝毒性効果	陰性	negative
NOAEL (NOEL)		
LOAEL (LOEL)		
統計的結果		
注釈	50mMの性関連劣性致死/染色体、及び割合 Brood 1: 9/3593 (0.25) Brood 2: 8/3624 (0.22) Brood 3: 17/3674 (0.46)	Sex-linked recessive lethals/chromosomes tested and percentage at 50 mM: Brood 1: 9/3593 (0.25) Brood 2: 8/3624 (0.22) Brood 3: 17/3674 (0.46)
結論		
*in vivo*遺伝毒性	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	基本データを与える。データは信頼できる二次情報からのものである。	Provides basic data. Data are from reliable secondary literature
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	Gocke E, King MT, Eckhardt K, Wild D (1981) Mutagenicity of cosmetics ingredients. Mutation Research 90:91-109.	Gocke E, King MT, Eckhardt K, Wild D (1981) Mutagenicity of cosmetics ingredients. Mutation Research 90:91-109.
備考	フラグ:SIDSエンドポイントの重要な試験	Flag : Critical study for SIDS endpoint

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈		
方法		
方法/ガイドライン		
	他:Zimmering et al (1985)	other: Zimmering et al (1985)
試験のタイプ	Drosophila SLRL test	Drosophila SLRL test
GLP適合	情報なし	no data
試験を行った年	1991年	1991
試験系(種/系統)	Drosophila melanogaster	Drosophila melanogaster
	other: Canton-s wild type	other: Canton-s wild type
性別(雄:M、雌:F)	雄	male
投与量	11,000 ppm	11,000 ppm
投与経路	他:混餌	other:feed (diet)
試験期間	72時間	72 hours

試験条件	原文参照	Initially, the study chemical was assayed in the sex-linked recessive lethal (SLRL) test by feeding for 3 days to adult Canton-S wild-type males no more than 24 hours old at the beginning of treatment. Because no response was obtained, the chemical was retested by injection into adult males. To administer a chemical by injection, a glass Pasteur pipette was drawn out in a flame to a microfine filament and the tip was broken off to allow delivery of the test solution. Injection was performed either manually, by attaching a rubber bulb to the other end of the pipette and forcing through sufficient solution (0.2 to 0.3 µL) to slightly distend the abdomen of the fly, or by attaching the pipette to a microinjector which automatically delivers a calibrated volume. Flies are anesthetized with ether and immobilized on a strip of double stick tape; the chemical was injected into the thorax under the wing with the aid of a dissecting microscope. Toxicity tests were performed to set concentrations of study chemical at a level which would induce 30% mortality after 72 hours of feeding or 24 hours after injection, while keeping induced sterility at an acceptable level. For the SLRL test, exposure by feeding was done by allowing Canton-S males (10 to 20 flies/vial) to feed for 72 hours on a solution of the study chemical in 5% sucrose. In the injection experiments, 24- to 72-hour-old Canton-S males were treated with a solution of the chemical dissolved in 0.7% saline and were allowed to recover for 24 hours.
試験条件	原文参照	Exposed males were mated to three Basc females for 3 days and given fresh females at 2-day intervals to produce three matings of 3, 2, and 2 days; sample sperm from successive matings were treated at successively earlier post-meiotic stages. F, heterozygous females were allowed to mate with their siblings and were then placed in individual vials. F, daughters from the same parental male were kept together to identify clusters. (A cluster occurs when a number of mutants from a given male result from a single spontaneous premeiotic mutation event, and is identified when the number of mutants from that male exceeds the number predicted by a Poisson distribution). If a cluster was identified, all data from the male in question were discarded. After 17 days, presumptive lethal mutations were identified as occurring in vials containing no wild-type males; these were retested. A minimum of two experiments were performed for each study chemical, resulting in the testing of approximately 5,000 treated and 5,000 control chromosomes. The only exceptions occurred when the results of the first experiment were clearly positive (induced frequency of recessive lethal mutations equal to or greater than 1%); then, the second trial was not run. Recessive lethal data were analyzed by the normal approximation to the binomial test (Margolin et al., 1983).
試験条件	原文参照	A test result was considered to be positive if the P value was less than 0.01 and the mutation frequency in the tested group was greater that 0.10%, or if the P value was less than 0.05 and the frequency in the treatment group was greater than 0.15%. A test was considered to be inconclusive if (a) the P value was between 0.05 and 0.01 but the frequency in the treatment group was between 0.10% and 0.15%, or (b) the P value was between 0.10 and 0.05 but the frequency in the treatment group was greater than 0.10%. A result was considered to be negative if the P value was greater than 0.10 or if the frequency in the treatment group was less than 0.10%.
統計学的処理		
結果		
性別及び投与量別の結果		
遺伝毒性効果	陰性	negative
NOAEL (NOEL)		
LOAEL (LOEL)		
統計的結果		
注釈	Resorcinol (11,000 ppm) を雄成虫のショウジョウバエ (Drosophila melangaster) に混餌投与した試験で、生殖細胞の性関連劣性致死突然変異の誘発性は陰性であった。	Resorcinol (11,000 ppm) was negative for induction of sex-linked recessive lethal mutations in germ cells of male Drosophila melangaster when administered to adult flies by feeding.
結論		
*in vivo*遺伝毒性	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	ガイドライン試験。GLPに関して情報なし。	Guideline study; No data regarding GLP
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009

引用文献(元文献)	・National Toxicology Program (NTP) (1991) Toxicology and Carcinogenesis Studies of Resorcinol (CAS No. 108-46-3) in F344/N Rats and B6C3F1 Mice. (Gavage Studies). Draft TR403. ・National Toxicology Program (NTP) (1992) Technical Report on the Toxicology and Carcinogenesis Studies of Resorcinol (CAS No. 108-46-3) in F344/N Rats and B6C3F1 Mice (Gavage Studies) NIH Publication No. 91-2858 Technical report TR403.	・National Toxicology Program (NTP) (1991) Toxicology and Carcinogenesis Studies of Resorcinol (CAS No. 108-46-3) in F344/N Rats and B6C3F1 Mice. (Gavage Studies). Draft TR403. ・National Toxicology Program (NTP) (1992) Technical Report on the Toxicology and Carcinogenesis Studies of Resorcinol (CAS No. 108-46-3) in F344/N Rats and B6C3F1 Mice (Gavage Studies) NIH Publication No. 91-2858 Technical report TR403.
備考	フラグ:SIDSエンドポイントの重要な試験	Flag : Critical study for SIDS endpoint

試験物質名	resorcinol	resorcinol
CAS番号	108-46-3	108-46-3
純度等		
注釈		
方法		
方法／ガイドライン		
	他:Zimmering et al (1985)	other: Zimmering et al (1985)
試験のタイプ	Drosophila SLRL test	Drosophila SLRL test
GLP適合	情報なし	no data
試験を行った年	1991年	1991
試験系(種／系統)	Drosophila melanogaster	Drosophila melanogaster
	other: Canton-s wild type	other: Canton-s wild type
性別(雄:M、雌:F)	雄	male
投与量	11,940 ppm	11,940 ppm
投与経路	other: 注射	other: injection
試験期間	72時間	72 hours
試験条件	原文参照	Initially, the study chemical was assayed in the sex-linked recessive lethal (SLRL) test by feeding for 3 days to adult Canton-S wild-type males no more than 24 hours old at the beginning of treatment. Because no response was obtained, the chemical was retested by injection into adult males. To administer a chemical by injection, a glass Pasteur pipette was drawn out in a flame to a microfine filament and the tip was broken off to allow delivery of the test solution. Injection was performed either manually, by attaching a rubber bulb to the other end of the pipette and forcing through sufficient solution (0.2 to 0.3 µL) to slightly distend the abdomen of the fly, or by attaching the pipette to a microinjector which automatically delivers a calibrated volume. Flies are anesthetized with ether and immobilized on a strip of double stick tape; the chemical was injected into the thorax under the wing with the aid of a dissecting microscope. Toxicity tests were performed to set concentrations of study chemical at a level which would induce 30% mortality after 72 hours of feeding or 24 hours after injection, while keeping induced sterility at an acceptable level. For the SLRL test, exposure by feeding was done by allowing Canton-S males (10 to 20 flies/vial) to feed for 72 hours on a solution of the study chemical in 5% sucrose.
試験条件	原文参照	In the injection experiments, 24- to 72-hour-old Canton-S males were treated with a solution of the chemical dissolved in 0.7% saline and were allowed to recover for 24 hours. Exposed males were mated to three Basc females for 3 days and given fresh females at 2-day intervals to produce three matings of 3, 2, and 2 days; sample sperm from successive matings were treated at successively earlier post-meiotic stages. F, heterozygous females were allowed to mate with their siblings and were then placed in individual vials. F, daughters from the same parental male were kept together to identify clusters. (A cluster occurs when a number of mutants from a given male result from a single spontaneous premeiotic mutation event, and is identified when the number of mutants from that male exceeds the number predicted by a Poisson distribution). If a cluster was identified, all data from the male in question were discarded.

試験条件	原文参照	After 17 days, presumptive lethal mutations were identified as occurring in vials containing no wild-type males; these were retested. A minimum of two experiments were performed for each study chemical, resulting in the testing of approximately 5,000 treated and 5,000 control chromosomes. The only exceptions occurred when the results of the first experiment were clearly positive (induced frequency of recessive lethal mutations equal to or greater than 1%); then, the second trial was not run. Recessive lethal data were analyzed by the normal approximation to the binomial test (Margolin et al., 1983). A test result was considered to be positive if the P value was less than 0.01 and the mutation frequency in the tested group was greater that 0.10%, or if the P value was less than 0.05 and the frequency in the treatment group was greater than 0.15%. A test was considered to be inconclusive if (a) the P value was between 0.05 and 0.01 but the frequency in the treatment group was between 0.10% and 0.15%, or (b) the P value was between 0.10 and 0.05 but the frequency in the treatment group was greater than 0.10%. A result was considered to be negative if the P value was greater than 0.10 or if the frequency in the treatment group
統計学的処理		
結果		
性別及び投与量別の結果		
遺伝毒性効果	あいまいな結果	ambiguous
NOAEL (NOEL)		
LOAEL (LOEL)		
統計的結果		
注釈	被験物質の注射による投与(11,940) の結果、突然変異の増加が認められたが、それはあいまいな結果であった(試験群で0.12%の突然変異頻度、P=0.06)。	Administration of the test substance (11,940) by injection yielded an increase in mutations which was equivocal (P=0.06 and mutation frequency of 0.12% in the treated group).
結論		
*in vivo*遺伝毒性	あいまいな結果	ambiguous
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	ガイドライン試験。GLPに関して情報なし。	Guideline study; No data regarding GLP
出典	OECD SIDS Dossier, 2009	OECD SIDS Dossier, 2009
引用文献(元文献)	・National Toxicology Program (NTP) (1991) Toxicology and Carcinogenesis Studies of Resorcinol (CAS No. 108-46-3) in F344/N Rats and B6C3F1 Mice. (Gavage Studies). Draft TR403. ・National Toxicology Program (NTP) (1992) Technical Report on the Toxicology and Carcinogenesis Studies of Resorcinol (CAS No. 108-46-3) in F344/N Rats and B6C3F1 Mice (Gavage Studies) NIH Publication No. 91-2858 Technical report TR403.	・National Toxicology Program (NTP) (1991) Toxicology and Carcinogenesis Studies of Resorcinol (CAS No. 108-46-3) in F344/N Rats and B6C3F1 Mice. (Gavage Studies). Draft TR403. ・National Toxicology Program (NTP) (1992) Technical Report on the Toxicology and Carcinogenesis Studies of Resorcinol (CAS No. 108-46-3) in F344/N Rats and B6C3F1 Mice (Gavage Studies) NIH Publication No. 91-2858 Technical report TR403.
備考	フラグ:SIDSエンドポイントの重要な試験	Flag : Critical study for SIDS endpoint

5-8 発がん性
CARCINOGENICITY

試験物質名	1.1～1.4で規定	as prescribed by 1.1 - 1.4
CAS番号		
純度等	NAPP Chemicals, Incorporated から入手、水に溶解して調製、純度 >99% ロットNo. IN-79-7087	Obtained from NAPP Chemicals, Incorporated. Preparation in water, purity >99% Lot No. IN-79-7087
注釈		
方法		
方法／ガイドライン	その他:NTPボード EPA/FDAガイドライン	other:NTP Board EPA/FDA guidelines
試験のタイプ		
GLP適合	はい	yes
試験を行った年	1981	1981
試験系(種／系統)	ラット	rat
	Fischer 344	Fischer 344
性別(雄:M、雌:F)	雌雄	male/female
投与量	0、112、225 mg/kg 体重 (雄) 0、50、100、150 mg/kg (雌)	0, 112, 225 mg/kg bw (males) 0, 50, 100 150 mg/kg (females)
各用量群(性別)の動物数		
溶媒(担体)		
投与経路	強制経口	gavage
処理頻度	毎日: 5日/週	Daily: 5 days a week
対照群と処理	あり	yes
試験条件	暴露期間 : 104週間 暴露後の期間 : データなし	Exposure period : 104 weeks Post exposure period : no data

試験条件	※英文参照	Groups of 60 male rats were administered 0, 112 or 225 mg/kg resorcinol in deionized water by gavage. The rats were 6–7 weeks at start of study. Groups of 60 females rats were initially administered the same doses as the male rats , but by week 22 of the study, 16 of the high dose females had died. Consequently, the female rat study was restarted using doses of 0, 50, 100 or 150 mg/kg. Doses were given at a volume of 5ml/kg, 5 days a week for 103 weeks.
試験条件	※英文参照	Clinical Examinations and Pathology All animals were observed twice daily. Clinical signs of toxicity were recorded every 4 weeks. Individual body weights were obtained weekly for the first 13 weeks and every 4 weeks thereafter until the last 3 months of the studies, when body weights were recorded every 2 weeks After 15 months on study, 10 male and 10 female rats from each dose group were sacrificed for evaluation of organ weights, hematology, and clinical chemistry.Parameters measured were: Hematology: hematocrit, hemoglobin, erythrocytes, mean cell volume, mean cell hemoglobin, mean cell hemoglobin concentration, leukocytes, segmented neutrophils, lymphocytes, monocytes, eosinophils, and nucleated erythrocytes. Clinical chemistry: urea nitrogen, alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, and sorbitol dehydrogenase. A necropsy was performed on all animals. During necropsy, all organs and tissues were examined for grossly visible lesions. Organ weights recorded for all brain, right kidney and liver of all animals sacrificed at 15 months except male rats receiving 225 mg/kg.
試験条件	※英文参照	Complete histologic examination was conducted on all control and high–dose male rats from the 15–month study and all rats from the 2–year study. Gross lesions only were examined from low–dose male rats and all female rats from the 15–month studies. In addition to tissue masses and gross lesions, the following organs and/or tissues were included in complete histopathologic examinations: adrenal glands, aorta, bone (femur including marrow), brain, clitoral gland (rats), epididymis, esophagus, eye (if grossly abnormal), heart, kidneys, large intestine (cecum, colon, rectum), liver, lungs, mammary gland, mesenteric lymph node, nasal cavity, ovaries, pancreas, parathyroids, pituitary, preputial gland (rats), prostate, salivary gland, skin, small intestine (duodenum, jejunum, ileum), spleen, stomach, testes, thymus, thyroids, trachea, urinary bladder, and uterus.
試験条件	※英文参照	Pathology evaluations were completed by the study laboratory pathologist and the pathology data were entered into the Toxicology Data Management System (TDMS). The slides, paraffin blocks, and residual wet tissues were sent to the NTP Archives for inventory, slide/block match, and wet tissue audit for accuracy of labeling and animal identification and for thoroughness of tissue trimming. The slides, individual animal data records, and pathology tables were evaluated by an independent quality assessment laboratory. The individual animal records and tables were compared for accuracy, slides and tissue counts were verified, and histotechnique was evaluated. A quality assessment pathologist reviewed selected tissues from the 15–month and 2–year studies for accuracy and consistency of lesion diagnosis. All diagnosed neoplasms in all animals, brains from all male rats were reviewed. In addition, all tissues were examined from six rats of each sex randomly selected from each control and high–dose group in the 15–month studies, and from five rats of each sex randomly selected from each control and high–dose group in the 2–year studies.

試験条件	※英文参照	The quality assessment report and slides were submitted to a PWG chairperson, who reviewed tissues for which there was a disagreement in diagnosis between the laboratory and quality assessment pathologists. Representative examples of nonneoplastic lesions and neoplasms and examples of disagreements in diagnosis between the laboratory and quality assessment pathologists were reviewed by the PWG. Each PWG included the quality assessment pathologist as well as other pathologists experienced in rodent toxicologic pathology, who examined these tissues without knowledge of dose group or previously rendered diagnoses. When the consensus diagnosis of a PWG differed from that of the laboratory pathologist, the final diagnosis was changed to reflect the opinion of the PWG. Details of these review procedures have been described, in part, by Maronpot and Boorman (1982) and Boorman et al (1985). For subsequent analysis of pathology data, the diagnosed lesions for each tissue type are evaluated separately or combined according to the guidelines of McConnell et al (1986).
試験条件	※英文参照	Quality Assurance Methods The 2-year studies were conducted in compliance with FDA Good Laboratory Practice Regulations (21 CFR Part 58). In addition, as study records were submitted to the NTP Archives, they were audited retrospectively by an independent quality assurance contractor. Separate audits covering completeness and accuracy of the pathology data, pathology specimens, final pathology tables, and preliminary review draft of this NTP Technical Report were conducted. Audit procedures are presented in the reports, which are on file at the NIEHS. The audit findings were reviewed and assessed by the NTP staff so that all had been resolved or were otherwise addressed during the preparation of this Technical Report.
統計学的処理	※英文参照	Statistical Methods Survival Analyses The probability of survival was estimated by the product-limit procedure of Kaplan and Meier (1958) and is presented in the Results section of this report. Animals were censored from the survival analyses at the time they were found dead from other than natural causes or were found missing; animals dying from natural causes were not censored. Statistical analyses for possible dose-related effects on survival used Cox's (1972) method for testing two groups for equality and Tarone's (1975) life table tests to identify dose-related trends. All reported P values for the survival analysis are two-sided.
統計学的処理	※英文参照	Calculation of Incidence. The incidence of neoplastic or nonneoplastic lesions is given as the ratio of the number of animals bearing such lesions at a specific anatomic site to the number of animals in which that site was examined. In most instances, the denominators include only those animals for which the site was examined histologically. However, when macroscopic examination was required to detect lesions (e.g., skin or mammary tumors) before tissue sampling for histopathology, or when lesions could have appeared at multiple sites (e.g., mononuclear cell leukemia), the denominators consist of the number of animals on which a necropsy was performed.
統計学的処理	※英文参照	Analysis of Tumor Incidence The majority of tumors in these studies were considered to be incidental to the cause of death or not rapidly lethal. Thus, the primary statistical method used was a logistic regression analysis, which assumed that the diagnosed tumors were discovered as the result of death from an unrelated cause and, thus, did not affect the risk of death. In this approach, tumor prevalence was modeled as a logistic function of chemical exposure and time. Both linear and quadratic terms in time were incorporated initially, and the quadratic term was eliminated if it did not significantly enhance the fit of the model. The dosed and control groups were compared on the basis of the likelihood score test for the regression coefficient of dose. This method of adjusting for intercurrent mortality is the prevalence analysis of Dinse and Lagakos (1983), further described and illustrated by Dinse and Haseman (1986). When tumors are incidental, this comparison of the time-specific tumor prevalences also provides a comparison of the time-specific tumor incidences (McKnight and Crowley, 1984).

統計学的処理	※英文参照	In addition to logistic regression, alternative methods of statistical analysis were used. These include the life table test (Cox, 1972; Tarone, 1975), appropriate for rapidly lethal tumors, and the Fisher exact test and the Cochran-Armitage trend test (Armitage, 1971; Gart et al., 1979), procedures based on the overall proportion of tumor-bearing animals. Tests of significance include pairwise comparisons of each dosed group with controls and a test for an overall dose-response trend. Continuity-corrected tests were used in the analysis of tumor incidence, and reported P values are one-sided. The procedures described above also were used to evaluate selected nonneoplastic lesions.
統計学的処理	※英文参照	Historical Control Data Although the concurrent control group is always the first and most appropriate control group used for evaluation, historical control data can be helpful in the overall assessment of tumor incidence. Consequently, control tumor incidences from the NTP historical control data base (Haseman et al., 1984, 1985) are included in the NTP reports for tumors appearing to show compound-related effects.
統計学的処理	※英文参照	Analysis of Continuous Variables Two approaches were employed to assess the significance of pairwise comparisons between dosed and control groups in the analysis of continuous variables. Organ and body weight data, which have approximately normal distributions, were analyzed using the parametric multiple comparison procedures of Williams (1971, 1972) and Dunnett (1955). Clinical chemistry and hematology data, which have typically skewed distributions, were analyzed using the nonparametric multiple comparison methods of Shirley (1977) and Dunn (1964). Jonckheere's test (Jonckheere, 1954) was used to assess the significance of the dose-response trends and to determine whether a trend-sensitive test (Williams' or Shirley's test) was more appropriate for pairwise comparisons than a test that does not assume a monotonic dose-response trend (Dunnett's or Dunn's test).
結果		
体重、体重増加量		
摂餌量、飲水量		
臨床所見(重篤度、所見の発現時期と持続時間)		
眼科学的所見(発生率、重篤度)		
血液学的所見(発生率、重篤度)		
血液生化学的所見(発生率、重篤度)		
尿検査所見(発生率、重篤度)		
死亡数(率)、死亡時間		
剖検所見(発生率、重篤度)		
臓器重量		
病理組織学的所見(発生率、重篤度)		
実際に摂取された量		
腫瘍発生までの時間		
用量反応性		
統計的結果		
注釈	腫瘍の型及び頻度は対照群のそれらと同様であった。 15ヶ月中間評価 各投与群の雌雄各10匹のラットを15ヶ月での中間評価用に予め指定した。高用量の雄では早期の死亡例のためにこの群の動物は15ヶ月で屠殺されなかった。代わりに、15ヶ月近くで死亡又は瀕死状態で屠殺した高用量の雄10匹を中間評価に含めた。血液検査又は臨床化学パラメータには投与に関連した差はみられなかった。病理組織学的検査では投与に関連した腫瘍又は非腫瘍性病変はみられなかった。	Tumor type and incidence were in the same range as those of the control. 15-Month Interim Evaluations Ten rats of each sex in each dose, group were predesignated for interim evaluations at 15 months. Due to early mortality in the high-dose males, animals from this group were not sacrificed at 15 months. Instead, 10 high-dose males that died or were sacrificed in a moribund condition near month 15 were included in the interim evaluation. No treat-ment-related differences in hematology or clinical chemistry parameters were seen. No treatment-related neoplasms or nonneoplastic lesions were found during histopathologic examination.

注釈	生存例 高用量の雌雄の生存率は対照群と比べて有意に低値であった。残りの投与群は対照群と同様の生存率を示した。 歩哨動物 センダイウイルス及びラットコロナウイルス/唾液腺涙腺炎に対する血清抗体価の陽性反応が6、12、18及び24ヶ月で歩哨動物で検出された。しかし、臨床的にも病理組織学的にも疾患の証拠はみられなかった。	Survival The survival of high-dose males and females was significantly lower than that of the control. The remaining dose groups had survival rates similar to those of the controls. Sentinel Animals Positive serological titers for Sendai virus and rat corona virus/ sialodacryoadenitis were found in sentinel animals at 6, 12, 18, and 24 months. However, there was no clinical or histopathologic evidence of disease.
注釈	病理検査及び結果の統計解析 本章で述べられた腫瘍性及び非腫瘍性病変の頻度の要約、個別動物の腫瘍の診断結果、少なくとも1つの動物群で少なくとも5%の頻度で生じた原発腫瘍の統計解析は雄及び雌ラットに対して報告書の付表A及びBに示されている。 雌雄のF344/Nラットにおける2年間レゾルシノール強制経口投与はいずれの部位でも腫瘍性又は非腫瘍性病変の頻度の統計的又は生物学的に有意な増加を生じなかった。高用量の雄での多様な腫瘍性病変、及び高用量の雌雄での多様な非腫瘍性病変の頻度は投与群での低生存率のために対照群と比べて減少した。	Pathology and Statistical Analysis of Results Summaries of the incidences of neoplasms and nonneoplastic lesions, individual animal tumor diagnoses, and statistical analyses of primary tumors that occurred with an incidence of at least 5% in at least one animal group mentioned in this section are presented in Appendixes A and B of the report for male and female rats. Administration of resorcinol by gavage to male and female F344/N rats for 2 years did not result in any statistically or biologically significant increases in the incidences of neoplasms or nonneoplastic lesions at any site. Incidences of a variety of neoplasms in high-dose males and nonneoplastic lesions in high-dose males and females were decreased as compared with controls due to the lower survival in the dosed groups
結論		
実験動物における発がん性の有無	陰性	negative
注釈		
信頼性	(1) 制限なく信頼性あり	(1) valid without restriction
信頼性の判断根拠	ガイドライン試験	Guideline Study
出典		
引用文献(元文献)	(233) (234)	(233) (234)
備考		

試験物質名	1.1～1.4で規定	as prescribed by 1.1 - 1.4
CAS番号		
純度等	NAPP Chemicals, Incorporated から入手、水に溶解して調製、純度 >99% ロットNo. IN-79-7087	Obtained from NAPP Chemicals, Incorporated. Preparation in water, purity >99% Lot No. IN-79-7087
注釈		
方法		
方法／ガイドライン	その他:NTPボード EPA/FDAガイドライン	other: NTP board EPA/FDA guidelines
試験のタイプ		
GLP適合	はい	yes
試験を行った年	1981	1981
試験系(種／系統)	マウス	mouse
	B6C3F1	B6C3F1
性別(雄:M、雌:F)	雌雄	male/female
投与量	0、112、225 mg/kg 体重	0, 112, 225 mg/kg bw
各用量群(性別)の動物数		
溶媒(担体)		
投与経路	強制経口	gavage
処理頻度	毎日: 5日/週	Daily: 5 days a week
対照群と処理	あり	yes
試験条件	暴露期間 : 104週間 暴露後の期間 : データなし	Exposure period : 104 weeks Post exposure period : no data
試験条件	※英文参照	Groups of 60 mice of each sex were administered 0, 112, or 225 mg/kg resorcinol in deionized water by gavage. Ten mice of each sex per dose group were designated for interim evaluations (organ weights, hematology, clinical chemistry, and histopathology) after 15 months (66 weeks) of chemical administration.

試験条件	※英文参照	Clinical Examinations and Pathology All animals were observed twice daily. Clinical signs of toxicity were recorded every 4 weeks. Individual body weights were obtained weekly for the first 13 weeks and every 4 weeks thereafter until the last 3 months of the studies, when body weights were recorded every 2 weeks. After 15 months on study, 10 male and 10 female mice from each dose group were sacrificed for evaluation of organ weights, hematology, and clinical chemistry. Parameters measured were: Hematolgy: hematocrit, hemoglobin, erythrocytes, mean cell volume, mean cell hemoglobin, mean cell hemoglobin concentration, leukocytes, segmented neutrophils, lymphocytes, monocytes, eosinophils, and nucleated erythrocytes. Clinical chemistry: urea nitrogen, alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, and sorbitol dehydrogenase.
試験条件	※英文参照	A necropsy was performed on all animals. During necropsy, all organs and tissues were examined for grossly visible lesions. Complete histologic examination was conducted all mice from the 15-month studies, and all control and high-dose mice from the 2-year studies. Only tissues containing gross lesions observed at necropsy were examined from the low-dose mouse groups from the 15-month and 2-year studies.. In addition to tissue masses and gross lesions, the following organs and/or tissues were included in complete histopathologic examinations: adrenal glands, aorta, bone (femur including marrow), brain, epididymis, esophagus, eye (if grossly abnormal), gallbladder (mice), heart, kidneys, large intestine (cecum, colon, rectum), liver, lungs, mammary gland, mesenteric lymph node, nasal cavity, ovaries, pancreas, parathyroids, pituitary, prostate, salivary gland, skin, small intestine (duodenum, jejunum, ileum), spleen, stomach, testes, thymus, thyroids, trachea, urinary bladder, and uterus.
試験条件	※英文参照	Pathology evaluations were completed by the study laboratory pathologist and the pathology data were entered into the Toxicology Data Management System (TDMS). The slides, paraffin blocks, and residual wet tissues were sent to the NTP Archives for inventory, slide/block match, and wet tissue audit for accuracy of labeling and animal identification and for thoroughness of tissue trimming. The slides, individual animal data records, and pathology tables were evaluated by an independent quality assessment laboratory. The individual animal records and tables were compared for accuracy, slides and tissue counts were verified, and histotechnique was evaluated. A quality assessment pathologist reviewed selected tissues from the 15-month and 2-year studies for accuracy and consistency of lesion diagnosis. All diagnosed neoplasms in all animals, and forestomachs from all female mice were reviewed. In addition, all tissues were examined from six mice of each sex randomly selected from each control and high-dose group in the 15-month studies, and from five mice of each sex randomly selected from each control and high-dose group in the 2-year studies.
試験条件	※英文参照	The quality assessment report and slides were submitted to a PWG chairperson, who reviewed tissues for which there was a disagreement in diagnosis between the laboratory and quality assessment pathologists. Representative examples of nonneoplastic lesions and neoplasms and examples of disagreements in diagnosis between the laboratory and quality assessment pathologists were reviewed by the PWG. Each PWG included the quality assessment pathologist as well as other pathologists experienced in rodent toxicologic pathology, who examined these tissues without knowledge of dose group or previously rendered diagnoses. When the consensus diagnosis of a PWG differed from that of the laboratory pathologist, the final diagnosis was changed to reflect the opinion of the PWG. Details of these review procedures have been described, in part, by Maronpot and Boorman (1982) and Boorman et aL (1985). For subsequent analysis of pathology data, the diagnosed lesions for each tissue type are evaluated separately or combined according to the guidelines of McConnell et aL (1986).

試験条件	※英文参照	Quality Assurance Methods The 13-week and 2-year studies were conducted in compliance with FDA Good Laboratory Practice Regulations (21 CFR Part 58). In addition, as study records were submitted to the NTP Archives, they were audited retrospectively by an independent quality assurance contractor. Separate audits cover-ing completeness and accuracy of the pathology data, pathology specimens, final pathology tables, and preliminary review draft of this NTP Technical Report were conducted. Audit procedures are presented in the reports, which are on file at the NIEHS. The audit findings were reviewed and assessed by the NTP staff so that all had been resolved or were otherwise addressed during the preparation of this Technical Report.
統計学的処理	※英文参照	Statistical Methods Survival Analyses The probability of survival was estimated by the product-limit procedure of Kaplan and Meier (1958) and is presented in the Results section of this report. Animals were censored from the survival analyses at the time they were found dead from other than natural causes or were found missing; animals dying from natural causes were not censored. Statistical analyses for possible dose-related effects on survival used Cox's (1972) method for testing two groups for equality and Tarone's (1975) life table tests to identify dose-related trends. All reported P values for the survival analysis are two-sided.
統計学的処理	※英文参照	Calculation of Incidence. The incidence of neoplastic or nonneoplastic lesions is given as the ratio of the number of animals bearing such lesions at a specific anatomic site to the number of animals in which that site was examined. In most instances, the denominators include only those animals for which the site was examined histologically. However, when macro-scopic examination was required to detect lesions (e.g., skin or mammary tumors) before tissue sampling for histopathology, or when lesions could have appeared at multiple sites (e.g., mononuclear cell leukemia), the denominators consist of the number of animals on which a necropsy was performed.
統計学的処理	※英文参照	Analysis of Tumor Incidence The majority of tumors in these studies were con-sidered to be incidental to the cause of death or not rapidly lethal. Thus, the primary statistical method used was a logistic regression analysis, which assumed that the diagnosed tumors were discovered as the result of death from an unrelated cause and, thus, did not affect the risk of death. In this approach, tumor prevalence was modeled as a logistic function of chemical exposure and time. Both linear and quadratic terms in time were incorporated initially, and the quadratic term was eliminated if it did not significantly enhance the fit of the model. The dosed and control groups were compared on the basis of the likelihood score test for the regression coefficient of dose. This method of adjusting for intercurrent mortality is the prevalence analysis of Dinse and Lagakos (1983), further described and illustrated by Dinse and Haseman (1986). When tumors are incidental, this comparison of the time-specific tumor prevalences also provides a comparison of the time-specific tumor incidences (McKnight and Crowley, 1984).
統計学的処理	※英文参照	In addition to logistic regression, alternative methods of statistical analysis were used, These include the life table test (Cox, 1972; Tarone, 1975), appropriate for rapidly lethal tumors, and the Fisher exact test and the Cochran-Armitage trend test (Armitage, 1971; Gart et al., 1979), procedures based on the overall proportion of tumor-bearing animals. Tests of significance include pairwise comparisons of each dosed group with controls and a test for an overall dose-response trend. Continuity-corrected tests were used in the analysis of tumor incidence, and reported P values are one-sided. The proce-dures described above also were used to evaluate selected nonneoplastic lesions. For further discussion of these statistical methods, see Haseman, 1984.

統計学的処理	※英文参照	Historical Control Data Although the concurrent control group is always the first and most appropriate control group used for evaluation, historical control data can be helpful in the overall assessment of tumor incidence. Conse-quently, control tumor incidences from the NTP historical control data base (Haseman et al., 1984, 1985) are included in the NTP reports for tumors appearing to show compound-related effects.
統計学的処理	※英文参照	Analysis of Continuous Variables Two approaches were employed to assess the signif-icance of pairwise comparisons between dosed and control groups in the analysis of continuous variables. Organ and body weight data, which have approximately normal distributions, were analyzed using the parametric multiple comparison proce-dures of Williams (1971, 1972) and Dunnett (1955). Clinical chemistry and hematology data, which have typically skewed distributions, were analyzed using the nonparametric multiple comparison methods of Shirley (1977) and Dunn (1964). Jonckheere's test (Jonckheere, 1954) was used to assess the signifi-cance of the dose-response trends and to determine whether a trend-sensitive test (Williams' or Shirley's test) was more appropriate for pairwise comparisons than a test that does not assume a monotonic dose-response trend (Dunnett's or Dunn's test).
結果		
体重、体重増加量		
摂餌量、飲水量		
臨床所見(重篤度、所見の発現時期と持続時間)		
眼科学的所見(発生率、重篤度)		
血液学的所見(発生率、重篤度)		
血液生化学的所見(発生率、重篤度)		
尿検査所見(発生率、重篤度)		
死亡数(率)、死亡時間		
剖検所見(発生率、重篤度)		
臓器重量		
病理組織学的所見(発生率、重篤度)		
実際に摂取された量		
腫瘍発生までの時間		
用量反応性		
統計的結果		
注釈	腫瘍の型及び頻度は対照群のそれらと同様であった。 15ヶ月中間評価 各投与群の雌雄各10匹のマウスを15ヶ月での中間評価用に予め指定した。絶対及び相対臓器重量には有意差はなかった。血液検査又は臨床化学パラメータには投与に関連した差はみられなかった。病理組織学的検査では投与に関連した腫瘍性又は非腫瘍性病変はみられなかった。	Tumor type and incidence were in the same range as those of the control. 15-Month Interim Evaluations Ten mice of each sex in each dose group were predesignated for interim evaluation at 15 months. There were no significant differences in absolute and relative organ weights. No treatment-related changes in hematology or clinical chemistry parameters were seen. No treatment-related neoplasms or nonneoplastic lesions were found during histopathologic examination.
注釈	生存例 レゾルシノールの投与を受けている雌雄の最終生存率は対照群の生存率と同様であった。試験の45週までに対照群及び低用量群の雄マスは1例も死亡しなかったが、高用量の雄マウスは8匹が死亡した。 歩哨動物 マウス肝炎ウイルスに対する陽性の抗体価が6、12、18及び24ヶ月で検査された歩哨動物で検出された。しかし、臨床的にも病理組織学的にも疾患の証拠はみられなかった。	Survival The terminal survival of males and females receiving resorcinol was similar to that of the controls. By week 45 of the study, no male mice in the control and low-dose groups had died, but eight high-dose male mice had died. Sentinel Animals Positive titers for mouse hepatitis virus were found in sentinel animals examined at 6, 12, 18, and 24 months. However, there was no clinical or histopathologic evidence of disease.
注釈	病理検査及び結果の統計解析 雌雄のB6C3F1マウスへの2年間レゾルシノール強制経口投与はいずれの部位でも腫瘍性又は非腫瘍性病変の頻度の統計的又は生物学的に有意な増加を生じなかった。 皮下組織: 雄における皮下の肉腫又は線維腫(組合わせ)の頻度は有意な陰性傾向を示し、頻度は高用量群で有意に低値を示した(8/50, 6/50, 1/50)。	Pathology and Statistical Analysis of Results Administration of resorcinol by gavage to male and female B6C3F, mice for 2 years did not result in any statistically or biologically significant increased incidence in neoplastic or nonneoplastic lesions in any site. Subcutaneous tissue: The incidence of subcutaneous sarcoma or fibroma (combined) in males occurred with a significant negative trend and the incidence was significantly lower in the high-dose group (8/50, 6/50, 1/50).
結論		

実験動物における発がん性の有無	陰性	negative
注釈		
信頼性	(1) 制限なく信頼性あり	(1) valid without restriction
信頼性の判断根拠	ガイドライン試験	Guideline Study
出典		
引用文献(元文献)	(233) (234)	(233) (234)
備考		

5-9 生殖・発生毒性(受胎能と発生毒性を含む)
REPRODUCTIVE TOXICITY(Including Fertility and Development Toxicity)

A. 受胎能
FERTILITY

試験物質名	1.1～1.4で規定	as prescribed by 1.1 - 1.4
CAS番号		
純度等		
注釈		
方法		
方法／ガイドライン	その他: EPA OPPTS 870.3800 及び OECD ガイドライン 416	other: EPA OPPTS 870.3800 and OECD Guideline 416
試験のタイプ	2世代試験	Two generation study
GLP適合	はい	yes
試験を行った年	2005	2005
試験系(種／系統)	ラット	rat
	Crj: CD(SD)	Crj: CD(SD)
性別(雄:M、雌:F)	雌雄	male/female
投与量	0、120、360、1000 及び 3000 mg/l	0, 120, 360, 1000 and 3000 mg/l
各用量群(性別)の動物数		
溶媒(担体)		
投与経路	飲料水	drinking water
試験期間	18ヶ月間	18 months
交配前暴露期間	雄 : F0: 70日間、F1: 離乳時から70日間 雌 : F0: 70日間、F1: 離乳時から70日間	Male : F0: 70 days, F1: 70 days beginning at weaning Female : F0: 70 days, F1: 70 days beginning at weaning
試験条件	暴露期間 : 交配前70日間及び交配、妊娠及び哺育を通して 処置頻度 : 連続 対照群 : あり、無処置対照群	Exposure period : 70 days prior to mating and throughout mating, gestation and lactation Frequency of treatm. : continuous Control group : yes, concurrent no treatment
試験条件	※英文参照	Study was conducted to evaluate the potential adverse effects of resorcinol on the reproductive capabilities, including gonadal function, estrous cyclicity, mating behaviour, conception, gestation, parturition, lactation and weaning of the F0 and F1 generations and F1 and F2 neonatal survival, growth and development. In addition, thyroid hormone analysis was evaluated along with a determination of plasma resorcinol concentations. One litter was produced in each generation. It is also important to note that specific clinical observations were performed to assess the potential for the autonomic and central nervous system function, somatomotor activity and behaviour patterns. These clinical observations were made to pay special attention to the degree of salivation and lacrimation, presence or absence of urination and defecation (including polyuria and diarrhea), pupil size, degree of palpebral closure, presence of convulsions, temors or abnormal movements, presence of posture and gait abnormalities, the presence of any unusual or abnormal behaviours and any repetitive actions (stereotypies).
試験条件	※英文参照	Four groups of male and female Crl:CD SD rats (30/sex/group) were administered resorcinol in drinking water for at least 70 consecutive days prior to mating. Exposure levels were 0, 120, 360, 1000 and 3000 mg/L for the F0 and F1 generations. The concurrent control group (30/sex/group) received reversed osmosis purified municipal water. The test article was administered to the offspring selected to become the F1 parental generation following weaning (post natal day 21). The F0 and F1 males continued to receive the test article throughout the mating and through the day of euthanasia, The F0 and F1 females continued to receive the test article throughout mating, gestation, lactation and through the day of euthanasia.

試験条件	※英文参照	Animals were observed twice daily for appearance and behaviour. Clinical observations, body weights and water and food consumption were recorded at appropriate intervals for males throughout the study and for females prior to mating and during gestation and lactation. Vaginal lavages were performed daily for determination of estrous cycles beginning 21 days prior to pairing. All F0 and F1 females were allowed to deliver and rear their pups until weaning on lactation day 21. For both generations (F1 and F2) eight pups per litter (four per sex when possible) were selected on postnatal day (PND) 4 to reduce the variability among the litters. Offspring (30/sex/group) from the pairing of the F0 animals were selected on PND 21 to constititue the F1 generation. Developmental landmarks were evaluated for the F1 rats (balanopreputial separation and vaginal patency.)
試験条件	※英文参照	Nonselected F1 and all F2 pups were necroposied on their respective PND 21; blood was collected from one pup/sex from 15 randomly selected litters per group for thyroid hormone analysis. Selected organs were weighed from one randomly selected F1 and F2 pup/sex/litter that was necropsied on PND 21. Each surviving F0 and F1 parental animal received a complete detailed gross necropsy following the complete weaning of the F1 and F2 pups, respectively. Selected organs were weighed from all F0 and F1 parental animals and blood was collected from the vena cava of 15 randomly selected parental animals/sex/group for horomone analysis. Spermatogenic endpoints (sperm motility [including progressive motility] , morphology and numbers were recorded for all F0 and F1 males, and ovarioan primoridal follicle counts were recorded for 10 F1 females each in the control and high concentration level groups. Reproductive tissues from all F0 and F1 parental animals and all low and mid concentration level group animals suspected of reduced fertility were examined microscopically. Selected tissues from all F0 and F1 parental animals in the control and high concentration level groups and all animals found dead or euthanized in extremis were examined microscopically, and thyriod glands from 15 randomly selected F0 males and females in the control and 3000 mg/L groups and 15 randomly selected F0 males in the 1000 mg/L group were examined stereologically. A peer review of the microscopic thyroid evaluation was also conducted.
試験条件	※英文参照	In addition, limited bioanalysis was conducted for selected F1 parental animals. Blood samples for determination of plasma resorcinol concentration were collected from 15 randomly selected F1 parental animals/sex/group via the retro-orbital sinus (under isoflurane anesthesia) during the week prior to necropsy.
統計学的処理	※英文参照	Statistical methods used: All statistical tests were performed using appropriate computing devices or programs. Minor study deviations were noted however these deviations did not adversly effect the quality or integrity of the data or the study outcome.
結果		
体重、体重増加量		
摂餌量、飲水量		
臨床所見(重篤度、所見の発現時期と持続時間)		
妊娠率(妊娠個体数/交配数)		
交尾前期間(交配までの日数及び交配までの性周期回数)		
妊娠期間(妊娠0日から起算)		
妊娠指数(生存胎仔数/着床痕数)		
哺乳所見		
性周期変動		
精子所見		
血液学的所見(発生率、重篤度)		
血液生化学的所見(発生率、重篤度)		
尿検査所見(発生率、重篤度)		
死亡数(率)、死亡時間		
剖検所見(発生率、重篤度)		
着床数		
黄体数		
未熟卵胞数		
臓器重量		

病理組織学的所見(発生率、重篤度)		
実際に摂取された量		
用量反応性		
同腹仔数及び体重		
性比		
生存率(生後4日目生存仔数/総分娩仔数)		
離乳までの分娩後生存率		
新生仔所見(肉眼的な異常)		
生後発育及び発育率		
膣開口又は精巣下降(包皮分離)		
生殖器-肛門間距離などその他の観察事項		
臓器重量		
統計的結果		
注釈	体重ベース(平均のF0及びF1動物)で表した場合、飲水中濃度は雄では全世代にわたり、それぞれ約0、11、31、86及び223 mg/kg/日、雌では交配前及び妊娠期間はぞれぞれ約16、48、126及び304 mg/kg/日、哺育期間中の雌に対してはそれぞれ約28、85、225、及び660 mg/kg/日に相当した。児動物(F1世代のみ)では、飲水濃度は雄では約0、11、33、93及び245 mg/kg/日、雌では0、16、41、126及び295 mg/kg/日に相当した。	When expressed on a body weight basis (average F0 and F1 animals), the water concentrations corresponded to: approximately 0, 11, 31, 86 and 223 mg/kg/day for males over the entire generation; 16, 48, 126 and 304 mg/kg/day for females during premating and gestation; and 28, 85, 225, and 660 mg/kg/day for females during lactation, respectively. In offspring (the F1 generation only), the water concentrations corresponded to approximately 0,11,33,93 and 245 mg/kg/day in males while in females 0, 16, 41, 126 and 295 mg/kg/day.
注釈	F0又はF1親動物には試験物質に関連した死亡、あるいは週ごとの詳細身体検査において臨床所見はなかった。F0及びF1動物において、生殖成績(性周期、交配及び受胎指数、交配から交尾までの日数、及び妊娠期間)及び分娩は試験物質による影響を受けなかった。F0及びF1雄の精子形成のエンドポイント(精巣及び精巣上体の平均精子数及び精子産生率、運動能、前進運動性及び形態)は試験物質による影響を受けなかった。F1及びF2児の生存率又は離乳前期間中の児動物の一般状態には試験物質に関連した影響はみられなかった。F0又はF1親動物には試験物質に関連した肉眼所見、臓器重量又は顕微鏡による標的臓器への有害影響はみられなかった。また、試験物質に関連した肉眼所見又は臓器重量への影響はF1又はF2児動物には計画剖検時に認められなかった。死亡発見されたF1又はF2児動物には試験物質に関連した肉眼所見は認められなかった。F1児動物の包皮分離及び膣開口の成立までの平均日数には試験物質の影響はみられなかった。	There were no F0 or F1 parental test article-related deaths or clinical findings during the weekly detailed physical examinations. Reproductive performance (estrous cycles, mating and fertility indices, number of days between pairing and coitus, and gestation length) and parturition in the F0 and F1 animals were unaffected by the test article. Spermatogenic endpoints (mean testicular and epididymal sperm numbers and sperm production rate, motility, progressive motility and morphology) in the F0 and F1 males were unaffected by the test article. No test article-related effects were observed on F1 and F2 pup survival or the general physical condition of the pups during the pre-weaning period. No test article-related macroscopic findings, organ weight or adverse microscopic target-organ effects were observed in the F0 or F1 parental animals. In addition, no test article-related macroscopic findings or effects on organ weights were noted in the F1 or F2 pups at the scheduled necropsies; no test article-related macroscopic findings were noted for found dead F1 or F2 pups. No effects of the test article were observed on the mean days of acquisition of balanopreputial separation and vaginal patency in the F1 pups.
注釈	3000 mg/L群のF0雄では試験第0-70日(交配前期間)及び試験0-126日(世代全体)を通して累積の平均体重増加量に減少(統計的に有意ではない)が認められた。対照群との週ごとの平均体重増加量の差は試験代91-98日の間のみ統計的に有意であったが、3000 mg/L群の雄の累積の平均体重増加量の減少は摂水量の減少に対応し、試験物質に関連した変化と考えられた。3000 mg/L群の雄では平均体重は影響を受けなかった。対照群との差は軽度で統計的に有意ではなかった。	Decreased (not statistically significant) mean cumulative body weight gains were noted in the 3000 mg/L group F0 males during study days 0-70 (pre-mating period) and study days 0-126 (entire generation). While weekly mean body weight gain differences from the control group were only statistically significant during study days 91-98, the reduced mean cumulative body weight gains in the 3000 mg/L group males corresponded to decreased water consumption and were considered test article-related. Mean body weights were unaffected in the 3000 mg/L group males; differences from the control group were slight and not statistically significant.
注釈	3000 mg/L群のF0雌では試験第0-70日(交配前期間)に累積の平均体重増加量に減少(統計的に有意ではない)が認められた。これらの雌では週ごとの平均体重増加量には明らかな傾向がなかった。しかし、平均体重は試験第56-70日(交配前;5.1%-6.3%)、及び哺育終了後の試験第126日(6.3%)にこれらの雌では減少した。試験第126日の減少のみ統計的に有意($p<0.01$)であった。この群における平均体重及び累積体重増加量の減少は摂水量の減少に対応し、試験物質に関連性があると考えられた。120、360及び1000 mg/L群の平均体重又は体重増加量には影響はなかった。対照群との差は軽度で暴露量に関連した様式では生じなかった、及び/又は統計的に有意ではなかった。	A decreased (not statistically significant) mean cumulative body weight gain was noted in the 3000 mg/L group F0 females during study days 0-70 (pre-mating period). There were no clear trends in the weekly mean body weight gains for these females; however, mean body weights were reduced in these females from study days 56 through 70 (prior to mating; 5.1% to 6.3%) and after the end of lactation on study day 126 (6.3%). Only the reduction on study day 126 was statistically significant ($p<0.01$). The decreased mean body weights and cumulative body weight gain in this group corresponded to decreased water consumption and were considered test article-related. There were no effects on mean body weights or body weight gains in the 120, 360 and 1000 mg/L groups. Differences from the control group were slight, did not occur in an exposure-related manner and/or were not statistically significant.

注釈	3000 mg/L群のF0及びF1親動物では交配前の期間（雌）又は全世代（雄）を通して、腹ごとに集団飼育されているF1児動物では生後21-28日に平均摂水量の減少が認められた。摂水量は1000 mg/L群の雌雄でもしばしば減少したが、3000 mg/L群と比べて減少は程度がより軽度で、開始時期も遅かった。1000 mg/L群の平均摂水量の減少は妊娠の最初の週まで継続したが、3000 mg/L群の雌の摂水量の減少は妊娠及び哺育期間を通して継続した。試験物質による摂水量の減少は摂餌量及び摂餌効率への関連影響の欠如のために有害性変化ではないと考えられた。	Decreased mean water consumption was noted for the 3000 mg/L group F0 and F1 parental animals during the pre-mating period (females) or the entire generation (males) and for the F1 pups gang-housed by litter from PND 21-28. Water consumption was also often decreased in the 1000 mg/L group males and females, although the decreases were less severe and the onset was later than in the 3000 mg/L group. Mean water consumption in the 1000 mg/L group was consistently reduced compared to the control group beginning on study days 21-24; however, slight decreases were also noted inconsistently earlier in the pre-mating period. The decreased water consumption in the 1000 mg/L group continued through the first week of gestation while the decreased water consumption in the 3000 mg/L group females continued throughout gestation and lactation. The test article-related decreases in water consumption were not considered an adverse change due to the lack of associated effects on food intake and food utilization.
注釈	ホルモン分析： T3、T4又はTSHの平均濃度における試験物質に関連した変化は、F0又はF1親動物、又は解析用に選択したF1又はF2動物（生後4又は生後21日）では統計的に有意ではなかった。計画剖検時にF0雄で認められたTSH値の高値はT3又はT4、臓器重量又は有害な肉眼又は顕微鏡所見への影響の非存在下で試験物質に関連しないと考えられた。3000 mg/LのF0雄において、甲状腺における試験物質に関連したコロイドの減少は関連した機能性影響がないため、有害影響とは考えられなかった。	Hormone Analysis: No statistically significant test article-related changes in the mean concentrations of T3, T4 or TSH were noted in the F0 or F1 parental animals or in the F1 or F2 pups selected for analysis (PND 4 or PND 21). The higher TSH values noted in the F0 males at the scheduled necropsy were not considered test article-related in the absence of effects on T3 or T4, organ weights or adverse macroscopic or microscopic findings. Test article-related decreased colloid within the thyroid glands of the 3000 mg/L F0 males was not considered adverse due to the lack of associated functional effects.
結論		
Pに対するNOAEL (NOEL)又はLOAEL (LOEL)	NOAEL 親動物 : = 3000 mg/l NOEL 親動物 : = 1000 mg/l	NOAEL parental : = 3000 mg/l NOEL parental : = 1000 mg/l
F1に対するNOAEL (NOEL)又はLOAEL (LOEL)	NOAEL F1 児動物 : = 3000 mg/l	NOAEL F1 offspring : = 3000 mg/l
F2に対するNOAEL (NOEL)又はLOAEL (LOEL)		
注釈	結果：いずれの生殖パラメータについても影響なし	Result : No effects on any of the reproductive parameters
注釈	注釈： 試験の著者には指摘されなかったが、雌雄に対する全体的な全身のNOELは3000 mg/Lでの体重の減少に基づいて1000 mg/Lであると我々は結論した。	Remark : Although not indicated by the study author, we have concluded that the overall systemic NOEL for males and females is 1000 mg/L based on reduced body weight at 3000 mg/L.
注釈	結論： 1000 mg/L (F0世代のみ)及び3000 mg/L群のF0及びF1親動物ではレゾルシノールの最高2濃度を含む水の嗜好性が悪かったために、平均摂水量の減少が認められた。摂水量の試験物質に関連した減少は、3000 mg/L群でさえも恒常性が破綻したことを示す摂餌量及び摂餌効率への関連影響がなかったので、有害影響とは考えられなかった。	Conclusion : Decreased mean water consumption was noted for the 1000 mg/L (F0 generation only) and 3000 mg/L group F0 and F1 parental animals due to the poor palatability of water containing the two highest concentrations of Resorcinol. The test article-related decreases in water consumption were not considered adverse even in the 3000 mg/L group because of the lack of associated effects on food intake and food utilization, which indicated that homeostasis was uncompromised.
注釈	平均体重及び体重増加量における試験物質に関連した減少が3000 mg/L群の両親世代でみられた。2世代にわたり評価した際、平均体重又は体重増加量への累積影響の証拠はみられず、性に関連した影響の証拠、あるいは妊娠及び哺育期間中に試験物質の雌への感受性が亢進するという証拠もなかった。	Test article-related reductions in mean body weights and/or body weight gains were observed in both parental generations in the 3000 mg/L group. However, there was no evidence of cumulative effects on mean body weights or body weight gains when evaluated across two generations, nor was there evidence of gender-related effects or of enhanced sensitivity of females to the test article during gestation and lactation.
注釈	3000 mg/LのF0群では平均の累積体重増加量の減少が交配前期間（雌）及び全世代（雄）の間に認められた。これらの動物に対する週ごとの平均体重増加量には明らかな傾向はみられなかったが、平均体重はF0雌では交配前（最大6.3%）、妊娠期間中（最大5.5%）、及び哺育期間を通して（最大8.4%）減少した。3000 mg/L群のF0雄では平均体重は影響を受けなかった。3000 mg/L群のF1雄では世代全体の平均累積体重増加量の減少が認められ、世代を通した平均体重の減少（最大7.1%）と対応した。	Decreased mean cumulative body weight gains were noted in the 3000 mg/L F0 group during the premating period (females) and the entire generation (males). While no definite trends were apparent in weekly mean body weight gains for these animals, mean body weights were reduced in the F0 females prior to mating (up to 6.3%), during gestation (up to 5.5%) and throughout lactation (up to 8.4%). Mean body weights were unaffected in the 3000 mg/L group F0 males. A decreased mean cumulative body weight gain was also noted for the 3000 mg/L group F1 males for the entire generation, corresponding to decreased (up to 7.1%) mean body weights throughout the generation.

注釈	3000 mg/L群のF1雌では平均体重増加量への明らかな影響はみられなかった。しかし、これらの雌では哺育期間中（最大6.1%）、及び哺育器官終了後（最大7.0%)に平均体重は減少した。これらの減少はこれらの動物で記録した摂水量が相応して減少したことにより証拠づけられたように、3000 mgレゾルシノール/Lを含む飲料水の嗜好性が良くないためによるものと思われた。F0及びF1の雌雄では3000 mg/Lで、F0雄では1000 mg/Lのレベルで交配前期間により軽度に摂水量の減少が認められた。しかしながら、120、360、及び1000 mg/L群のF0及びF1の雌雄では平均体重又は体重増加量への影響はみられなかった。妊娠及び哺育期間中、摂水量は3000 mg/L群のF0及びF1雌ともに減少した。摂水量は哺育期間の終了後もこれらの雌では継続して減少した。また、摂水量はF1世代では3000 mg/Lの暴露レベルで動物を腹ごとで飼育した離乳後の週（生後21-28日)に減少した。摂水量における試験物質関連性の減少は恒常性が破綻したことを示す摂餌量及び摂餌効率に関連した影響がなかったことから有害影響ではないと考えられた。	There were no clear effects on mean body weight gains in the 3000 mg/L group F1 females; however, mean body weights were decreased in these females during lactation (up to 6.1%) and after the lactation period ended (up to 7.0%). These reductions were most likely due to poor palatability of the drinking water containing 3000 mg Resorcinol/L as evidenced by the correspondingly reduced water consumption recorded for these animals. Decreased water consumption was noted in F0 and F1 males and females at 3000 mg/L and, to a lesser extent, in F0 males and females at an exposure level of 1000 mg/L during the pre-mating period. However, there were no effects on mean body weights or body weight gains in the 120, 360 and 1000 mg/L group F0 and F1 males and females. During gestation and lactation, water consumption was decreased in both the F0 and F1 females in the 3000 mg/L group. Water consumption remained decreased for these females after the end of the lactation period. In addition, water consumption was reduced at an exposure level of 3000 mg/L in the F1 generation during the week following weaning (PND 21-28) when the animals were housed by litter. The test article-related decreases in water consumption were not considered adverse due to the lack of associated effects on food intake and food utilization, which indicated that homeostasis was uncompromised.
注釈	親の全身毒性及び児動物の毒性に対するNOAELは3000 mgレゾルシノール/L（F0及びF1世代で平均およそ223 mg/kg/日(雄)、304 mg/lg/日(雌(交配前及び妊娠期)、660 mg/kg/日(雌(哺育期))、(F1世代(雄)245 mg/kg/日及び(雌)295 mg/kg/日)、一方、NOELは1000 mgレゾルシノール/L（約 86 mg/kg/日(雄)、126 mg/kg/日(雌(交配前及び妊娠期))、及び225 mg/kg/日（雌(哺育期))、(F1世代(雄) 93 mg/kg/日及び（雌)126 mg/kg/日。	The NOAEL is considered to be 3000 mg Resorcinol/L for parental systemic and offspring toxicity (ca. Average F0 and F1 generation 223 mg/kg/day (males), 304 mg/kg/day (females(premating and gestation)), 660 mg/kg/day (females(lactation)) (F1 generation (males) 245 mg/kg/day and (females) 295 mg/kg/day, while the NOEL is 1000 mg Resorcinol/L (ca. 86 mg/kg/day (males), 126 mg/kg/day (females(premating and gestation), and 225 mg/kg/day (females(lactation)) (F1 generation (males) 93 mg/kg/day and (females) 126 mg/kg/day.
注釈	レゾルシノールは容易に吸収され、排泄されることが知られていたが、3000 mg/L群の一部の動物では血中レゾルシノールレベルが検出された。甲状腺の病理組織所見におけるコロイドの減少が、本試験では有害影響とはみなされなかったものの、3000 mg/L群のF0雄でのみ観察された。従って、本試験ではレゾルシノールの影響は適切に評価された。	Although Resorcinol was known to be readily absorbed and eliminated, blood Resorcinol levels could be detected in some animals in the 3000 mg/L group. Decreased colloid in the thyroid histopathology, although a non-adverse effect in this study, was observed only in the 3000 mg/L group F0 males. Therefore, the effects of Resorcinol have been appropriately evaluated in this study
信頼性	(1) 制限なく信頼性あり	(1) valid without restriction
信頼性の判断根拠	ガイドライン試験	Guideline and GLP study
出典		
引用文献(元文献)	(339)	(339)
備考	フラグ : SIDSエンドポイントにとって重要な試験	Flag : Critical study for SIDS endpoint

B. 発生毒性
DEVELOPMENTAL TOXICITY

試験物質名	1.1～1.4で規定	as prescribed by 1.1 - 1.4
CAS番号		
純度等	レゾルシノール (AO11) 純度 >95%	Resorcinol (AO11) >95% purity.
注釈		
方法		
方法／ガイドライン	OECDガイドライン414 "催奇形性"	OECD Guide-line 414 "Teratogenicity"
GLP適合	はい	yes
試験を行った年	2004	2004
試験系(種／系統)	ラット	rat
	Sprague-Dawley	Sprague-Dawley
性別(雄:M、雌:F)	雌	female
投与量	0、40、80 及び 250 mg/kg/日	0, 40, 80 and 250 mg/kg/day
各用量群(性別)の動物数		
投与経路	強制経口	gavage
試験期間		
交配前暴露期間		
試験条件	暴露期間 : 妊娠6-19日 処置頻度 : 毎日 対照群 : あり、媒体対照	Exposure period : 6-19 days of gestation Frequency of treatm. : daily Control group : yes, concurrent vehicle
試験条件	試験は2001年1月22日付けOECD414に準拠するように計画された。	Study was designed to comply with OECD 414 dated Jan. 22, 2001.

試験条件	※英文参照	A total of 96 pregnant Sprague-Dawley female rats were allocated to four groups (24 per group). Three groups were administered with the test item, Resorcinol (A011), by gavage once daily from day 6 to day 19 of gestation, inclusive, at the dose-level of 40, 80 or 250 mg/kg/day. One group of females was only administered with the vehicle, purified water, at the same constant dose volume of 5 mL/kg; individual volumes were adjusted according to the most recently recorded body weight.
試験条件	※英文参照	The females were sacrificed on day 20 of gestation and subjected to a macroscopic examination. The numbers of corpora lutea, implantations and live fetuses were recorded. The fetuses were removed from the uterus, weighed, sexed and externally examined. Half of the fetuses underwent soft tissue examination while the remaining fetuses received a skeletal examination.
統計学的処理	※英文参照	Statistical analysis: Mean values were compared by one-way analysis of variance and the Dunnett test (mean values being considered as normally distributed and variances being considered as homogeneous). Percentage values were compared by the Fisher exact probability test.
結果		
死亡数(率)、死亡時間		
用量あたり妊娠数		
流産数		
早期/後期吸収数		
着床数		
黄体数		
妊娠期間(妊娠0日から起算)		
体重、体重増加量		
摂餌量、飲水量		
臨床所見(重篤度、所見の発現時期と持続時間)		
血液学的所見(発生率、重篤度)		
血液生化学的所見(発生率、重篤度)		
剖検所見(発生率、重篤度)		
臓器重量(総子宮量への影響)		
病理組織学的所見(発生率、重篤度)		
同腹仔数及び体重		
生存数(生存胎仔数及び胎仔数)		
性比		
生存率(生後4日目生存仔数/総分娩仔数)		
生後発育		
分娩後生存率		
肉眼的異常(外表観察、内臓標本、骨格標本)		
実際に投与された量		
用量反応性		
統計的結果		
注釈	結果 : 胚毒性、胎児毒性又は催奇形影響なし	Result : No embryotoxic, fetotoxic or teratogenic effects
注釈	結果 : 死亡率及び臨床所見: 試験中には早期の死亡例はなく、試験物質に関連すると考えられる臨床症状はなかった。	Result : Mortalities and clinical observations: No premature deaths occurred during the study and no clinical observations were considered to be treatment-related.
注釈	母動物: 母動物の体重及び摂餌量: 250 mg/kg/日で正味の体重変化量は対照群の値と比べて有意に低値 (p>0.05, -19%)であった。この他には母動物の体重、体重増加量又は摂餌量に投与による影響はなかった。 肉眼的な剖検所見: 母動物の剖検時に投与に関連すると考えられる所見は記録されなかった。 妊娠のデータ: 各群の着床数及び生存胎児数の平均値、並びに着床前及び着床後の胚損失の程度は対照群と同程度であった。	Maternal: Maternal body weight and food consumption: At 250 mg/kg/day, the net body weight change was significantly lower (p>0.05%, -19%) than the control group value. There were no other treatment effects on maternal body weight, body weight gain or food consumption. Macroscopic post-mortem examination: No findings recorded at maternal necropsy were considered to be treatment-related. Pregnancy data: All the group mean numbers of implantations and live fetuses and the extent of pre- and post-implantation losses were comparable with the controls.

注釈	胎児のデータ: 投与群では平均の黄体数、着床部位数、生存胎児数、吸収胚数(早期及び後期)は対照群の値と同様であった。 雌雄の平均胎児重量は対照群と比べて250 mg/kg/日では有意に増加した。この所見は投与による影響というよりはむしろ対照群の値（歴史的対照データの最終版の範囲 3.8g-4.5gの外で、本試験が行われた期間内の対照群の値の範囲内: 3.6g-3.9g)が低値であった結果と考えられた。対照群の低値により生じる胎児体重における影響を覆い隠す可能性が評価されたが、個別の胎児体重が均一であり、胎児体重、に用量相関性傾向がない、あるいは骨格の骨化が全般に良好であることにより、可能性は極めて低いと考えられた。雄の胎児の比率は全群で対照群と同様であった。結果として、胎児体重への投与による影響はないと結論された。	Fetal data: In the treated groups, the mean numbers of corpora lutea, implantation sites, live fetuses, resorptions (early and late) were similar to the control group values. The mean male and female fetus weights were significantly greater at 250 mg/kg/day, when compared to the controls. This observation was considered to be the consequence of the low control group values (outside the range of the last version of Historical Control Data 3.8 g - 4.5 g, and within the range of the control group values during the period where this study was conducted: 3.6 g - 3.9 g), rather than, an effect of the treatment. The probability to mask an effect in fetal body weights resulting from the low control group value was evaluated but was considered to be with a very low probability according to the homogeneity of individual fetal body weights, the absence of a dose-related trend in fetal body weights or the good general ossification of the skeletons. The percentage of male fetuses was similar to controls for all groups. As a result, it was concluded that there were no effects of treatment on fetal body weight.
注釈	胎児の異常: 投与に関連していると考えられる外表、軟組織又は骨格の奇形又は変異はなかった。 40及び80 mg/kg/日では頭頂間骨の骨化不全を示す胎児の頻度が対照群と比べて有意に増加（それぞれp<0.05及びp<0.01）した。80 mg/kg/日では頭頂骨の骨化不全の頻度も対照群と比べて有意に大きかった（p<0.05)。250 mg/kg/日では何ら影響がみられなかったので、これらの所見は投与に関連したものではないと考えられた。 250 mg/kg/日では対照群と比べて第5胸骨の骨化不全の頻度が有意に大きかった（p<0.01)。胸部から腰部はラットでは特に変化しやすいことが知られており、他の変異や奇形がないことから、この所見は投与に関連したものではないと考えられた。 投与に関連したと考えられる胎児の奇形又は変異はなかった。	Fetal abnormalities: No external, soft tissue or skeletal malformations or variations were considered to be treatment-related. There was a significantly increase in the incidence of fetuses with an incompletely ossified interparietal at 40 and 80 mg/kg/day, when compared to controls (p<0.05 and p<0.01, respectively). The incidence of incompletely ossified parietals was also significantly greater at 80 mg/kg/day, when compared to controls (p<0.05). In the absence of any effects at 250 mg/kg/day these observations were not considered to be treatment-related. There was a significantly greater incidence of incompletely ossified 5th sternebra at 250 mg/kg/day, when compared to controls (p<0.01). The thoraco-lumbar region is known to be particularly labile in the rat and, in the absence of other variations or malformations, this observation was not considered to be treatment-related. No fetal malformations or variants were considered to be related to treatment.
結論		
PIに対するNOAEL (NOEL)又はLOAEL (LOEL)	NOAEL 母動物毒性. : = 80　mg/kg 体重	NOAEL maternal tox. : = 80　mg/kg bw
F1に対するNOAEL (NOEL)又はLOAEL (LOEL)	NOAEL 催奇形性 : = 250　mg/kg 体重	NOAEL teratogen. : = 250　mg/kg bw
F2に対するNOAEL (NOEL)又はLOAEL (LOEL)		
注釈	注釈 : 本試験の用量レベル（40、80及び250 mg/kg/日)は40、80及び250 mg/kg/日でラットで行われた胚-胎児発生試験(Hazleton, 64-213/5, 1982)の結果に基づき、委託者と合意して選択されたが、その試験では高用量レベルは胚-胎児発生には影響はなく、体重増加量のごく軽度の減少（-9%)からなる母動物毒性がみられた。	Remark : The dose-levels (40, 80 and 250 mg/kg/day) of the present study were selected in agreement with the Sponsor based on the results of an embryo-fetal development study performed in rats at 40, 80 and 250 mg/kg/day (Hazleton, 64-213/5, 1982) in which the high dose-level was associated with maternal toxicity consisting in minimal decrease in body weight gain (-9%), without any effect on embryo-fetal development.
注釈	結論 : 妊娠雌ラットに経口経路（強制経口)で投与したレゾルシノール(A011)の母動物の無毒性量（NOAEL)は統計的に有意な体重変化に基づき80 mg/kg/日、発生毒性のNOAELは250 mg/kg/日（試験した最高用量)であると考えられらた。	Conclusion : The maternal No Observed Adverse Effect Level (NOAEL) of Resorcinol (A011) administered by oral route (gavage) to pregnant female rats was considered to be 80 mg/kg/day based on statistically significant body weight changes and the developmental NOAEL was considered to be 250 mg/kg/day (highest dose tested).
信頼性	(1) 制限なく信頼性あり	(1) valid without restriction
信頼性の判断根拠		
出典		
引用文献(元文献)	(54)	(54)
備考	フラグ : SIDSエンドポイントにとって重要な試験	Flag : Critical study for SIDS endpoint

試験物質名	1.1～1.4で規定	as prescribed by 1.1 - 1.4
CAS番号		
純度等		

注釈	レゾルシノール（ロット番号　21005013)はLowenstein Dyes, Cosmetics, Inc., Brooklyn, New York. から入手した。	Resorcinal (Lot No. 21005013) was obtained from Lowenstein Dyes, Cosmetics, Inc., Brooklyn, New York.
方法		
方法／ガイドライン	その他	other
GLP適合	データなし	no data
試験を行った年	1985	1985
試験系（種／系統）	ラット	rat
	Sprague-Dawley	Sprague-Dawley
性別（雄：M、雌：F）	雌	female
投与量	125、250、500 mg/kg 体重	125, 250, 500 mg/kg bw
各用量群（性別）の動物数		
投与経路	経口、明記なし	oral unspecified
試験期間		
交配前暴露期間		
試験条件	暴露期間：　妊娠6-15日 処置頻度：　毎日 対照群：　あり	Exposure period : 6-15 days of gestation Frequency of treatm. : daily Control group : yes
試験条件	※英文参照	Following acclimation, each male was caged with two females. Day 0 of gestation was defined as the day on which a copulatory plug or the presence of sperm in a vaginal smear was detected. Following mating, each female was separately housed. Ten to thirteen pregnant females were assigned on a random basis to resorcinol. The doses were 125, 250, and 500 mg/kg for resorcinol. The dyes were dissolved in propylene glycol and administered by gavage to the dams on Days 6 to 15 of gestation. Doses were determined from previous maximum tolerated dosage (MTD) studies performed on five non-pregnant female Sprague-Dawley rats per dose, weighing between 200 and 225 g for each compound. The dose which produced no more than a 10% reduction in body weight after 10 consecutive administrations at 10 ml/kg, or the highest concentration which did not produce mortality if a weight reduction could not be obtained was deemed the MTD and selected as the high-dosage group for the study. Intermediate- and low-dosage groups were obtained by dividing the MTD by a factor of approximately 2 and 4, respectively.
試験条件	※英文参照	Solutions were prepared fresh daily and administered at 10 ml/kg. Each of the dyes was evaluated individually with each study containing a concurrent vehicle control, propylene glycol, which was administered at 10 mg/kg in the same manner as described above. Dams were observed daily throughout gestation for general health and condition and were weighed to the nearest gram on Days 0, 6, 16, and 20 of gestation. A positive control, vitamin A (Aquasol A Drops, USV Laboratories, N.Y.) was included. Vitamin A was administered in a single po dose (100,000 IU/rat) on Day 9 of gestation. On Day 20 of gestation, estimated as 24 hr before parturition, dams were killed by carbon dioxide inhalation. The abdominal wall was incised longitudinally and both uterine horns were exposed. The viability of each fetus was determined. The metrial glands were counted, identifying original implantation sites. An implantation site not occupied by a fetus was designated a resorption site. Each fetus was sexed and weighed to the nearest 0.1 g. Any external fetal malformations were recorded. One-half of the fetuses were randomly selected from each litter and placed in Bouin's fixative for subsequent visceral examination according to Wilson's procedure (1965). The remaining half of the fetuses were eviscerated, fixed in 95% isopropyl alcohol, macerated in 2% potassium hydroxide, and stained with 0.5% potassium hydroxide and alizarin red S (Dawson, 1926) for skeletal evaluation.
試験条件	※英文参照	Male and female Sprague-Dawley rats (Charles River, Wilmington, Mass.) weighing 225 to 250 g were acclimated for 2 weeks under standard laboratory conditions (50 ± 10% relative humidity, 21 ± 2° C, and 12-hr light cycle). Rodent feed (Purina Laboratory Rodent Chow, Ralston Purina Co., Inc., St. Louis, Mo.) and water were available ad libitum.

統計学的処理	※英文参照	Statistical Methods: Mean number of corpora lutea, total implantations, viable fetuses, mean fetal body weight, and mean maternal body weight gain were analyzed by Student's t test (Hoover, 1970). The number of abnormal fetuses were compared by chi-square analysis (Wart and Neidt, 1954) and resorption were standardized to litter by Wilcoxon-Mann-Whitney u test (Siegel, 1956). Probability for all statistical analyses was at the 0.05 level.
結果		
死亡数(率)、死亡時間		
用量あたり妊娠数		
流産数		
早期/後期吸収数		
着床数		
黄体数		
妊娠期間(妊娠0日から起算)		
体重、体重増加量		
摂餌量、飲水量		
臨床所見(重篤度、所見の発現時期と持続時間)		
血液学的所見(発生率、重篤度)		
血液生化学的所見(発生率、重篤度)		
剖検所見(発生率、重篤度)		
臓器重量(総子宮量への影響)		
病理組織学的所見(発生率、重篤度)		
同腹仔数及び体重		
生存数(生存胎仔数及び胎仔数)		
性比		
生存率(生後4日目生存仔数/総分娩仔数)		
生後発育		
分娩後生存率		
肉眼的異常(外表観察、内臓標本、骨格標本)		
実際に投与された量		
用量反応性		
統計的結果		
注釈	結果 : 胚毒性、胎児毒性又は催奇形影響なし	Result : No embryotoxic, fetotoxic or teratogenic effects
注釈	レゾルシノールは用いた高用量では母動物で体重低下を示したが、平均体重増加量には有意な減少を生じなかった。また、外観、内臓又は骨格に異常を持つ胎児の頻度に有意差はみられず、胎児体重、胚吸収率又は検討した他のいずれのパラメータも変化しなかった。陽性対照のビタミンAは催奇形性を示し、異常な胎児の数の有意な増加を生じた。異常の頻度は28-95%の範囲で、主な異常には脳水腫、外脳症、上顎前突、巨舌症、開眼、小眼症、口蓋裂、水腎症、及び頭蓋骨無形成が含まれた。	Resorcinol did not produce a significant decrease in mean maternal weight gain at the high doses utilized, although a reduction was observed. No additional significant differences were observed in the incidence of fetuses with gross, visceral, or skeletal anomalies or the foetal weights and resorptions rates are not modified or any of the other parameters investigated. Vitamin A, the positive control, was teratogenic, producing a significant increase in the number of abnormal fetuses. Frequency of anomalies ranged from 28 to 95% with major anomalies including hydrocephaly, exencephaly, prognathia, macroglossia, open eye, microphthalmia, cleft palate, hydronephrosis, and agenesis of skull bones.
結論		
PIに対するNOAEL (NOEL)又はLOAEL (LOEL)		
F1に対するNOAEL (NOEL)又はLOAEL (LOEL)	NOAEL 催奇形性 : > 500 mg/kg 体重	NOAEL teratogen. : > 500 mg/kg bw
F2に対するNOAEL (NOEL)又はLOAEL (LOEL)		
注釈	注釈 : 高用量は最大耐用量の範囲内。	Remark : high dose lay in the maximum tolerable range.
注釈	結論 : レゾルシノールは催奇形影響を生じなかった。	Conclusion : Resorcinol did not produce teratogenic effects.
信頼性	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	ガイドライン試験と同様、GLPに関してデータなし	Similar to a guideline study, no data regarding GLP
出典		
引用文献(元文献)	(83)	(83)
備考		

5-10その他関連情報
OTHER RELEVANT INFOMATION

試験物質名		
CAS番号		
純度等		
注釈		
方法		

方法／ガイドライン	タイプ：その他：ホルモン分析（甲状腺） 方法： その他：OECD TG 416に適合した2世代生殖毒性試験変法の一部として	Type : other: Hormone Analysis (thyroid) Method : Other: as part of a modified 2 generation reproductive toxicity study in accordance OECD TG 416.
GLP適合		
試験を行った年		
試験条件	※英文参照	Remark : 15 randomly selected F1 and F2 litters per exposure group. The pooled blood samples derived from the culled offspring on PND 4, without consideration of sex. Nonselected F1 and all F2 pups were necroposied on their respective PND 21; blood was collected from one pup/sex from 15 randomly selected litters per group for thyroid hormone analysis. Selected organs were weighed from one randomly F1 and F2 pup/sex/litter that was necropsied on PND 21. Each surviving F0 and F1 parental animal received a complete detailed gross necropsy following the complete weaning of the F1 and F2 pups, respectively. Selected organs were weighed from all F0 and F1 parental animals and blood was collected from the vena cava of 15 randomly selected parental animals/sex/group for horomone analysis. Spermatogenic endpoints (sperm motility [including progressive motility] , morphology and numbers were recorded for all F0 and F1 males, and ovarioan primoridal follicle counts were recorded for 10 F1 females each in the control and high concentration level groups. Reproductive tissues from all F0 and F1 parental animals and all low and mid concentration level group animals suspected of reduced fertility were examined microscopically. Selected tissues from all F0 and F1 parental animals in the control and high concentration level groups and all animals found dead or euthanized in extremis were examined microscopically, and thyriod glands from 15 randomly selected F0 males and females in the control and 3000 mg/L groups and 15 randomly selected F0 males in the 1000 mg/L group were examined stereologically. A peer review of the microscopic thyroid evaluation was also conducted. In addition, limited bioanalysis was conducted for selected F1 parental animals. Blood samples for determination of plasma resorcinol concentration were collected from 15 randomly selected F1 parental animals/sex/group via the retro-orbital sinus (under isoflurane anesthesia) during the week prior to necropsy.
結果		
結果	ホルモン分析： 分析用に選択したF0又はF1親動物、あるいはF1又はF2児動物（生後4日又は21日)には、T3、T4又はTSHの平均濃度に試験物質に関連した統計的に有意な変化は認められなかった。計画剖検時にF0雄で認められたTSHの高値はT3又はT4、臓器重量への影響あるいは有害な肉眼ないし顕微鏡変化がないことから試験物質に関連したものではないと考えられた。3000 mg/LのF0雄の甲状腺内における試験物質関連性のコロイド減少は機能的な関連性の影響を欠いていることから有害影響とは考えられなかった。	Hormone Analysis: No statistically significant test article-related changes in the mean concentrations of T3, T4 or TSH were noted in the F0 or F1 parental animals or in the F1 or F2 pups selected for analysis (PND 4 or PND 21). The higher TSH values noted in the F0 males at the scheduled necropsy were not considered test article-related in the absence of effects on T3 or T4, organ weights or adverse macroscopic or microscopic findings. Test article-related decreased colloid within the thyroid glands of the 3000 mg/L F0 males was not considered adverse due to the lack of associated functional effects
結論		
結論		
注釈		
信頼性	(1) 制限なく信頼性あり	(1) valid without restriction
信頼性の判断根拠		
出典		
引用文献（元文献）	(339)	(339)
備考		

試験物質名		
CAS番号		
純度等		
注釈		
方法		
方法／ガイドライン	タイプ：その他：in vitro透過試験	Type : other: in vitro permeability studies
GLP適合		
試験を行った年		
試験条件		
結果		
結果	10% w/v レゾルシノールを試験するヒトの皮膚を用いたin vitro透過試験において、レゾルシノールは長い遅延時間（80分)を示した。定常状態での透過係数（Kp）は0.00024 cm/時と算出された。	Remark : In in vitro permeability studies using human skin testing 10% w/v resorcinol, resorcinol showed a long lag time (80 min). A steady state permeability coefficient (Kp) of 0.00024 cm/h was calculated.
結論		
結論		

注釈		
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典		
引用文献(元文献)	(260)	(260)
備考		

5-11 ヒト暴露の経験
EXPEIENCE WITH HUMAN EXPOSURE

試験物質名		
CAS番号		
純度等		
注釈		
製造／加工／使用情報		
研究デザイン	経験のタイプ : その他: ヒト/経皮適用	Type of experience : other: human/dermal application
仮説検証		
データ収集方法		
被験者の説明		
暴露期間		
測定又は評価曝露データ		
結果		
統計的結果		
発病頻度		
相関		
分布		
研究提供者等		
注釈	注釈 : ヒトでは経皮適用後に以下の全身中毒症状が文献に記載されている。呼吸困難、頻脈、胃痙攣、肝臓及び腎臓傷害、メトヘモグロビン形成、溶血、チアノーゼ、溶血性貧血、ヘモグロビン尿、甲状腺機能低下、局所の組織褐変症及び粘液浮腫。乳児及び幼児ではレゾルシノールの経皮適用は致死性である。	Remark : For humans, the following symptoms of systemic intoxication after dermal application are found in literature: dyspnoea, tachycardia, cramps, liver and kidney damage, methaemoglobin formation, haemolysis, cyanosis, haemolytic anemia, haemoglobinuria, hypothyroidism and localochronosis and myxoedema. For babies and infants, dermal application of resorcinol can prove lethal.
結論		
結論		
注釈		
信頼性	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典		
引用文献(元文献)	(16) (21) (38) (73) (108) (117) (118) (171) (176) (207) (229) (237) (314) (342)	(16) (21) (38) (73) (108) (117) (118) (171) (176) (207) (229) (237) (314) (342)
備考		

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