

[Form 4] Report on the Results of the 28-day Repeated Dose Toxicity Test Using Mammals

1. General information

Name of new chemical substance (based on the IUPAC nomenclature system)			
Other name			
CAS no.			
Structural or rational formula (if neither is available, summarize its formulation method)			
Molecular weight			
Purity of the novel chemical substance used for the test (%)			
Lot number of the new chemical substance used for the test			
Names and contents of impurities			
Vapor pressure			
Solubility in water			
1-Octanol/water partition coefficient			
Melting point			
Boiling point			
Properties at room temperature			
Stability			
Solubility in solvents, etc.	Solvent	Solubility	Safety in solvent

[Notes] Provide the physicochemical properties wherever possible.

1. Fill in the “Vapor pressure” column with the vapor pressure of the test substance.
2. Fill in the “Stability” column with the stability of the test substance against temperature, light, etc.
3. Fill in the “Solubility in solvents, etc.” column with the solubility and stability of the test substance in a solvent.

2. Acute Toxicity Test, Repeated Dose Preliminary Test, etc.

Test No.	Type and period of test	Animal type	Number of animals per group	Route of administration	Dosage (mg/kg)	Approximate lethal dose and NOEL (mg/kg)	Test site
1							
2							
3							

* NOEL: no observed effect level

3. 28-day Repeated Dose Toxicity Test

Test substance administration period		From (day) (month) (year) to (day) (month) (year)					
Type and species of animal used		Number of animals per group					
Route of administration		Male:			Female:		
Purity of the chemical substance (%)	Dosage	ppm mg/kg	Control group	Low dosage group	Medium dosage group	High dosage group	Satellite group
Body weight change							
Food intake							
General condition							
Function observation findings							
Urinary findings							
Hematologic findings							
Blood biochemistry findings							
Findings with the naked eye							
Internal organ weight changes							
Histopathological findings							
Others							
NOEL (mg/kg)							
Changes used as the estimated basis of NOEL							

[Note] Establish three or more dosage group stages (low dosage group, medium dosage group, high dosage group)

5. Others

Testing agency	Name	
	Address	Tel: Fax:
Test director	Name and status	
	Years of experience	
Test number		
Test period	From (month) (day) (year) to (month) (day) (year)	

[Notes]

1. Fill in the present form by transcribing from the final report.
2. Fill in the test number reported in the final report.
3. In the margin of this form, provide the name and affiliation of the person in charge of filling in this form.