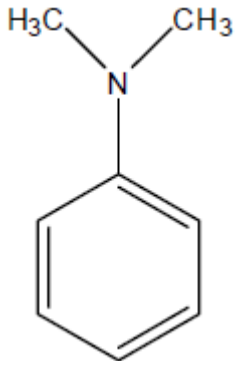
Combined Repeated Dose Toxicity Study with the Reproduction/ Developmental Toxicity Screening Test(OECD TG422) -Data Sheet-

MITI No.	3-114 3-129		CAS No.	121-69-7
Test substance	Chemical name Synonym Molecular weight Molecular formula Structural formula	: N,N-dimethylaniline : (Dimethylamino)benzene N,N-Dimethylbenzenamine N,N-Dimethylphenylamine : 121.18 : $C_8H_{11}N$: 		
Appearance	Oily liquid			
Solubility	1,450 mg/L (in water, 25 degC)			
Biodegradation	Non-biodegradable (Official Bulletin of the Ministry of International Trade and Industry dated May 28, 1976)			
Bioconcentration	Low bioconcentration (Official Bulletin of the Ministry of International Trade and Industry dated May 28, 1976)			
Purity	>=99%			
Range finding study	Dose level	0, 30, 100, 300, 1,000 mg/kg/day		
	Dosing period	14 days		
	Results	1,000: All animals dead 30, 100, 300: Enlargement of the spleen, Cyanosis		
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Experimental Method	Test animals	Crl:CD (SD) male and female rats, 9 weeks old (initiation of dosing)		
	Administration	Oral gavage Vehicle: Olive oil		
	Dose level	0, 1, 10, 100 mg/kg/day, Recovery 0, 100 mg/kg/day (R100)		
	Dosing period	M: 42days F: 42 - 46 days (from 14 days before mating to day 4 of lactation)		
Results of Repeated dose toxicity	Clinical signs	M, F: Dark red discoloration of the skin (all animals) (100, R100)		
	FOB	M, F: Dark red discoloration of the skin (all animals) (100)		
	Body weight	F: Body weight ↓ (100, R100)		

	Food consumption	NE
	Urinalysis	NE
	Hematology	M: RBC ↓ (100), Hgb ↓ (100), Hct ↓ (100), MCHC ↓ (100, R100), MCV ↑ (100, R100), MCH ↑ (100, R100), WBC ↑ (100) F: RBC ↓ (100, R100), Hgb ↓ (100), Hgb ↑ (R100), Hct ↓ (100), Hct ↑ (R100), MCV ↑ (100, R100), MCH ↑ (100, R100)
	Blood chemistry	M: TP ↓ (100), alfa 1-glb ↓ (100), T-Bil ↑ (100) F: alfa 1-glb ↓ (10, 100), T-Bil ↑ (100), T-Bil ↓ (R100), BUN ↑ (100), Cr ↓ (R100)
	Organ weight	M: Liver R ↑ (10, 100), Spleen A,R ↑ (100), Kidney R ↑ (100), Testes R ↑ (R100) F: Kidney R ↑ (10), Heart R ↑ (100), Spleen A,R ↑ (100, R100)
	Necropsy	M: Dark red discoloration of the spleen (100), Swelling of the spleen (100, R100) F: Dark red discoloration and swelling of the spleen (100)
	Histopathology	M: Congestion in the spleen (10, 100, R100), Extramedullary hematopoiesis in the spleen (100), Atrophy of white pulp in the spleen (100), Yellowish-brown pigmentation in the spleen (100, R100), Extramedullary hematopoiesis in the liver (100), Yellowish-brown pigmentation in the liver (100, R100), Erythroid hyperplasia in the bone marrow (100) F: Congestion in the spleen (1, 10, 100), Atrophy of white pulp in the spleen (100), Extramedullary hematopoiesis in the spleen (10, 100), Yellowish-brown pigmentation in the spleen (100, R100), Extramedullary hematopoiesis in the liver (100), Yellowish-brown pigmentation in the liver (100, R100), Erythroid hyperplasia in the bone marrow (1, 10, 100, R100)
	Target organ	Hematopoietic system, Spleen, Liver
Results of Reproduction and developmental toxicity	Parent	NE
	Offspring	NE
NOAEL		Repeated dose toxicity: M 1, F less than 1 Reproductive and developmental toxicity: 100
	Basis for NOAEL	Repeated dose toxicity: M 10: Liver R ↑, Congestion in the spleen F 1: Congestion in the spleen, Erythroid hyperplasia in the bone marrow Reproductive and developmental toxicity: No adverse effect
NOEL		Repeated dose toxicity: M 1, F less than 1 Reproductive and developmental toxicity: 100
	Basis for NOEL	Repeated dose toxicity: M 10: Liver R ↑, Congestion in the spleen F 1: Congestion in the spleen, Erythroid hyperplasia in the bone marrow Reproductive and developmental toxicity: No effect
Note		

↑; increase, ↓; decrease M; male, F; female

A; absolute organ weight, R; relative organ weight

The data was reviewed by Hazard-Data Evaluation Committee of National Institute of Technology and Evaluation in fiscal 2007.