

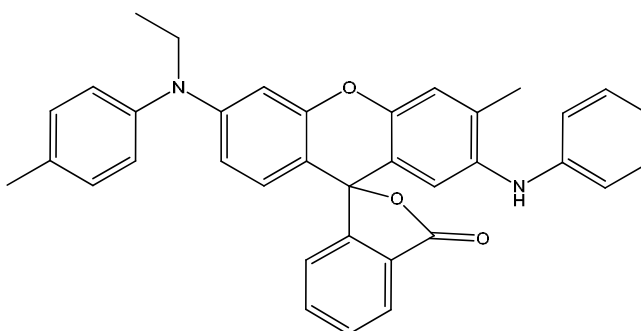
Combined Repeated Dose Toxicity Study with the Reproduction/ Developmental Toxicity Screening Test(OECD TG422) -Data Sheet-

Japan Bioassay Research Center
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The data sheet was reviewed and created by Hazard-Data Evaluation Committee of National Institute of Technology and Evaluation in fiscal year 2011 based on the study report obtained by Ministry of Economy, Trade and Industry.

Test substance

MITI No. : 5-3629
CAS No. : 59129-79-2
Chemical name : 2'-Anilino-6'-[N-ethyl-N-(4-tolyl)amino]-3'-methylspiro
[isobenzofuran-1(3H), 9'-[9H]xanthen]-3-one
Synonym : ETAC
Molecular weight : 539
Molecular formula : $C_{36}H_{30}N_2O_3$
Structural formula :



Appearance : Slightly colored powder
Solubility : Insoluble in water
Purity : 99.0%

Experimental Method

Test animals : Crl:CD (SD) male and female rats, 10 weeks old (initiation of dosing)
Number of animals : M; 7 rats/group (control and high dose groups of main study)+5 rats/group (control and high dose groups of recovery).
12 rats/group (low and middle dose groups of main study)
F; 12 rats/group (all groups of main study)
+ 5 rats/group (control and high dose groups of recovery)

Dosing period : M; 42days
 F; 42-55days (from 14 days before mating to day 4 of lactation)

Administration : Oral gavage

Vehicle : Olive oil (suspended)

Dosing volume : 5 mL/kg

Dose level : 100, 300, 1000 mg/kg/day

Rationale for selection of dosage: In the 14 days range finding study (0, 100, 300, 600, 1000 mg/kg/day), there were no abnormal changes in all of the parameters examined (clinical sign, body weight, food consumption, hematology, blood chemistry, organ weight and necropsy).

Results

Dose(mg/kg/day)	100	300	1000
Repeated Dose Toxicity			
Dead or killed in extremis	M; 0/12 F; 0/12	M; 0/12 F; 0/12	M; 0/12, F; 0/12
Clinical sign	NE	NE	NE
FOB	NE	NE	NE
Body weight	NE	NE	NE
Food consumption	NE	NE	NE
Urinalysis(M)	NE	NE	NE
Hematology	NE	NE	NE
Blood chemistry	NE	NE	NE
Organ weight	NE	NE	NE
Necropsy	NE	NE	NE
Histopathology	NE	NE	NE
Target organ	-		
NOAEL	M: 1000 mg/kg/day F: 1000 mg/kg/day		
Basis for NOAEL	MF1000: no adverse effect		
NOEL	M: 1000 mg/kg/day F: 1000 mg/kg/day		
Basis for NOEL	MF1000: no effect		

Reproductive Developmental toxicity			
Parent	NE	NE	NE
Offspring	NE	NE	NE
NOAEL	1000 mg/kg/day		
Basis for NOAEL	1000: no adverse effect		
NOEL	1000 mg/kg/day		
Basis for NOEL	1000: no effect		

NE: No effect

Note