

US EPA ARCHIVE DOCUMENT

EPA Reviewer: M. Hashim

Date: May 17, 2006

Risk Manager (EPA): 25

STUDY TYPE: Acute Dermal Toxicity – Rat; OPPTS 870.1200; OECD 402

TEST MATERIAL: SP1022 (Triclopyr-Triethylamine salt 14.8%), Lot #870IP506-2A, Gray granules

CITATION: Moore, G. (2006). Acute Dermal Toxicity in Rats. Product Safety Laboratories, Dayton, NJ 08810, Study #: 18013 dated 1-30-06 MRID 46791904. Unpublished.

SPONSOR: SePRO Corporation, Carmel, IN 46032-4565.

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 46791904), SD rats, 5/sex (Weight: males 282-316 g and 207-220 g, Source: Ace Animals, Boyertown, PA) were dermally exposed to a single application of SP1022 (Triclopyr-Triethylamine salt 14.8%) at a limit dose of 5,000 mg/kg. The test substance was moistened in dist. water and applied to the back of the test animals, covering approx. 10% of the animals BSA, covered with a gauze pad held in place by elastic tape and wrap and left in place for 24 hours. Individual animal body weights were recorded prior to the test substance application and then each week, thereafter. Cage-side (clinical) observations were conducted at least once a day for the remainder of the study period. All animals were necropsied at the end of the study.

All animals survived the study period. There were no dermal lesions or apparent toxic signs. All animals gained normal body weight. No gross lesions were observed at necropsy.

Dermal LD₅₀ Males > 5,000 mg/kg
Females > 5,000 mg/kg
Combined > 5,000 mg/kg

Based on the observed LD₅₀ in rats, SP1022 is classified as EPA Toxicity Category IV for acute dermal toxicity.

This acute dermal study is classified acceptable. It does satisfy the guideline requirement for an acute dermal study (OPPTS 870.1200; OECD 402) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Dose (mg/kg bw)	Mortality/Number Tested		
	Males	Females	Combined
5000	0/5	0/5	0/10

A. Mortality - None, as noted in table.

B. Clinical observations - All animals survived the study period. There were no dermal lesions or apparent toxic signs. All animals gained normal body weight

C. Gross Necropsy - No gross lesions were observed at necropsy.

D. Reviewer's Conclusions: TRB agrees with the study author that the combined (m+f) dermal LD₅₀ > 5,000 mg/kg, with EPA Tox Cat IV.