

EPA Reviewer: M. Hashim

Date: May 17, 2006

Risk Manager (EPA): 25

STUDY TYPE: Primary Eye Irritation - NZW Rabbit, OPPTS 870.2400; OECD 405

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

CITATION: Moore, G. (2006). Primary Eye Irritation Study in Rabbits. Product Safety Laboratories, Dayton, NJ 08810, Study #: 18015 dated 1-30-06 MRID 46791906. Unpublished.

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

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 46791906), 0.1 mL (approx. 0.06 g) aliquot SP1022 (Triclopyr-Triethylamine salt 14.8%) in powder was instilled into the conjunctival sac of the right eye in each of the 3 young adult New Zealand White rabbits (Source: Robinson Services, Clemmons, NC). The untreated left eye served as a control. Animals were evaluated for ocular irritation at 1, 24, 48, 72 hours and up to 7 days post-instillation according to Draize Method of scoring.

One-hour post instillation 3 of 3 treated eyes exhibited iritis and conjunctivitis (Table 1). Corneal opacity was also seen at 24 hours in 2 of 3 rabbits. At the 7th day observation no positive irritation was noted and all eyes appeared normal. The mean score of severity of irritation was 15.0 at one hour, 22.7 at 24 hours and 0 on day 7.

Under the conditions of the study SP1022 is moderately irritating to the rabbit eye. The test substance is classified as EPA Toxicity Category III for primary eye irritation.

This study is classified as acceptable. It does satisfy the guideline requirement for a primary eye irritation study (OPPTS 870.2400; OECD 405) in the rabbit.

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

RESULTS AND DISCUSSION:

Table 1. Score of irritation

Time Hrs/days	Corneal opacity	Iritis	Conjunctivitis	Severity of Irritation mean values
1 hour	0/3	3/3	3/3	15.0
24 hours	2/3	3/3	3/3	22.7
48 hours	2/3	2/3	3/3	19.0
72 hours	1/3	1/3	3/3	9.3
Day 4	0/3	1/3	1/3	3.7
Day 7	0/3	0/3	0/3	0

* Score of 2 or more required to be considered “positive”

A. Observations – (Table 1) One-hour post instillation 3 of 3 treated eyes exhibited iritis and conjunctivitis. Corneal opacity was also seen at 24 hours in 2 of 3 rabbits At the 7th day irritation subsided and all eyes appeared normal. The mean score of severity of irritation was 15.0 at one hour, 22.7 at 24 hours and 0 on day 7.

B. Reviewer’s Conclusions: The study is in compliance with EPA guidelines. The study meets EPA Category III.