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Reviewer: Tracy Keigwin May 15, 2007
Product Manager (EPA): 23

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

TEST MATERIAL (% a.i.): GF-1274, Batch 422556-08-9, Purity: 8.1% w/w Cloquintocet-mexyl, 7.8% w/w XDE-742, Light brown granules.

CITATION: Janssen, P.J.M. Acute Eye Irritation/Corrosion Study with GF-1274 in the Rabbit. NOTOX B.V., Hambakenwetering 7, 5231 DD's-Hertogenbosch, The Netherlands. NOTOX Project 434036, DAS study no. 050156. October 14, 2005. MRID 46907706. Unpublished.

SPONSOR: The Dow Chemical Company, Midland, MI for Dow Agro Sciences LLC, Indianapolis, IN

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 46907706), 0.1 mL (approximately 56 mg) of undiluted GF-1274, Batch 422556-08-9, Purity: 8.1% w/w Cloquintocet-mexyl, 7.8% w/w XDE-742, Light brown granules was instilled into the conjunctival sac of one eye of 3 male New Zealand White (SPF-Quality) albino rabbits (source: Charles River Deutschland, Sulzfeld, Germany; age: at least 6 weeks old; weight: at least 2.0 kg). Note that the test substance was ground to a powder prior to weighing. The lower lid was gently pulled away from the eyeball to form a cup and 0.1 mL of the test substance was instilled. After instillation the eyelids were held together for approximately 1 second to limit test article loss. The other eye was untreated to serve as a control. Animals were observed for mortality/viability twice daily and for signs of toxicity at least once daily. Observations for eye irritation were conducted at 1, 24, 48 and 72 hours and additionally at 7 days post instillation. Bodyweights were taken on the day of treatment and at termination. Following the 24 hour observation, "a solution of 2% fluorescein in water (adjusted to pH 7.0) was instilled into both eyes of each animal to quantitatively determine corneal epithelial damage

No corneal opacity was observed during the study. Iritis was observed in 2/3 animals at the one hour observation only. Positive signs of conjunctivitis were observed in 3/3 animals at the 1 hour observation, resolving within 24 hours in 2/3 animals and within 48 hours in the remaining test animal. EPA Toxicity Category III.

This study is classified as acceptable, and will satisfy the guideline requirement for a

US EPA ARCHIVE DOCUMENT

primary eye irritation study (OPPTS 870.2400; OECD 405) in the rabbit.

US EPA ARCHIVE DOCUMENT

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

RESULTS AND DISCUSSION:

	Number "positive"/number tested				
	Hours				Days
Observations	1	24	48	72	7
Corneal Opacity	0/3	0/3	0/3	0/3	0/3
Iritis	2/3	0/3	0/3	0/3	0/3
Conjunctivae[a]:					
Redness	3/3	1/3	0/3	0/3	0/3
Chemosis	3/3	0/3	0/3	0/3	0/3
Discharge	0/3	0/3	0/3	0/3	0/3

[a] Score of 2 or more required to be considered a positive.

A. Observations - No corneal opacity was observed during the study. Iritis was observed in 2/3 animals at the one hour observation only. Positive signs of conjunctivitis were observed in 3/3 animals at the 1 hour observation, resolving within 24 hours in 2/3 animals and within 48 hours in the remaining test animal. Please note that the study does record some additional signs of conjunctivitis, however the scores (grade 1) are not considered positive per 870.2400.

B. Reviewers Conclusions: Test substance is Category III for primary eye irritation.

C. Deficiencies - None

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