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

STUDY TYPE: Primary Dermal Irritation - New Zealand White rabbit; OPPTS 870.2500; OECD 404

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. Primary Skin Irritation/Corrosion Study with GF-1274 in the Rabbit. NOTOX B.V., Hambakenwetering 7, 5231 DD's-Hertogenbosch, The Netherlands. NOTOX Project 434003, DAS study no. 050154. September 29, 2005. MRID 46907707. Unpublished.

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

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 46907707), 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) were dermally exposed to 0.5g (moistened with 0.5 mL of water) of GF-1274, Batch 422556-08-9, Purity: 8.1% w/w Cloquintocet-mexyl, 7.8% w/w XDE-742, Light brown granules. Note that the test substance was ground in a mortar and pestle prior to weighing. Twenty four hours prior to test substance application an area of fur approximately 150 square centimetres was clipped from the dorsal area of test animals. An application of 0.5g of the test substance (moistened with 0.5 mL of water) was placed on the skin of one flank, "using a metalline patch of 2 x 3 cm. The patch was mounted on Micropore tape, which was wrapped around the abdomen and secured with Coban elastic bandage". After 4 hours all binding materials were removed and the test sites washed with tap water to remove any remaining test substance. Animals were observed for mortality/viability twice daily and for signs of toxicity at least once daily. Observations for dermal irritation were conducted at 1, 24, 48 and 72 hours after patch removal. Bodyweights were taken on the day of treatment and at termination.

No erythema or edema was observed during the study. EPA Toxicity Category IV. PDI = 0.0.

This study is classified as acceptable. It does satisfy the guideline requirement for a primary dermal irritation study (OPPTS 870.2500; OECD 404) in the rabbit.

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

RESULTS and DISCUSSION:

		Hours			
		1	24	48	72
685-M	Erythema	0	0	0	0
	Edema	0	0	0	0
676-M	Erythema	0	0	0	0
	Edema	0	0	0	0
6684-M	Erythema	0	0	0	0
	Edema	0	0	0	0

A. Observations – No erythema or edema were observed during the study. EPA Toxicity Category IV.

B. Results - PDII – 0.0

C. Reviewers Conclusions – Test substance is Category IV for dermal irritation.

D. Deficiencies - None