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HH0028-2008

ABSTRACT FOR STUDY HH-0028-2008

TITLE: Inhalation Toxicity for F10 Superconcentrate Batch no. 100811

Determination of acute toxicity is usually an initial step in the assessment and evaluation of the toxic characteristics of a substance that may be inhaled such as a gas, volatile substance, or aerosol/particle. It provides information on health hazards likely to arise from short-term exposure by the inhalation route. Data from an acute study may serve as a basis for classification and labelling.

The Series 870 Health Effects test guidelines have been harmonized between OPP and OPPTS and, where possible, with OECD and South African test guidelines. This study was conducted according to EPA Guideline 870.1100 Acute Toxicity and 870.1300 Acute Inhalation Toxicity; August 1998, EPA 712-C-98-193 USA Printing Office.

As the toxicity of the test substance is known to be low, only one group of animals was exposed to a concentration > 2mg per litre air for 4 hours. The undiluted test substance was nebulised in a Medactive Clearway 1000 Nebulisor. Subsequently, observations of effects and death were made. At the conclusion of the study surviving animals were euthanized and necropsied. There were 10 animals (5 of each sex) in the treatment group

All animals showed signs of slight respiratory distress during the first hour of inhalation of the test substance. No animals died during the observation period. No macro pathology was observed in all the organs of all the animals.

This study indicated that the inhalation LC 50 for the test substance is above 2mg per litre. According to EPA Toxicity Categories this falls within category IV.

Toxicity Categories for Pesticide Products

	Category I	Category II	Category III	Category IV
Acute Inhalation	Up to and including 0.05mg/litre	>0.05 through 0.5 mg/litre	>0.5 through 2 mg/litre	>2 mg/liter

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HH-0022-2008

ABSTRACT FOR STUDY HH-0022-2008

TITLE: Skin Sensitization for F10 Superconcentrate Batch no. 100124

The purpose of the study was to identify whether the test substance has skin sensitization potential. Determination of the potential to cause or elicit skin sensitization reactions (allergic contact dermatitis) is an important element in evaluating a substance's toxicity. Information derived from skin sensitization tests serves to identify possible hazards to a population exposed repeatedly to a test substance.


This study was conducted according to EPA Guideline 870.100 and 870.2600 Skin Sensitization (Buehler Method) and complied with registration requirements in South Africa, USA and Europe. Following initial exposure to a test substance, the animals were subjected, after a period of not less than 1 week, to a challenge exposure with the test substance to establish whether a hypersensitive state has been induced. Sensitization was determined by examining the reaction to the challenge exposure and comparing this reaction with that of the initial induction exposure.

All of the surviving animals were sacrificed at the end of the study.

The experimental technique in naive animals was assessed by the use of a positive control substance known to have mild-to-moderate skin-sensitizing properties.

Animal weights indicate that the animals in both the test and control group gained weight over the study period. This showed that the test substance had no general adverse affect on the animals health.

Skin sensitivity assessment showed that the test substance causes no skin sensitization in the animals tested.



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HH- 2% F10

TOXICITY ASSESMENT OF A 2% SOLUTION OF F10 SUPERCONCENTRATE

1. ACUTE DERMAL IRRITATION TEST OF A 2% SOLUTION OF F10 SUPERCONCENTRATE (Batch no:071202) STUDY HH-0005-2007

The test system was in accordance with the OPPTS 870.2500: Acute Dermal Irritation Standards.

Three healthy adult Duncan Hartly Guinea Pigs were used during this study. Test patches were applied to the shaved skin of the animals. The patches were removed after 4 hours when observations started and continue for 72 hours..

No corrosive effect was observed after 4 hours and up to 72 hours.

It is therefore concluded that the 2% solution of F10 Superconcentrate causes no dermal irritation.

According to EPA Toxicity Categories this falls within category IV.

Acute Toxicity Categories for Pesticide Products

Hazard Indicators	I	II	III	IV
Skin irritation.....	Corrosive at 72 hours	Severe irritation irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight

2. ACUTE EYE IRRITATION TEST OF A 2% SOLUTION OF F10 SUPERCONCENTRATE (Batch no: 071202) STUDY HH-0004-2007

The test system was in accordance with the OPPTS 870.2400: Acute Eye Irritation Standards.

Three healthy adult female New Zealand White rabbits were used during this study.

The test substance was placed in the conjunctival sacs of the right eye of the animals after gently pulling the lower lid away from the eyeball. The lids were then gently held together for about one second in order to limit loss of the test material. The left eye, which remained untreated, served as the control. The animals were observed for 72 hours.

No eye imitation was observed in any of the animals.

It is concluded that a 2% solution of F10 Superconcentrate causes no eye irritation.

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HH- 2% F10

Acute Toxicity Categories for Pesticide Products

Hazard Indicators	I	II	III	IV
Eye irritation.....	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation

3. ACUTE ORAL TOXICITY OF A 2% SOLUTION OF F10 SUPERCONCENTRATE (BATCH: 071202)

The test system was in accordance with the OPPTS 870.1100: Acute Oral Toxicity Standards.

Acute oral toxicity tests had been conducted on a 100% (undiluted) solution of F10 Superconcentrate, batch 071202 (Report No A34-01-06 dated 10/08/06). In the study eight female Sprague Dawley rats, 50 days of age were used. Only young healthy animals were admitted to the study. No animals were withdrawn from the study. A total of three dosage groups were used in the study. The dosage groups were chosen on the basis of previous literature, which indicates that the dermal toxicity of F10 Superconcentrate is very low.

The study indicated that the oral toxicity of the F10 Superconcentrate formulation lies between 2000 and 5000 mg/kg.

For a 2% solution of F10 Superconcentrate the oral toxicity will be >5,000 mg/kg.

According to EPA Toxicity Categories this falls within category IV.

Acute Toxicity Categories for Pesticide Products

Hazard Indicators	I	II	III	IV
Oral LD50.....	Up to and including 50 mg/kg	50 thru 500 mg/kg	500 thru 5,000 mg/kg	>5,000 mg/kg

4. DETERMINATION OF THE ACUTE DERMAL TOXICITY OF F10 SUPERCONCENTRATE (BATCH: 071202)

The test system was in accordance with the OPPTS 870.1200: Acute Dermal Toxicity Standards.

Acute dermal toxicity test had been conducted on a 100% (undiluted) solution of F10 Superconcentration batch 071202 (Report No A35-01-06 dated 13 Sep 2006). Fifteen female Sprague Dawley rats, 50 days of age were used.

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HH- 2% F10

Only young healthy animals with no skin lesions were admitted to the study. No animals were withdrawn from the study.

A total of three dosage groups were used in this study. The dosage groups were chosen on the basis of previous literature, which indicates that the dermal toxicity of F10 superconcentrate is very low.

The first group was treated with a concentration of 300mg/kg F10 super concentrate, the second group with 2000 mg/kg and the third with 5000 mg/kg.

The animals were observed 2 hours after exposure and once every day thereafter for a period of 14 days for signs of toxicity.

No toxicological symptoms were recorded in any of the experimental groups during the study period. Furthermore no pathological lesions were recorded in any of the animals at the post mortems. There were also no significant weight loss recorded

This study indicated that the dermal toxicity of the F10 Superconcentrate formulation lies above 5000 mg/kg.

For a 2% solution of F10 Superconcentrate the dermal toxicity dose will be above 20,000 mg/kg.

According to EPA Toxicity Categories this falls within category IV.

Acute Toxicity Categories for Pesticide Products

Hazard Indicators	I	II	III	IV
Dermal LD50.....	Up to and including 200 mg/kg	200 thru 2000 mg/kg	2000 thru 20,000 mg/kg	>20,000 mg/kg

A handwritten signature in black ink, appearing to read 'D J Goosen', is written over a horizontal line.

Dr D J Goosen (BVSc Hons)