

7-9-91



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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

008767

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

~~APR 9 1991~~

SUBJECT: EPA Reg. No./File Symbol 10.31-1290

~~JUN 9 1991~~

MGK Intermediate 2007

FROM: Mary L. Waller *Mary L. Waller*
Precautionary Review Section
Registration Support Branch
Registration Division (H75-05C)

E 7/9/91

TO: Phil Hutton (PM 5)
Insecticide-Rodenticide Branch
Registration Division (H75-05C)

APPLICANT: McLaughlin Gormley King Co.
8810 Tenth Avenue North
Minneapolis, MN 55427

FORMULATION FROM LABEL:

	Active Ingredient(s):	% by wt.
346	<u>N,N-diethyl-m-toluidide</u>	<u>73.67%</u>
	<u>Other isomers</u>	<u>3.85%</u>
613	<u>N-octyl-bicycloheptene dicarboximide MGK264</u>	<u>15.35%</u>
400	<u>D-n-propyl isocinchroteronate (SoyA 3)</u>	<u>7.76%</u>
	Inert Ingredient(s):	
	Total	100.0%

mgc 320 1000

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BACKGROUND: The registrant has submitted an acute oral, acute dermal, primary eye irritation, primary skin irritation and dermal sensitization studies. The studies were conducted by Biosearch, Incorp. The MRID numbers are 416781-01 through -04 and 418127-01.

RECOMMENDATION: RSB/PRS findings are as follows:

1. The data is acceptable and classified as core guideline data.
2. The registrant must submit an acute inhalation toxicity study.
3. The signal word is "CAUTION".

LABELING:

1. Revise the precautionary statements as follows:

"Harmful if swallowed or absorbed through the skin. Causes eye injury. Avoid contact with skin, eyes, or clothing. Avoid breathing vapors or spray mist. Wash thoroughly with soap and water after handling. *"Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals."*

2. Revise the statements of practical treatments for oral and dermal exposure as follows:

"IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention."

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DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§81-1)

Product Manager: (17) Reviewer: M. Waller
 MRID No.: 416781-01 Report Date: 6-29-90
 Testing Facility: Bioscience Incorp. Report No. 90-6978A
 Author(s): David Gabriel
 Species: Sprague-Dawley Rats
 Age: None Not Specified Observation Days (Post
 Weight: ♂=232-282; ♀=207-237g Exposure): (14); other ()
 Source: Buckshire Corp., Perkasie, PA
 Test Material: MGK Intermediate 2007 Code No. 356-90
 Quality Assurance (40 CFR §160.12): attached

Conclusion:

1. LD₅₀ (mg/kg): Males = 3.90 (2.90 - 5.24) g/kg^{95% C.L.}; Females =
3.02 (1.71 - 5.31) g/kg; Combined =
 2. The estimated LD₅₀ is
 3. Tox. Category: III. Classification: Guideline Data

Procedure (Deviations From §81-1): -----

Results:

Reported Mortality

DOSAGE (/kg)	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
2.0 g/kg	0/5	1/5	1/10
3.16 g/kg	1/5	/	1/5
5.0 g/kg	4/5	4/5	8/10
6.31 g/kg	5/5	5/5	10/10

Symptomology & Gross Necropsy Findings:

Animals exhibited lethargy, ruffled appearance, prostration,
and comatose state.

Gross necropsy revealed clear/tan fluid in
G.I. tract and stomach, and nasal stain.

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DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2)

Product Manager: (17)
 MRID No.: 418127-001
 Testing Laboratory: Biosearch Incorp.
 Author(s): David Gabriel
 Species: New Zealand White rabbit
 Sex: ♂ & ♀ Wt.: 2.08 - 2.60 kg
 Test Material: MGR Intermediate 2007 Code # 356-90
 Quality Assurance (40 CFR §160.12): Attached

Reviewer: M. Waller
 Report Date: 5/17/90
 Report No. 90-6478A

Summary:

- LD₅₀ (mg/kg): Males = _____; Females = _____; Combined = _____;
- The estimated LD₅₀ is > 20 g/kg
- Tox. Category: III. Classification: Guideline

Procedure (Deviations From §81-2): _____

Results:

Reported Mortality

DOSAGE (/kg)	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
20 g/kg	0/5	0/5	0/10

Symptomology & Gross Necropsy Findings:

One out of 5 males and one out of five females exhibited soft stools. One out of 5 males exhibited scales and nasal discharge. Erythema, edema and cracking skin were noted at test site. To other toxic symptoms were observed.

Gross necropsy revealed liquid in stomach & lower G.I. tract of one male. No other abnormalities were noted.

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DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4)

Product Manager: (17)
 MRID No.: 416781-02
 Testing Laboratory: Bioscience Incorp.
 Author(s): Jennifer Bielucke
 Species: New Zealand white rabbit
 Sex: Not specified
 Source: Buckshire Corp., Perkasie, PA.
 Dosage: 0.1 ml
 Test Material: MGK Intermediate 2007 Code No. 356-90
 Quality Assurance (40 CFR §160.12): Attached

Reviewer: M. Waller
 Report Date: 4/30/90
 Report No. 90-6978A

Summary:

Tox. Category: III Classification: Guideline

Procedure (Deviation From §81-4):

Results:

	Observations (number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Cornea								
Opacity	0/6	1/6	1/6	0/6	0/6	0/6		
Iris	0/6	1/6	0/6	0/6	0/6	0/6		
Conjunctivae								
Redness	0/6	6/6	2/6	0/6	0/6	0/6		
Chemosis	6/6	6/6	6/6	1/6	0/6	0/6		
Discharge	0/6	2/6	0/6	0/6	0/6	0/6		

Comments:

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DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5)

Product Manager: (17)
MRID No.: 416781-03
Testing Laboratory: Biosearch Incorp.
Author(s): Pamela Ventura
Species: New Zealand white rabbit
Age: not specified
Sex: not specified
Weight: not specified
Dosage: 0.5 ml
Test Material: MGK Intermediate 2007 Code No. 356-90
Quality Assurance (40 CFR §160.12): Attached

Reviewer: M. Waller
Report Date: 4/17/90
Report No. 90-6978A

Summary:

The Primary Irritation Index = _____

Toxicity Category: IV

Classification: Guideline Data

Procedure (Deviations From §81-5): _____

Results:

At 4 hours, $\frac{2}{6}$ animals exhibited well-defined erythema and $\frac{3}{6}$ animals exhibited very slight erythema. At 24 hours, $\frac{1}{6}$ animals exhibited well-defined erythema and $\frac{5}{6}$ animals exhibited very slight erythema. At 48 hours, $\frac{2}{6}$ animals exhibited very slight erythema and at 72 hours, $\frac{1}{6}$ animals exhibited very slight erythema.

Special Comments:

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DATA REVIEW FOR SKIN SENSITIZATION TESTING (§81-6)

Product Manager: (17)
 MRID No.: 416781-04
 Testing Laboratory: Biosearch Incorp.
 Author(s): Pamela Romanelli
 Species: Hartley Guinea Pigs
 Sex: male Weight: 417-528 g
 Source: Davidson Mill Farm, Jamesburg, NJ
 Test Material: MGK Intermediate 2007 Code # 356-90
 Positive Control Material: 1-chloro-2,4-dinitrobenzene
 Quality Assurance (40 CFR §160.12): attached

Reviewer: M. Waller
 Report Date: 6-15-90
 Report No. 90-6978A

Method: Modified Buehler

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Summary:

1. This product is / is not a dermal sensitizer.
2. Classification: Guideline Data

Procedure (Deviation From §81-6): Induction - 9 treatments
 + challenge concentration
 Induction - 50% v/v in mineral oil; test site moved for
 Induction treatment 6-9 due to significant irritation

Results: No irritation observed in test group after the 1st & 2nd induction treatment. After the 3rd induction treatment, 5/12 animals exhibited well-defined erythema and 2/12 exhibited very slight edema. Irritation observed in treatments 4 and 5 increased in severity and number of animals involved. Animals exhibited very slight to severe erythema with dry flakey skin and very slight to slight edema. No irritation was observed after treatment #6 (test site moved). Irritation observed in test group during treatments 7-9 ranged from very slight to moderate erythema and up to very slight edema. At 24 hour Challenge observation, the test group exhibited the following: 5/12 - very slight erythema, 4/12 - well-defined erythema, 1/12 - moderate-severe erythema, 1/12 - slight edema and 3/12 - very slight edema. At rechallenge, test group exhibited 6/12 - moderate-severe erythema, 4/12 - well-defined erythema & 1/12 - very slight edema. Naive control groups at challenge & rechallenged did not exhibit irritation. At rechallenge, 1/4 Naive control animals exhibited very slight erythema. Positive control group exhibited irritation indicating sensitization.