IRB/TSS PRECAUTIONARY LABEL REVIEW

IN 8-28-87 OUT 10/29/87

ACTION CODE: 310

REVIEWER: Dona Williams

PRODUCT MGR. NO. 16

Record Number(s)
201, 987

310 10/29/87
12

Picked-up in person by Mobay 11/4/87

FILE OR REG NO. 3125-339

PETITION OR EUP NO.

PRODUCT NAME PRYFON ™ 6 INSECTICIDE

COMPANY NAME & Mobay Corp., Ag Chemicals Division

ADDRESS P.O. Box 4913, Kansas City, MO 64120

SUBMISSION PURPOSE Revision of precautionary labeling from tox category I to tox category II. Removal of restricted use class.

CHEMICAL & FORMULATION Flowable liquid [65% oftanol ai., 35% inert ingredients]

PRODUCT USES Pre and post-construction treatment to control subterranean termites.

COMMENTS AND RECOMMENDATIONS:

1. Revised precautionary statements are acceptable.

2. This product based on submitted studies still meets the criteria for restricted Use Pesticide is outlined under 40 CFR 162.11(c) for acute dermal and inhalation.

3. Submitted studies were reviewed and the product assigned the following categories.

	CORE CLASS	TOX CAT	MRID#
Acute Oral LD50	GUIDELINE	II	402977-01
Acute Dermal LD50	MINIMUM	II	402977-03
Acute Inhalation LC50	GUIDELINE	II	402977-02
Primary Eye Irritation	MINIMUM	IV	402977-04
Dermal Irritation	GUIDELINE	IV	402977-05
Dermal Sensitization	GUIDELINE	Non-Sensitization	

G. T. McNamara
Received 11/4/87

87

FILE OR REG NO. 3125-339

TEST ARTICLE: OFTANOL 6 Flowable (71% ai)

TEST FACILITY & Mobay Corp., Health, Environment & Safety, Corp Tox Dept.

ADDRESS 17745 South Metcalf

Stilwell, KS 66085-9104

STUDY SUMMARIES:

1. ACUTE ORAL LD_{50} EPA ACC/MRID NO. 402977-01
STUDY NO. 94768 ; STUDY INITIATED 2-16-87
Conforms with Health Assessment Guidelines (81-1) Y/N Yes
Deviations from guidelines None.
Level(s) Tested Groups of 5M & 5F SD rats: 50, 58, 65, 68, 72, 75, 100, 108, 117, 125, and 150 mg/kg undiluted in corn oil. Oral gavage. 14 day observations.
Significant Toxic Signs Muscle fasciculations, tremors, ataxia and decreased activity.
Significant Necropsy Findings Ocular, nasal, and oral stains.

LD_{50}= (Males) 109 mg/kg (99-116) 95% CL
(Females) 65 mg/kg (59-69) 95% CL
NOEL (males 75 mg/kg) (females 50 mg/kg)
Core Classification GUIDELINE (If Supplementary list deficiencies)

Product Toxicity Category for this route of exposure II
(See addendum for sex specific mortalties)

2. ACUTE DERMAL LD_{50} EPA ACC/MRID NO. 402977-03
STUDY NO. 94770 ; STUDY INITIATED 3-02-87
Conforms with Health Assessment Guidelines (81-2) Y/N Yes
Deviations from guidelines None
Level(s) Tested Groups of 5M & 5F NZ White rabbits: 600, 1000, 1400, 1800, 2200, and 2600 mg/kg undiluted. Clipped intact skin. 24-hr occluded dermal exposure. 14-day observation period.
Significant Toxic Signs Muscle fasciculation, ataxia, decreased activity, hyperreactivity, salivation, diarrhea, and reduced body weight.
Significant Necropsy Findings Oral, nasal stains, fluid-filled stomach.

LD_{50}= (Males) 900 mg/kg (267-1287) 95% CL
(Females) 1701 mg/kg (812-2627) 95% CL
NOEL (males & females 600 mg/kg)
Core Classification MINIMUM (If Supplementary list deficiencies)

Product Toxicity Category for this route of exposure II
(See addendum for sex specific mortalties)

FILE OR REG NO. 3125-339

3. ACUTE INHALATION LC_{50} EPA ACC/MRID NO. 402977-02
STUDY NO. 94769 ; STUDY INITIATED 4-20-87
Conforms with Health Assessment Guidelines (81-3) Y/N Yes
Deviations from guidelines None.
Level(s) Tested Groups of 10M & 10F SD rats: 94, 145, 330, and 435 mg/m^3 test material mixed in PEG:ETOH. 4-hour head-only exposure. 14-day observations.
Method of Analysis Analytical (Gas Chromatography)
Significant Toxic Signs Ocular and nasal stains, hypoactivity, salivation, tremors, muscle fasciculation, dyspnea, ataxia, alopeica, and rales.
Significant Necropsy Findings lacrimation, salivation, nasal stains, red lungs and alopeica.
MMAD See table ; Percent of particles within respirable range
LC_{50}= (Males) 220 mg/m^3 (168-278)95% CL
(Females) 123 mg/m^3 (85-167) 95% CL
NOEL < 94 mg/m^3
Core Classification GUIDELINE (If Supplementary list deficiencies)
Product Toxicity Category for this route of exposure II
(See addendum for sex specific mortalities)

4. PRIMARY EYE IRRITATION EPA ACC/MRID NO. 402977-04
STUDY NO. 94580 ; STUDY INITIATED 11-17-86
Conforms with Health Assessment Guidelines (81-4) Y/N Yes
Deviations from guidelines None
Level(s) Tested 6 NZ White rabbits: 0.1 ml undiluted. Instilled into left eye. Eyes held closed 1 second. No wash. 72-hr observation period.
Ocular Findings [list number of animals elicting response and period of duration]
corneal opacity: None exhibited
iristis: None exhibited
conjunctivae: grade(1) redness (6/6) clear by day-1
Core Classification MINIMUM (If Supplementary list deficiencies)
Product Toxicity Category for this route of exposure IV

FILE OR REG NO. 3125-339

5. PRIMARY DERMAL IRRITATION EPA ACC/MRID NO. 402977-05
STUDY NO. 94557 ; STUDY INITIATED 12-01-86
Conforms with Health Assessment Guidelines (81-5) Y/N Yes
Deviations from guidelines None
Level(s) Tested 6 NZ White rabbits: 0.5 mls undiluted. Clipped intact skin. 4-hour occluded dermal exposure. 72-hour observation period.
Dermal Findings [list number of animals eliciting response and period of duration]
erythema None elicted
edema None elicted
PDIS 0.00
Core Classification GUIDELINE (If Supplementary list deficiencies)

Product Toxicity Category for this route of exposure IV

6. DERMAL SENSITIZATION EPA ACC/MRID NO. 402977-06
STUDY NO. 94783 ; STUDY INITIATED 11-11-86
Test Method Used Buehler Test
Deviations from accepted test method None
Concentration Tested 15M Hartely guinea pigs: 100% undiluted. Three 6-hr occluded dermal induction applications. Challenge (100% concen) 2-wks post-final induction at virgin site. 24 and 48-hr readings.
Postive Control 0.05% DNCB in 50% ethanol/distilled water.
Induction Findings/ Mean Score No dermal irritation
Challenge Findings/ Mean Score No dermal irritation
Product Classification Non-Sensitizer
Core Classification GUIDELINE

FILE OR REG NO. 3125-399

ADDENDUM

ACUTE ORAL LD50

CONCENTRATION (mg/kg)	PERCENT MORTALITY Males	Females
50	-	0
58	-	10
65	-	10
68	-	40
72	-	40
75	0	100
100	10	100
108	40	-
117	80	-
125	100	100
150	100	-

ACUTE DERMAL LD50

CONCENTRATION (mg/kg)	PERCENT MORTALITY Males	Females
600	10	0
1000	60	60
1400	100	-
1800	60	40
2200	100	100
2600	-	100

ACUTE INHALATION LC50

CONCENTRATION (mg/m^3)	PERCENT MORTALITY Males	Females	MMAD ± GSD (microns)
94	0	30	2.0 ± 1.8
145	10	60	1.9 ± 1.9
330	100	100	2.2 ± 2.3
435	90	100	2.0 ± 2.0