

US EPA ARCHIVE DOCUMENT



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

OFFICE OF PREVENTION,
PESTICIDES AND TOXIC SUBSTANCES

27/OCT/ 2002

MEMORANDUM

Product Name: CYHALOTHRIN TECHNICAL
EPA Reg No.: 100-1013
DP Barcode: D284097
Case: 052970
PC Code: 128867 Cyhalothrin

From: Masih Hashim, Toxicologist *MUH*
Technical Review Branch *scr*
Registration Division (7505C)

To: William Sproat, PM Team 03
Insecticide Branch
Registration Division (7505C)

Registrant: Syngenta Crop Protection, Inc.

Ingredients from Label:

Active ingredient	Lambda-cyhalothrin	87.08%
Other ingredients		12.92%

ACTION REQUESTED: "Please review the attached study MRID 45698201, label and CSF for EPA Reg. No. 100-1013 to determine if the attached mouse study would have an impact on the signal word."

William Sproat
pm-03

BACKGROUND: The Registrant has submitted an acute toxicity study in mice to determine if this would affect the outcome of previously submitted study for the Product 100-1013.

COMMENTS AND RECOMMENDATIONS:

The new study Number MRID 456982- 01 has Tox Category I, and this replaces the outcome of previous study (D273287) on the product. The signal word is also changed to Danger.

Acute oral toxicity	I	Acceptable MRID 456982-01
Acute dermal toxicity	II	cited #100-1013
Acute inhalation toxicity	II	cited #100-1013
Primary eye irritation	II	cited #100-1013
Primary dermal irritation	IV	cited #100-1013
Dermal sensitization	No	cited #100-1013

Label Review System

Label Review System

COMPLETED

PRODUCT ID #: 000100-01013

PRODUCT NAME: PP 321 TECHNICAL

PRECAUTIONARY STATEMENTS

SIGNAL WORD: DANGER

POISON ☠

SPANISH SIGNAL WORD: PELIGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

Hazards to Humans and Domestic Animals:

Restricted Use Pesticide due to toxicity categories. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification. Child Resistant Packaging Required.

Fatal if swallowed. May be fatal if absorbed through skin. May be fatal if inhaled. Causes substantial but temporary eye injury. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Do not get in eyes, on skin, or on clothing. Wear long-sleeved shirt and long pants, socks, chemical-resistant footwear, and gloves. Remove and wash contaminated clothing before reuse. Do not breathe dust. Do not get in eyes or on clothing. Wear protective eye wear (goggles, face shield, or safety glasses). Wear: Long-sleeved shirt and long pants, Socks, Shoes, and gloves.

For handling activities, use a non-powered air purifying respirator equipped with an N-, R-, or P-series filter.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. For overhead exposure wear chemical-resistant headgear. When cleaning equipment wear a chemical-resistant apron.

First Aid:

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If inhaled:

- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN: Note to PM/CRM/Registrant: The proposed label should contain a Note to Physician which addresses the category I Acute Oral Toxicity. The following statements are suggested types of information that may be included, if applicable:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

NOTE TO PHYSICIAN: Note to PM/CRM/Registrant: The proposed label should contain a "Note to

Physician". The following statements are suggested types of information that may be included, if applicable: - technical information on symptomatology; - use of supportive treatments to maintain life functions; - medicine that will counteract the specific physiological effects of the pesticide; - company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

DATA EVALUATION RECORD

STUDY TYPE: ACUTE ORAL TOXICITY TESTING (870-1100)

PRODUCT MANAGER: 03

REVIEWER: M. HASHIM

TEST MATERIAL: Cyhalothrin (87%), Off white colored solid, Reference No. P13, D3239/11

CITATION: Southwood, J. (1984) Acute Oral Toxicity Study to the Mouse. Central Toxicology Laboratory, Cheshire, UK, Study No. CLT/P/1066 dated 11-28-84, MRID 456982-01. Unpublished.

SPONSOR: Syngenta Crop Protection, Inc. P. O. Box 18300 Greensboro, NC 27419-8300

EXECUTIVE SUMMARY: In an acute oral toxicity study (456982-01), Lambda-Cyhalothrin (87%) was administered to 5 male and 5 female albino mice (SPF, Source Animal Breeding Unit, Imperial Chemical Industries, Pharmaceutical Division, Alderley park, Macclesfield, Cheshire, UK) at a dose of 1, 5, 25 or 100 (equivalent to 0.99, 4.9, 24.6, or 95.7) mg/kg body weight. The test substance was formulated in corn oil and given by oral gavage. Animals were assessed daily for systemic toxicity for a subsequent period up to 15 days. Initial and weekly body weights and (terminal) necropsy findings were recorded.

Oral LD50 for the test substance in male mice was /female mice was > 19.9 mg/kg. The study is classified as Tox Category I.

All animals died at 95.7 mg/kg. Six of 10 animals died at 24.6 mg/kg group. Clinical signs were 1-7 were piloerection, upward curvature of the spine, ataxia and salivation (1-7) days.

This study (870-1100) is Acceptable in accordance with the Sub-Division F guideline.

COMPLIANCE: The study is in compliance with GLP, signed and dated.

RESULTS:

Table 1. Number of Deaths/ Total No. of Animals

Dosage mg/kg	Male	Female
0.99	0/5	0/5
4.9	0/5	0/5
24.6	3/5	3/5
95.7	5/5	5/5

Necropsy Findings: Necropsy findings were not significant.

ACUTE TOX ONE-LINERS

1. DP BARCODE: D284097
2. PC CODE: 128867
3. CURRENT DATE: 10-27-02
4. TEST MATERIAL: Lamda- Cyhalothrin Technical

Study/Species/Lab Study #/Date	MRID	Results	Tox. Cat.	Core Grade
Acute Oral toxicity study/rat/ CTL- UK/ CTL/P/ 1066/ 11-28-84	456982-01	LD ₅₀ = 19.9 mg/kg m+f	I	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable