1/1. 38906-15 - PM 32

JUL 16 1987

Glyco, Inc.
22-10 Rt. 208
Fair Lawn, NJ 07410

Attention: Joseph A. Conti
Manager Governmental Relations

Gentlemen:

Subject: Dantobrom P
EPA Registration No. 38906-15
Your Applications Dated August 15, 1986 and January 27, 1987

This is to inform you that we have completed our evaluation of the data submitted in accordance with the conditions of this product's registration issued on July 22, 1986.

1. The results of our evaluation of these data are as follows:

   a. In order for us to determine whether the teratology study in Sprague-Dawley rats satisfies the Guideline requirements, clarification of the composition and purity of the test substances must be submitted.

   b. Before we can complete our review of the teratology study in New Zealand White rabbits, historical control data on the incidence of fetal resorptions and on fetal body weights observed in the investigators' laboratory on the strain of rabbits used in the study must be submitted. Clarification of the chemical composition and purity of the test compounds must also be submitted.

   c. The 90-day oral study is also deficient. Submit the individual animal data supporting the investigators' conclusions. The chemical composition and purity of the test compounds also need to be clarified.

91564:I/C:Douglas:K-8:KENCO:7/13/87:7/23/87:aw:vo:ek
~~R:91566:Douglas:K-8:KENCO:7/15/87:7/27/87:EK~~

CONCURRENCES

SYMBOL	ORIGIONATOR							
SURNAME								
DATE								

OFFICIAL FILE COPY

d. The primary eye irritation and primary dermal irritation studies submitted are adequate to place the product in the following Toxicity Catagories:

Eye irritation - III
Skin irritation - IV

No precautionary labeling changes are required based on these studies.

e. In order for us to determine whether the dermal sensitization studies meet Guideline requirements, information relative to the identification, purity or strength as required by Section 160.105 of Title 40 of the Code of Federal Regulations must be submitted.

f. Both the hydrolysis and the aqueous photolysis data requirement are satisfied for the registration of halogenated dimethylhydantoin for indoor and outdoor swimming pools and spas use.

The data indicate that halogenated hydantoins undergo a very fast hydrolysis at pH 5, 7, and 9 to monohalogenated hydantoins. Sunlight does not appear to enhance the degradation of dihalohydantoins in water.

g. The metabolism studies on 5,5-dimethylhydantoin (DMH) and 5-ethyl-5-methylhydantoin (EMH) were unacceptable to support registration of the compounds because they were deficient in the following respects: the radiochemical purity and specific activity of the test compounds were not reported; individual animal weights were not reported; except for the repeat section of the EMH study in which all females received the same dose regardless of weight, the individual doses administered were not reported; inadequate numbers of animals were used in the studies; data were reported as cpm without correction for background counts, quenching or counting efficiency rather than as ^{14}C equivalents of parent compound. In addition, the TLC plates used to identify the metabolites seemed to have been contaminated.

2. The data/information requested in items 1a, b, c, e, and g above must be submitted by August 28, 1987.

3. The revised labeling submitted on January 27, 1987 is being accepted under section 3(c)(7)(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) with the understanding that the data deficiencies noted above will be satisfied.

4. As indicated on the Registration Notice, if the conditions of the registration are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e).

3/4

A stamped copy of the label is enclosed for your records.

For your records, please note the following EPA Accession Numbers which have been assigned to the data submitted:

- Acute toxicity of hydrolysis and photolysis of halogenated compounds . . . 263983 and 263899.
- Primary eye irritation study on 5,5-dimethylhydantoin (DMH) . . . 265027, 263899, and 263983.
- Primary eye irritation study on 5-ethyl-5-methylhydantoin (EMH) . . . 265030, 263899, 265039, and 263983.
- Primary dermal irritation study on DMH . . . 265034, 263899, 265029, and 263983.
- Primary dermal irritation study on EMH . . . 265028, 263899, 265035, and 263983.
- Distribution study of 5,5'-dimethylhydantoin-[5-^{14}C] in New Zealand White rabbits . . . 265036 and 265025.
- Distribution study of 5-methyl-5-ethylhydantoin-[5-^{14}C] in New Zealand White rabbits . . . 265038 and 265026.
- Delayed contact hypersensitivity study in guinea pigs (DMH) . . . 401616-01 and 401617-01.
- Delayed contact hypersensitivity study in guinea pigs (EMH) . . . 401616-02 and 401617-02.
- 90-Day repeated dose oral toxicity study on EMH and DMH in rats . . . 265032 and 265042.
- Developmental toxicity study in rabbits on EMH and DMH (limit test - TSCA Guidelines) . . . 265033 and 265040.
- Developmental toxicity study in rats on EMH and DMH (limit test TSCA Guidelines) . . . 265031 and 265041.

Sincerely yours,

Jeff Kempter
Product Manager (32)
Disinfectants Branch
Registration Division (TS-767C)

Enclosure

DANTOBROM™ F

BROMINATING DISINFECTANT FOR SWI

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

HARMFUL IF SWALLOWED. HIGHLY CORROSIVE. DO NOT TAKE INTERNALLY.Causes eye and skin damage.Irritating to nose and throat.Avoid breathing dust.Use with adequate ventilation.Do not get into eyes, on skin or clothing.Wear rubber gloves and goggles or face shield when handling. Wash thoroughly after handling.Immediately remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish.Do not discharge into lakes, streams, ponds, or public water unless in accordance with a NPDES permit.For guidance contact your Regional Office of the EPA.Do not contaminate water by cleaning of container and equipment or disposal of wastes.

PHYSICAL AND CHEMICAL HAZARDS

CHEMICAL HAZARD:STRONG OXIDIZING AGENT.Mix only with water.Use clean dry utensils.Do not add this product to any dispensing device containing remnants of any other product.Such use may cause a violet reaction leading to fire or explosion.Contamination with moisture, organic matter, or other chemicals may start a chemical reaction with generation of heat, liberation of hazardous gases, and possible generation of fire and explosion. In case of contamination or decomposition, do not reseal container.If possible, isolate container in open air or well ventilated area.Flood with large volumes of water if necessary.

KEEP CONTAINER TIGHTLY CLOSED
STORE IN A COOL DRY PLACE
DO NOT STORE AT ELEVATED TEMPERATURES

Active Ingredients:	
1-bromo-3-chloro-5,5-dimethyl-hydantoin	60.0%
1,3-dichloro-5,5-dimethylhydantoin	27.4%
1,3-dichloro-5-ethyl-5-methyl-hydantoin	10.6%
Inerts	2.0%
Available bromine	39.2%
Available chlorine	44.4%

EPA Reg. No. 38906-15
EPA Est. No. 38906-PA 01

KEEP OUT OF REACH OF CHILDREN

DANGER

STATEMENT OF PRACTICAL TREATMENT

In case of ingestion,feed gruel,cooked cereal or bread soaked in milk followed by olive oil.Immediately contact physician.

In case of contact with eyes,flush eyes immediately with plenty of water for at least 15 minutes. Immediately contact physician.

In case of contact with skin,wash immediately with soap, and plenty of water.Immediately contact physician.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

ACCEPTED
with COMMENTS
In EPA Letter Dated:

GLYCO®
A LONZA COMPANY
Williamsport, PA 17701

JUL 16 1987

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 38906-15

NET CONTENTS