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

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MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Subject: 5,5-Dimethylhydantoin and 5,ethyl,5 methylhydantoin
EPA ID# 38906-3, -4, -7, -9, -12, -13, -14, 15.
Tox. Chem. No(s)366D, 568E, 309C

From: Joycelyn E. Stewart, Ph.D. 2/24/88
Section VII, Toxicology Branch
Hazard Evaluation Division (TS-769C)

To: Jeffrey Kempter/John Wilson, PM# 32
Disinfectants Branch (TS-767C)
Registration Division

Thru: Albin B. Kocialski, Ph.D. ABK 2/26/88
Supervisory Pharmacologist
Toxicology Branch/HED (TS-767C)

Registrant: Glyco Inc.
Norwalk, Connecticut 06856-5100

Action Requested: Evaluate the request to waive the requirement for subchronic and chronic data imposed by the Data Call-In Notice for Antimicrobial Pesticide Active Ingredients for the following halogenated hydantoin compounds:

Glychlor Powder: dichlorodimethylhydantoin, 97% [redacted]

Bromochlor Powder: 1-bromo-3-chloro-5,5 dimethylhydantoin, 90%
1,3 dibromo-5,5, dimethylhydantoin, 10%

Dantochlor RW: 1,3, dichloro-5,5 dimethylhydantoin, 75.6%
1,3, dichloro-5,ethyl-5 methylhydantoin, 13.5%
[redacted]

Dantochlor: 1,3 dichloro-5-5-dimethylhydantoin, 75.6%;
1,3-dichloro-5-ethyl-5-methylhydantoin, 13.5%
[redacted]

Dantobrom RW: 1-bromo-3-chloro-5,5,dimethylhydantoin, 60%
1,3 dichloro-5,5 dimethylhydantoin, 27.4%
1,3 dichloro-5-ethyl-5 methylhydantoin, 10.6%

PRODUCT FORMULATION INFORMATION IS NOT INCLUDED

Dantobrom S: 1-bromo-3-chloro-5,5, dimethylhydantoin, 60%
1,3,dichloro-5-dimethylhydantoin, 27.4%
1,3,dichloro-5-ethylmethylhydantoin, 10.6%.

Dantobrom: 1-bromo-3-chloro-5,5, dimethylhydantoin, 60%
1,3-dichloro-5,5 dimethylhydantoin, 27.4%
1,3-dichloro-5-ethyl-5-methylhydantoin, 10.6%

Dantobrom P: 1-bromo-3-chloro-5,5-dimethylhydantoin, 60%
1,3-dichloro-5,5-dimethylhydantoin, 27.4%
1,3, dichloro-5-ethyl-methylhydantoin, 10.6%

The company is requesting waiver of these data based on their submission of 90 day oral studies on EMH and DMH in rats, and teratology studies of EMH and DMH in rabbits and rats, which were submitted to support the registration of Dantobrom S and Dantobrom P as disinfectants for spas and swimming pools (Submission #s 265031/265032/265033).

Recommendations

Toxicology Branch recommends that the data waiver request be denied at this time for the reasons stated in the review.

Discussion

Glyco has submitted subchronic and teratology studies on dimethylhydantoin (DMH) and ethylmethylhydantoin (EMH) to support the registration of Dantobrom P and Danntobrom S. The subchronic studies(teratology and 90 day feeding) are still undergoing Agency review. If these studies are classified as core-Minimum or better, they may be used along with the exposure data to negate further chronic testing of DMH and EMH (i.e the currently registered halogenated hydantoins in the above noted products; see also Data Call-In Notice Tier III, chronic feeding) provided that the confidential statement of formula lists no other active ingredient. The registrant needs to contact the Exosure Assessment Branch (EAB) with regard to satisfying the data requirements for exposure. The Toxicology Branch is unable at this time to determine whether or not chronic or other studies will be required or considered based upon the subchronic studies alone. Therefore, the data waiver request based on subchronic studies is denied at this time for the subject products.

A battery of mutagenicity studies on DMH has also been submitted to support registration of Dantobrom P and Dantobrom S. These acceptable studies were all negative for mutagenicity and fulfilled the data requirements for the Tier I mutagenicity testing for DMH. A battery of acceptable mutagenicity studies on EMH has also been submitted. These studies were all negative with the exception of the chromosomal aberration study in Chinese Hamster Ovary (CHO) cells which was positive only with metabolic activation but not at any dose level in the nonactivated system. These studies fulfilled the data requirements for Tier I mutagenicity testing for EMH. The registrant has recently submitted a CHO mutagenicity study with 1,3,dichloro, 5,ethyl 5, methylhydantoin. Under the test conditions, dose related chromosomal aberrations were observed.

Based on the weight of the available mutagenicity evidence, Toxioclogy Branch believes that the mutagenicity data does not trigger additional subchronic or chronic studies.