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TECHNICAL SUPPORT SECTION TOXICITY REVIEW - I

Disinfectants Branch

IN 07/24/86 OUT 11/26/86

Reviewed by James E. Wilson, Jr. 12-1-86 Date 11/25/86

EPA Reg. No. or File Symbol 38906-13, 15

EPA Petition or EUP No. NONE

Date Division Received 07/17/86

Type Product(s): I,(D), H, F, N, R, S

Data Accession No(s) 263899

Product Mgr. No. 32 (Kempter)

Product Name(s) Dantobrom S & P

Company Name (s) Glyco, Inc.

Submission Purpose Resubmission - Tox. Data

Chemical & Formulation Briquette

Active ingredient (s):	%
1-Bromo-3-chloro-5,5-dimethylhydantoin	60.0
1,3-Dichloro-5,5-dimethylhydantoin	27.4
1,3-Dichloro-5-ethyl-5,methylhydrantoin	10.6

BACKGROUND

Dantobrom RW, Dantobrom S, Dantobrom, and Dantobrom P all are the same formulation; the EPA Reg. Nos. are 389906-12, 13, 13 and 14, respectively. The uses are as follows:

		Date Registered
Dantobrom RW -	Recirculating industrial water systems and airwashers	9/12/84
Dantobrom S -	Spas and hot tubs	7/22/86
Dantobrom -	Reformulating and repacking	09/84
Dantobrom P -	Swimming Pools	7/22/86

This reviewer, in an evaluation of 2/23/84 submission for the RE (12) formulation, stated that no additional acute toxicity data needed to be submitted based on the corrosive nature of the active ingredients, pH and an acute oral study on the product. The actual acute oral study is found in the Dantobrom file (14). A matrix of acute studies on the three actives in the formulation and the formulation itself appear in the Dantobrom P file (15) with a letter from the company dated July 9, 1984 (Section 5 of 9). All the studies characterize the test materials as corrosive and dermally sensitizing; Dantobrom P was not test for dermal sensitivity.

HED/TB in a memo from Mauer to Castillo dated July 12, 1984, stated that the data submitted was inadequate to assess the acute and chronic hazards of DMH and adequate but insufficient to evaluaate MEH (EMH) (both are hydrolysis products of the active ingredients). An HED/TB memo dated September 12, 1984, accepted the proposed uses of these formulations excluding pools and spas; the safety of MEH was again questioned.

Glyco rebutted the toxicology data requirements in a letter dated November 20, 1984, and made a proposal as to how they would like to fill the data graps. HED/TB responded by insisting that subchronic oral, one teratogenic, a mutagenicity battery and metabolism data be submitted prior to further action. Subsequent to Glyco receiving that information, they, in a letter dated May 9, 1985 requested that the chronic and subchronic data only be required on DMH since the only difference is an ethyl group rather than a methyl. TB agreed with this since the acute comparisions were similar and the formulation would contain approximately 90% DMH. TB,

in its October 31, 1985 memo, also added the second species teratology study, rat reproduction, chronic rodent and non-rodent, oncogenic study in two species and a 21-day dermal study to its recommendations.

Our letter of acceptance of these products for pool and spa use only included teratology (2 species), 90-day subchronic oral and physiological disposition studies. (The acute studies requested probably serve no useful purpose in the matter.) The registrations are conditional that the above mentioned studies he submitted on or before August 20, 1986.

OBSERVATION

It, to the best of this reviewer's knowledge, is a deviation in policy to register products whose uses result in high exposure such as those experienced in swimming pools and spas prior to revieving and evaluating the requested toxicology data. The damage to public health could be far reaching. I strongly disagree with this action.

The precautionary labeling is deficient in that there is no warning with regard to the dermal sensitization produced by all the active ingredients. This resulted from not having a second review prior to registration.

Eye and skin irritation data submitted on DMH and EMH will not be reviewed since precautionary labeling is based on acute toxicity studies using the formulated product.