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FEDERAL BUREAU OF INVESTIGATION
DEPARTMENT OF JUSTICE

MEMORANDUM

SUBJECT: DantoBrom™, Dantobrom S & Dantobrom P, Data requirements for Use in SPAs, and swimming Pools, Glycol

TO: Arturo Castillo PM-32
Registration Division (TS-767)

FROM: ~~Robert P. Zendzian~~ PhD, Acting head
Review Section IV
Toxicology Branch
HED (TS-769)

3/12/85
W. W. P. S. 3/12/85

THROUGH: Theodore M. Farber PhD, Chief
Toxicology Branch

Compound, 1-Bromo-3-chloro-5,5-dimethylhydantion
1-3-dichloro-5,5-dimethylhydantion
1-3-dichloro-5-ethyl-5-methylhydantion

Tox Chem #114A, 360 & 309C Registration #38906-14 & 38906-RL
Registrant, Glycol Accession #N/A

Action Requested

The Registrant questions the toxicity data requirements for registration of their product for use in swimming pools and SPAs and proposes to perform the following studies on the organic portion of the active ingredients.

1. Primary dermal irritation - DMH, EMH
2. Primary eye irritation - DMH, EMH
3. Skin sensitization - DMH, EMH
4. Physiological disposition of DMH using radio-labeled DMH.

Recommendation

The Agency is interested in the human safety of two things in this product, the use product Dantabrom and the organic moities thereof (5,5-dimethylhydantion and 5-ethyl-5-methylhydantion).

1). The use product is well established as a highly caustic material. The precautionary statements re: hazard to humans and domestic animals adequately describe its danger. Toxicity testing of this material is not required.

2) 5,5-dimethylhydantion and 5-ethyl-5-methylhydantion. Toxicology Branch recommends acceptance of the Registrant's proposed studies but further recommends the following data as part of a tier approach to generating data on these compounds for the projected uses. The following studies should be requested with the understanding that additional studies may be required depending upon the results of these studies and/or the amount of human exposure.

§82-1 Subchronic oral toxicity in the rat.

§83-3 Teratogenicity study in the rat or rabbit, the rabbit is suggested.

§84-2 Mutagenicity battery (this requirement is satisfied by the studies previously submitted and referenced by the Registrant)

§85-1 Metabolism in the rat (dependent upon the results of the physiological disposition study proposed by the Registrant)