Disinfectants Branch

Reviewed by James E. Wilson, Jr. 7/10/87 Date 07/06/87

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

Data Accession No(s) 265027-30, 265034, 35, 39

Product Mgr. No. 32 (Kempter)

Product Name(s) Dantobrom S and Dantobrom P

Company Name(s) Glyco, Inc.

Submission Purpose Resubmission

Chemical & Formulation Power

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-methylhydantoin ............... 10.6%
These products will be used as disinfectants for swimming pools, hot tubs and spas. The two chemicals DMH and EMH were tested separately. See OSS Toxicology review dated 11/25/86 for previous action.

RECOMMENDATION

The data submitted are adequate to place the product in the following toxicity categories:

Skin Irritation - 4
Eye Irritation - 3

Even though the irritation studies on the individual chemicals indicated they are not very irritating the studies on the formulation do not give the same results. No changes will be recommended based on these studies.

LABELING

No changes required.

CRP STATUS

Special packaging not required.

DATA REVIEW


The following studies were done on 5,5-Dimethylhydantoin. (MRID Nos. 265027,029,035).

Skin Irritation

Method - Six white rabbits received single dermal applications of 5 g of the test material on one intact site. After application the areas was covered with a gauze patches and occluded for 4 hours. The residual chemical was washed from the skin. Reactions were examined and recorded 5, 24, 48 and 72 hours after application.

Results - No irritation was observed at any observation period.

Conclusion - The product is not a skin irritant.
**Eye Irritation**

**Method** - The eyes of six New Zealand white rabbits were examined before the test. One-tenth gm of the test material was instilled into the conjunctival sac of one eye of each rabbit. None of the eyes were rinsed. All eyes were examined periodically for 21 days after instillation or until irritation disappeared.

**Results** - Twenty-four hours after instillation all eyes exhibited mild conjunctival irritation. Corneal opacity and iritis did not appear. Four of six showed irritation after 72 hours; all cleared by day 7.

**Conclusion** - The product is mild irritation to ocular tissue.

The following studies were conducted on 5, Ethyl-5-methyl-hydantoin. (MRID Nos. 265028, 030, 035, 039).

**Skin Irritation**

**Method** - Six white rabbits received single dermal applications of 0.5 ml of the test material on one intact site. After application the areas were covered with a gauze patches and occluded for 4 hours. The residual chemical was washed from the skin. Reactions were examined and recorded 5, 24, 48 and 72 hours after application.

**Results** - No irritation was observed at any observation period.

**Conclusion** - The product is not a skin irritant.

**Eye Irritation**

**Method** - The eyes of six New Zealand white rabbits were examined before the test. One-tenth gm of the test material was instilled into the conjunctival sac of one eye of each rabbit. None of the eyes were rinsed. All eyes were examined periodically for 21 days after instillation or until irritation disappeared.
Results - Twenty-four hours after instillation 5/6 eyes exhibited mild conjunctival irritation. Corneal opacity and iritis did not appear. Five of six showed irritation after 72 hours; all cleared by day 7.

Conclusion - The product is mild irritant to ocular tissue.