

Shaughnessy No.: (A) 006315
(B) 028501

Date out of EAB: 12 SEP 1984

To: Castillo/Laird
Product Manager #32
Registration Division (TS-767)

From: Samuel M. Creeger, Chief *SMC*
Environmental Chemistry Review Section 1
Exposure Assessment Branch
Hazard Evaluation Division (TS-769c)

COPY

Attached, please find the EAB review of:

Reg./File No.: 38906 - RL

Chemical: (A) 1-bromo-3-chloro-5,5 dimethyl hydantoin (60%);
(B) 1,3-dichloro-5,5-dimethylhydantoin (27%); (C) 1,3-dichloro-5-
ethyl-5-methylhydantoin (10.6%)

Type Product: Microbiocide

Product Name: DantoBrom P

Company Name: Glyco

Submission Purpose: use in swimming pools

ZBB Code: other

Action Code: 115

Date In: 8/3/84

EAB No.: 4496

Date Completed: 9/12/84

TAIS (Level II) Days

Deferrals To:

61

1.5

Ecological Effects Branch

Residue Chemistry Branch

Toxicology Branch

158017

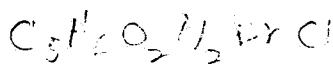
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1.0 INTRODUCTION

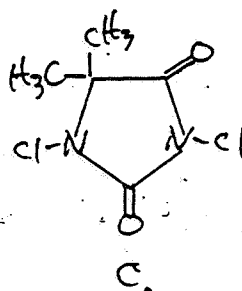
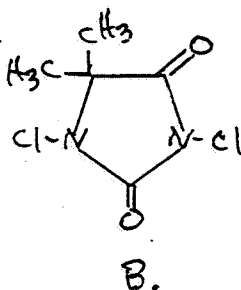
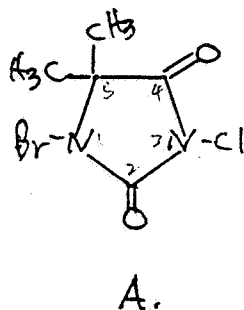
Chemical Name and Type of Pesticide: swimming pool disinfectant

- A. 1-bromo-3-chloro-5,5-dimethylhydantoin, 60% ai.
- B. 1,3-dichloro-5,5-dimethylhydantoin, 27.4% ai.
- C. 1,3-dichloro-5-ethyl-5-methylhydantoin, 10.6% ai.

Trade Name: DantoBrom P



Chemical Structure:



Glyco, Inc. is applying for the registration of DantoBrom P as a disinfectant in swimming pools. Each of the active ingredients in this submission (above) are in products that Glyco or other companies made application to register with the EPA. Two pages that are the introduction to Glyco's Product Registration Application were copied intact and are attached. The label (attached) prohibits use in marine and/or estuarine oil fields. Direct discharge into lakes, streams, or ponds must be in accordance with NPDES permit.

2.0 DIRECTIONS FOR USE

See attached label.

3.0 DISCUSSION OF DATA

The three active ingredients in the product (DantoBrom P) of this review were also in the biocide DantoBrom RW, the registration application of which was previously reviewed (13 April 1984).

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The studies reviewed were hydrolysis and aqueous photolysis. The hydrolysis requirement is part of our guidelines. The aqueous photolysis data was requested because of the indirect discharge aquatic impact of the biocide. Both studies were judged inadequate. The conclusions of the studies and the recommendations of the review were copied intact and are attached.

4.0 RECOMMENDATION

4.1 The data requirements for a product used in swimming pools depend upon whether there is Direct Discharge, Indirect Discharge, or No Discharge.

4.2 Direct discharge means "the release, treatment, or application of a pesticide product directly to water at sites within or directly connected to bodies of water to which wild animals, birds, fish, and similar organisms have free access." The requirements for this type of discharge are:

- Hydrolysis
- Photodegradation-water
- Aerobic aquatic metabolism
- Anaerobic aquatic metabolism
- Leaching (Adsorption/desorption)
- Water field dissipation
- Fish accumulation
- Aquatic nontarget accumulation

4.3 Indirect Discharge means "release, treatment, or application of a pesticide product to water at sites not directly connected to bodies of water to which wild animals, birds, fish, and similar organisms have free access."

The data requirements for this type of discharge is a hydrolysis study only.

4.4 No Discharge - A hydrolysis study is still required.

4.5 If direct discharge of DantoBrom P residues occurs (in accordance with NPDES permit) then the data required are those in Section 4.2.

Herbert L. Manning
Herbert L. Manning, Ph.D.
Microbiologist
EAB/HED

Disinfectant For Swimming Pools

DIRECTY

It is a violation of Federal Law inconsistent with its labeling.

When used as directed, DantoBrom and keep the water clear and free

When refilling or filling, remove Clean the sides with a non-abrasive rinse thoroughly. The filter system properly cleaned, the pH adjusted to 7.8, and the water chemically balanced with bromine per 1000 gallons of water that a chlorine residual of 1 to 3 ppm is maintained. Add DantoBrom P briquettes to the feeder in accordance with the instructions as to maintain 1 to 3 ppm of free available chlorine residual. Use the reliable bromine test kit.

If it is necessary to "shock" the pool during the swimming season, add a chlorine residual

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Store in a well ventilated area away from open flame. Open dumping is prohibited. Do not store in an empty container.

In case of decomposition, isolate container, if possible, and flood with large amounts of water to dissolve material before discarding.

Pesticide or rinsate that cannot be used or otherwise processed should be disposed of in a landfill or other approved site for pesticides.

TRIPLE RING THE FIBER AND PLASTIC CONTAINERS BEFORE DESTROYING BY PERFORATION OR CRUSHING in a safe place away from water supplies. Rinsed containers may be disposed of by incineration. Consult federal, state or local authorities for appropriate alternative procedures.

FPA REG. NO.

EPA EST. NO.

ACTIVE INGREDIENTS:

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%
Inerts	2.0%

Available bromine.....39.2%

Available chlorine....44.4%

KEEP OUT OF REACH OF CHILDREN

DANGER

STATEMENT OF PRACTICAL TREATMENT

In case of ingestion, feed gruel, cooked cereal or broad beans 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 be indicated by the use of gastric lavage.

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 violent reaction leading to fire or explosion. Contamination with fertilizer, 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 resal 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

NET CONTENTS:

Approx. 10g./briquette

ALYCO[®]

Williamsport, Pa 17701

Swimming Pools

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

When used as directed, DantoBrom P will disinfect swimming pools, and keep the water clear and free of odor.

When refilling or filling, remove all leaves and debris from pool. Clean the sides with a non-abrasive, low foaming cleaner, and rinse thoroughly. The filter system should be backwashed or properly cleaned, the pH adjusted and maintained between 7.2 to 7.8, and the water chemically balanced. Add 0.21 lb. of sodium bromide per 1000 gallons of water. Superchlorinate the pool so that a chlorine residual of 1 to 3 ppm of chlorine is obtained. Add DantoBrom P briquettes to a suitable feeding device. Adjust the feeder in accordance with the manufacturer's instructions so as to maintain 1 to 3 ppm of free bromine as determined by a reliable bromine test kit.

If it is necessary to "shock" treat or superchlorinate the pool during the swimming season, add 0.21 lb. of sodium bromide, increase the chlorine residual to 1 to 3 ppm of chlorine, then resume feeding DantoBrom P, maintaining 1 to 3 ppm of free bromine.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Store in a well ventilated area away from heat or open flame. Open dumping is prohibited. Do not reuse empty container.

In case of decomposition, isolate container, if possible, and flood with large amounts of water to dissolve all material before discarding.

Pesticide or rinsate that cannot be used or chemically reprocessed should be disposed of in a landfill approved for pesticides.

TRIPLE RINSE THE FIBER AND PLASTIC CONTAINERS BEFORE DESTROYING by perforation or crushing and burying in a safe place away from water supplies. The rinsed containers may be disposed of by incineration. Consult federal, state or local authorities for approved alternative procedures.

EPA REG. NO. _____

EPA EST. NO. _____

ACTIVE INGREDIENTS:

-bromo-3-chloro-5,5-dimethyl-hydantoin	60.0%
3-dichloro-5,5-dimethylhydantoin	27.4%
3-dichloro-5-ethyl-5-methyl-hydantoin	10.6%
nerfts	2.0%

Available bromine....39.2%

Available chlorine....44.4%

KEEP OUT OF REACH OF CHILDREN

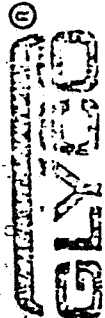
DANGER

STATEMENT OF PRACTICAL TREATMENT

In case of ingestion, feed gruel, cooked cereal or bread **WASHED** 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 be indicated by the use of gastric lavage.



Williamsport, Pa 17701

Page 6 is not included in this copy.

Pages ___ through ___ are not included in this copy.

The material not included contains the following type of information:

- Identity of product inert ingredients.
- Identity of product inert impurities.
- Description of the product manufacturing process.
- Description of quality control procedures.
- Identity of the source of product ingredients.
- Sales or other commercial/financial information.
- A draft product label.
- The product confidential statement of formula.
- Information about a pending registration action.
- FIFRA registration data.
- The document is a duplicate of page(s) _____.
- The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

DantoBrom™ P

Product Registration Application

Glyco Inc.

Introduction

DantoBrom™ P is intended for use as a pesticide to control the growth of objectionable bacteria, fungi, and algae in

...swimming pools...

The chemical composition of DantoBrom™ P is the following:

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%
Inerts-----	2.0%

The mixture is not a formulated product; the individual components are not made separately and combined. The product is made by adding bromine and chlorine to a mixture of dimethylhydantoin and ethylmethylhydantoin. The DantoBrom™ precipitates as a powder which is filtered, dried, and compacted into 10g briquettes. The briquettes are DantoBrom™ P.

Related applications have been filed. They are the following:

- DantoBrom™ 38906-RW Manufacturing use
- DantoBrom™ RW-38906-RE Product Registration (recirculating water)
- DantoBrom™ S-38906-RG Product Registration (spa disinfection)

All the above products are identical in composition. They are all made by compressing DantoBrom™ (a white powder) into briquette form without additives.

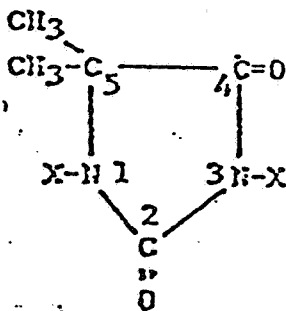
The halogenated dialkyl substituted hydantoins are not new chemical compounds. They have been used commercially for over thirty years. They are extensively utilized for the formulation of a variety of products used industrially and in the household. The principals used are (1) industrial bleaches, (2) cleaners, (3) household laundry bleaches, (4) spa and pool disinfectants, (6) disinfectants for paper and pulp processes.

There are currently thirteen (13) products registered with the Environmental Protection Agency which contain halogenated dialkyl substituted hydantoins as the principal active ingredient. Two (2) are registered for manufacturing use; six (6) for use in industrial water systems; two (2) for use in the pulp and paper industry; two (2) for spas; one (1) for swimming pools. The registrations are listed in Table I.

Introduction (continued)

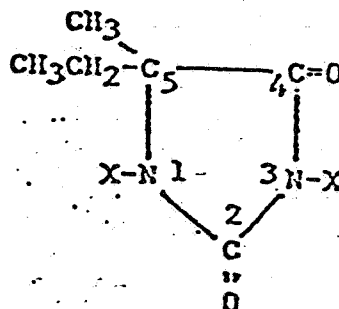
The currently registered halogenated dialkyl substituted hydantoins are either fine, extraordinarily dusty powders or forms such as sticks, pellets, and tablets which are fragile and degrade readily into fragments and dust during shipment and handling. Since the dust of halogenated hydantoins is irritating, corrosive, and sensitizing, improved technology was developed by Glyco to minimize these hazards, and yet maintain equivalent or improved effectiveness. The Glyco technology yields products which are low dust powders, and essentially dust-free tablets, briquettes, and granulas. DantoBrom™ P is a readily compactible powder of bromochlorinated dimethylhydantoin which is obtained by manufacturing a mixture of bromochlorinated dimethylhydantoin (85.9%) and bromochlorinated ethylmethylhydantoin (12.1%). Despite the low concentration of the latter, it acts as an incredibly powerful binder. Compaction of this industrial equipment yields briquettes (10 g.) which are hard and quite resistant to fracturing and powdering when exposed to rough treatment. For example, a 200 lb. container was shipped to the west coast (by truck) and returned with <1% breakage.

The chemical difference between these two halogenated hydantoins is minor. Dimethylhydantoin has two methyl groups in position 5, while ethylmethylhydantoin has a methyl and an ethyl group in this same position as shown in the following structural formulas:



X=halogen

Halogenated
Dimethylhydantoin



Halogenated
Ethylmethylhydantoin

Not unexpectedly, toxicity tests reveal that the properties of DantoBrom™ P are, for all practical purposes, equivalent to those of currently registered halogenated dialkyl substituted hydantoins. No significant changes in toxicology due to the presence of an ethyl rather than a methyl group were observed. DantoBrom™ P is actually safer to use than current products because of its improved physical properties.

Copied from review of 13 April 1984.

Conclusion - HYDOLYSIS

The study is inadequate. EAB is unable to draw a conclusion as to the hydrolytic half-life of the hydantoin as active ingredients in Dantobrom RW. The study did not follow the Environmental Fate Guidelines. Some deficiencies include:

- Study was conducted at 1 pH range, not 3.
- Temperature was excessive.
- Was distilled water sterilized?
- Only one sampling was taken (after 30 minutes).
- Analysis should have included the monohalogenated degradation products.
- No half-life calculations could be determined.

The registrant should provide data on hydrolysis at "use" concentration. The registrant makes the statement that at "use" concentrations of 3 to 5 ppm of Br₂ (total free halogen expressed as Br₂) products formed were limited to the simple parent hydantoin stripped of halogen. Also, the registrant should relate this "use" concentration (of 3 to 5 ppm of Br₂) to the label directions which call for up to 120 ppm formulation (1 lb. formulation per 1,000 gallons water). From the above statement, it would appear that the dehalogenated hydantoin ring would be the residue of concern in the environment (and not the imine or ketone fragments as reported of the 100 ppm concentrations).

3.2 Photolysis

Note: While this study is not required under the Guidelines, EAB does request this study in support of registration of pesticides for aquatic impact-indirect discharge uses.

A water/Dantobrom RW solution was prepared with sufficient product for a theoretical hydantoin concentration of 100 ppm. The solution was divided with one part exposed to sunlight for 30 days and the other kept in the dark.

Conclusion - PHOTOLYSIS

This study was not conducted according to the Environmental Fate Guidelines. Some deficiencies are:

- Only one sample was taken (after 30 days).
- No half-life can be calculated.
- Formulated product, not separate active ingredients were used. However, only one active needs to be studied if the registrant can conclude that the other actives should degrade similarly. Most likely that would be the case here.

However, the results show that, with the exception of increased loss of free chlorine in exposed sample, the results of the exposed sample and the unexposed sample were essentially the same.

EAB concludes that, at the concentration used, exposure of Dantobrom RW active ingredients to sunlight has little affect on degradation of the active ingredients. However, EAB does not accept the study as satisfying the photo-degradation data requirement. A study must be submitted using a concentration approximating the actual use concentration since the data in the hydrolysis study suggest the simple hydantoin is stable at "use" concentrations.

RECOMMENDATION

- 5.2 The registrant should submit a hydrolysis and photolysis study conducted at use concentrations. The registrant should consult the Environmental Fate Guidelines for information on conducting these studies.

EAB suggests that the registrant submit protocols for review before initiating these studies. The protocols should describe fully how the registrant intends to conduct the study.

- 5.3 The registrant should clarify the statement that at "use" concentrations of 3 to 5 ppm of Br₂ (total free halogen expressed as Br₂) products formed were limited to the simple parent hydantoins stripped of halogen. From the above statement, it would appear that the dehalogenated hydantoin ring would be the residue of concern in the environment.

- 5.4 The registrant should relate this "use" concentration (of 3 to 5 ppm of Br₂) to the label directions which call for up to 120 ppm formulation concentration in