

FILE COPY

Shaughnessy No: 006315

Date Out: EFB: 28 JUL 1981

PROPRIETARY

To: Product Manager 32 Castillo
TS-767

From: Dr. Willa Garner
Chief, Review Section No. 1
Environmental Fate Branch

Shawn for

Attached please find the environmental fate review of:

Reg./File No.: 1729-REE, 1729-REG

Chemical: Bromochloro-5,5-dimethylhydantoin

Type Product: Disinfectant

Product Name: Spa Brom

Company Name: Aquabrom/Tesco

Submission Purpose: Use in spas - incremental exposure

ZBB Code: 3(c)(7)

ACTION CODE: 176

Date in: 7/15/81

EFB # 889, 890

Date Completed: 28 JUL 1981

TAIS (level 11)

Days

Deferrals To:

62

2

Ecological Effects Branch

Residue Chemistry Branch

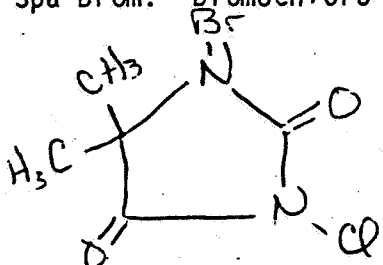
Toxicology Branch

1.0 INTRODUCTION

Aquabrom/Tesco has submitted data for dimethylhydantoin incremental risk assessment in spas and hot tubs. Dimethylhydantoin (DMH) is the dehalogenated derivative of the active ingredient, bromo-chloro-5,5-dimethylhydantoin (Spa Brom)

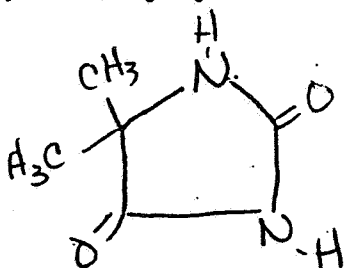
- 1.1 PM Note: EFB has been notified that the active ingredient is registered for use in swimming pools. EFB has not received any environmental data for review.

2.0 Spa Brom: bromochloro-5,5-dimethylhydantoin



1-bromo-3-chloro-5,5-dimethylhydantoin

2.1 5,5-dimethylhydantoin



3.0 DISCUSSION OF DATA

A large part of the submission presented data concerning the toxicology of diphenylhydantoin (DPH).

- 3.1 One section in the submission is entitled DMH Toxicology. EFB has two comments concerning this section.

o The following statements are made:

"Introduction of bromochloro-5,5-dimethylhydantoin (Spa Brom) into water results in the rapid hydrolysis of the compound to generate 5,5-dimethylhydantoin along with hypobromous and hypo-chlorous acids and their derivatives. By the time the human exposure occurs in a spa halogenated dimethylhydantoin species are no longer detectable and the toxicology of 5,5 dimethylhydantoin is the only relevant data to be considered."

No details concerning the hydrolysis of either the active ingredient or its major degradate are provided.

o In the toxicological summary of 5,5-dimethylhydantoin provided, among the studies summarized was a radiolabeled activated sludge study of the degradate of Spa Brom. Apparently by the 19th day, 94% of the 14-carbon had been recovered as carbon dioxide. The summary concludes that "5,5-dimethylhydantoin and its metabolites degrade with no obvious toxic effects upon the organisms."

3.2 Another section is called "DMH and DPH Comparison". Here, physical and biological comparisons are made on the basis of water solubility and acute oral toxicity data. Conclusions are drawn which seems to be based on intuition rather than those on actual physical, chemical, or biological data.

4.0 CONCLUSIONS

4.1 EFB would be interested in reviewing the hydrolysis and activated sludge studies alluded to in the submission.

4.2 EFB would also be interested in reviewing any physical-chemical data the registrant may have concerning the active ingredient and its dehalogenated derivative.

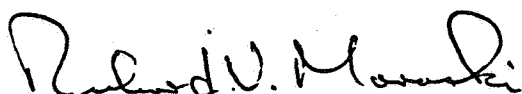
5.0 RECOMMENDATIONS

5.1 EFB does not concur with the conditional registration of Spa-Brom until the following data gaps are filled:

o EFB recommends that a hydrolysis study on the active ingredient be required. If hydrolysis data already exists, it should be submitted for review.

o On the basis that Spa Brom may be used in outdoor tubs, EFB is requiring an aqueous photolysis study.

o EFB recommends that the activated sludge study cited in the submission be submitted for review since regular draining of the spas could result in an indirect discharge into wastewater treatment plants.



Richard V. Moraski
Review Section No. 1
EFB/HED