

Shaughnessy No.: 216400

Date Out of EAB: _____

12/15/86

To: John lee
Product Manager #31
Registration Division (TS-767)

From: Herbert Manning Ph.D., Acting Chief *HJM*
Environmental Chemistry Review Section 1
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

Attached, please find the EAB review of...

Reg./File # : 148-REIG
Chemical Name: 2-Bromo-2-nitorpropane-1,3 diol (Bronopol)
Type Product : Bactericide
Product Name : BIOCIDE M-95
Company Name : Thomposon-Hayward
Purpose : Review of Hydrolysis Study

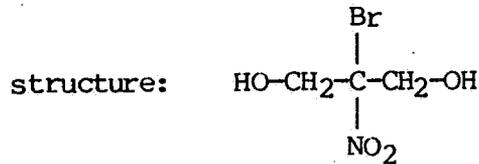
Action Code: 161 EAB #(s) : 70099
Date Received: 11-12-86 TAIS Code: _____
Date Completed: 12-12-86 Total Reviewing Time: 4.0
Monitoring study requested: _____
Monitoring study voluntarily: _____

Deferrals to: _____ Ecological Effects Branch
_____ Residue Chemistry Branch
_____ Toxicology Branch

3

1.

1. CHEMICAL: common name: Bronopol
chemical name: 2-bromo-2-nitropropane-1,3-diol
trade name: BIOCID MS-2



2. TEST MATERIAL: BIOCID MS-2
3. STUDY/ACTION TYPE: THOMPSON-HAYWARD CHEMICAL COMPANY
has submitted a hydrolysis study
for review in response to a previous
(12/3/85) review.
4. STUDY IDENTIFICATION: Crampton, E.L. 1986. BRONOPOL-
HYDROLYSIS STUDY. The Boots Company
PLC Industrial Division, Nottingham
Acc. No. 265269

5. REVIEWED BY:

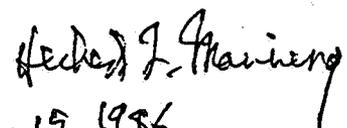
Alan N. Evans
Chemist
EAB/HED

Signature: 

Date: DEC 12 1986

6. APPROVED BY:

Herbert L. Manning
(Acting) Chief, Section 1
EAB/HED

Signature: 

Date: Dec 15, 1986

2

7. CONCLUSION:

- The label has been amended to forbid direct discharge, unless this product is specifically identified and addressed in an NPDES permit.
- The following information was cited in an earlier review dated Dec. 3, 1985, and is summarized below:

Hydrolysis- Aqueous solutions of Bronopl (0.2% w/v) prepared @ 20° C in buffer solutions of pH 4, 6, and 8 have half lives respectively; at pH 4, 1.5 yrs, at pH 6, 18 yrs, and at pH 8, 2 months. Hydrolysis products were formaldehyde and bromonitroethanol. Formaldehyde reacts with bronopol to form 2-hydroxy-methyl-2-nitro-1,3-propanediol.

The 12/3/85 review found the following deficiencies with the study:

- a. Was the study conducted in the dark?
- b. Give a complete description of the analytical method.
- c. A material balance was not provided.

If these issues can be adequately addressed, the study will be accepted. The registrant's response is discussed in the reviews in section 10 below.

8. RECOMMENDATIONS:

The registrant has replied to and met the conditions of an earlier request for information from EAB to satisfy the deficiencies of the study. The hydrolysis study is now acceptable.

9. BACKGROUND:A. Introduction

See sections # 3 and 7 of this review.

B. Direction for use

See attached proposed label.

10. DISCUSSION OF INDIVIDUAL TESTS OR RESULTSA. Study Identification

Bronopol-Hydrolysis study, Acc. # 265943

B. Materials and Methods

Bronopol was identified along with its degradates by the following instruments: IR spectrometry, gas chromatography, and thin-layer chromatography.

C. Results

Bronopol decomposes in alkaline, aqueous, and unbuffered solutions. Its degradation products were found to be formaldehyde, bromonitroethanol, and "tris". In alkaline solutions bronopol decomposes to formaldehyde with a half-life of about 2 months at pH 6 and 18 months at pH 8. On exposure to light bronopol decomposes in aqueous solutions. This process can be accelerated by raising the temperature (see attached graph). In unbuffered solutions bronopol decomposes in the presence of cupric or ferric ions.

D. Authors Conclusion

Bronopol is stable at pH 4, 6, and 8 at 20°C.

E Reviewers Comments

The study was done in 1968 and does not follow our present guidelines. However, based upon the study and its results, bronopol is very stable to hydrolysis. The registrant's responses to the deficiencies of the 12/3/85 review are as follows:

- a. EAB comment: Give a complete description of the analytical method.
Response: This was provided.
- b. EAB comment: A material balance was not provided.
Response: All degradates could not be identified at the time of the study, so a material balance was not done.
- c. EAB comment: Was the study conducted in the dark.
Response: Because our guidelines were not followed/available, the study was not done in the dark. However, photolysis of the sample was not a factor since degradation essentially did not occur.

11. COMPLETION OF ONE-LINER:

Not applicable

12. CONFIDENTIAL INDEX:

This review does not contain a CBI.

5

Bronopol remaining (%)

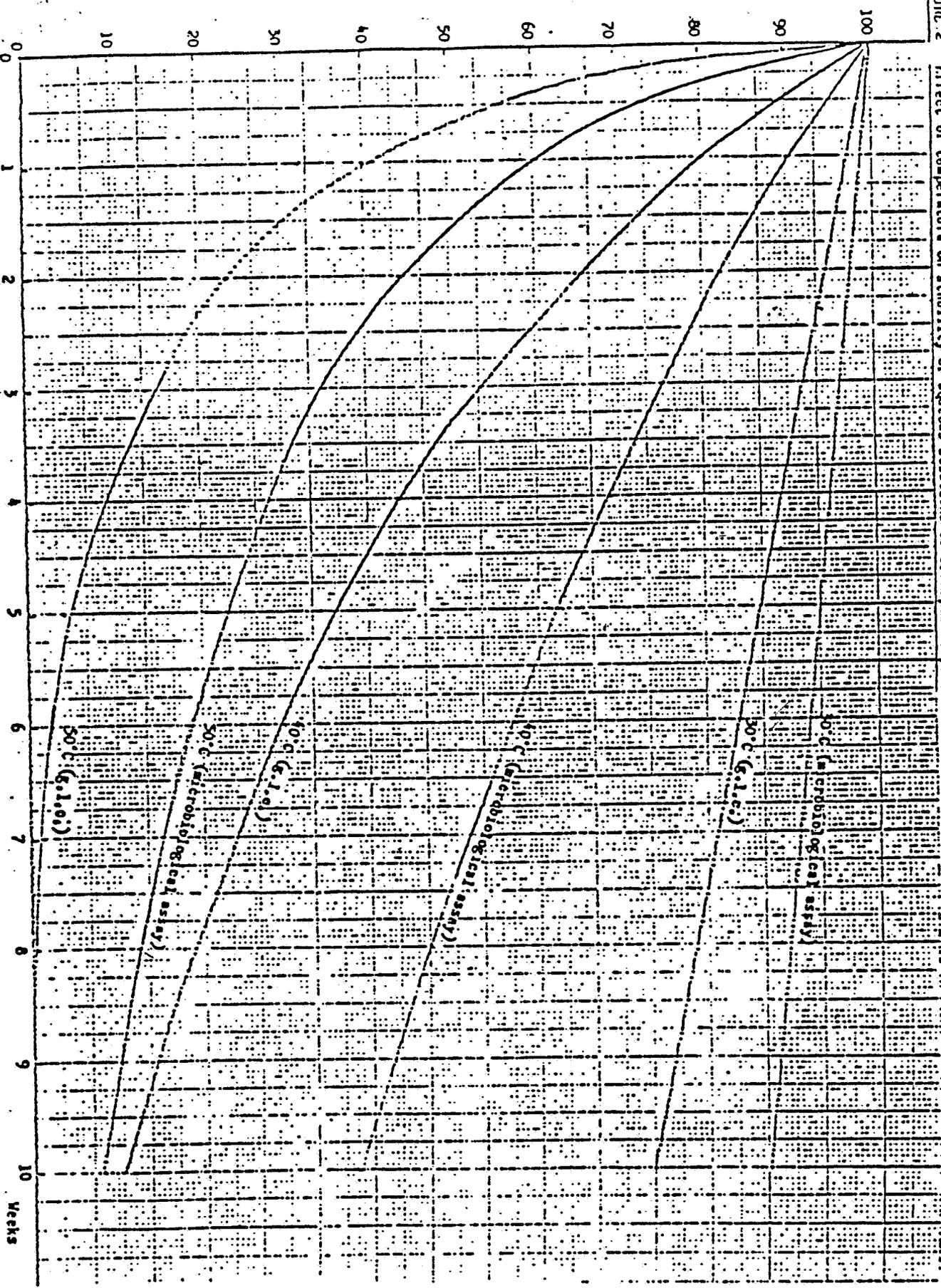


FIGURE 2 Effect of temperature on stability of aqueous solutions of bronopol at pH 6

6