US EPA ARCHIVE DOCUMENT
Mr. Ruben Wichy  
AmeriBrom, Inc.  
52 Vanderbilt Avenue  
New York, NY 10017

SUBJECT: Review of product chemistry and toxicology studies for the chemical 1-Bromo-3-chloro-5,5-dimethylhydantoin.

Dear Mr. Wichy:

The Agency has reviewed the Series 62 product chemistry studies, the acute inhalation, 81-3, and the upgrade information for the mutagenicity (Ames), 84-2(a), studies for the chemical bromo-chloro-dimethylhydantoin (Chem no. 6315, Case 3055) and has reached the following decisions:

Gdln 62-1 Preliminary Analysis of Product Samples  MRID 43219001

The analysis of product samples is performed by an iodometric titration procedure. Bromine and chlorine containing compounds which are present in Halobrom technical grade (TGAI) are determined by this procedure. This study is acceptable. No further information is required for this guideline.

Gdln 62-2 Certification of Ingredient Limits  MRID 43219001

All of the components of the product Halobrom are included in the Confidential Statement of Formula (CSF, EPA Form 8570-4, dated April 26, 1994). This information is acceptable. No further information is required for this guideline.

Gdln 62-3 Analytical Methods  MRID 43219001

Adequate analytical methods have been submitted to verify the certified limits of the TGAI. This information is acceptable. No further information is required for this guideline.

Gdln 81-3 Acute Inhalation Toxicity in Rats  MRID 43125601

The results of the acute inhalation study demonstrated LC₅₀s of 0.41 mg/l for male and 0.68 mg/l for female rats. For combined sexes the LC₅₀ was 0.53 mg/l. Based on the male LC₅₀ this chemical is placed in Tox Category II for acute inhalation. This study is acceptable. No further information is required for this guideline. A copy of the DER is enclosed.
Gdln 84-2(a) Gene Mutation - Ames (upgrade information)
MRID 43125602  Original MRID 42387201

The additional information on the purity of the test material is acceptable. Halobrom is mutagenic in this test system and that S9 activation was required to demonstrate the genotoxicity. This study is upgraded to acceptable. No further information is required for this guideline. A copy of the DER is enclosed.

If you have any questions regarding this letter, please contact Tom Myers in the Accelerated Reregistration Branch at (703) 308-8074.

Sincerely yours,

Mark Wilhite, Acting Section Leader
Accelerated Reregistration Branch
Special Review and
Reregistration Division

Enclosures:

cc: Ruth Douglas, PM-32
    Stanley Gross, HED
    Alfred Smith, PCRS