REVIEW NO.

EEB REVIEW

DATE: IN 1-13-88     DATE: OUT 1-5-89

FILE OR REG. NO. 5785-IU

PETITION OR EXP. NO.

DATE OF SUBMISSION 6-27-88

DATE RECEIVED BY EFED 1-12-89

RD REQUESTED COMPLETION DATE 7-12-89

EEB ESTIMATED COMPLETION DATE 7-12-89

RD ACTION CODE 170

TYPE OF PRODUCT(S): I,D,H,F,N,R,S Microicide

DATA ACCESSION NO(S).

PRODUCT MANAGER (NO.) J. KEMPTER (32)

PRODUCT NAME(S) CN-501 TABLETS

COMPANY NAME GREAT LAKES CHEMICAL COMPANY

SUBMISSION PURPOSE PROPOSED REGISTRATION OF USES IN BREWERY PASTEURIZERS AND RECIRCULATING COOLING WATER SYSTEMS

SHAUGHNESSY NO. CHEMICAL & FORMULATION(S) % A.I.

006315 BCDMH 55.5

031405 TRICHLORO-S-TRIAZINE TRIONE 28.9
MEMORANDUM

SUBJECT: Proposed registration of uses in brewery pasteurizers and recirculating cooling water systems of CN-501.

FROM: James W. Akerman, Branch Chief, Ecological Effects Branch, EFED

TO: Jeff Kempter, (PM-32) Disinfectants Branch, RD

—The registrant, Great Lakes Chemical Company, has requested a registration for use in brewery pasteurizers and recirculating cooling water systems. In their submission they indicated that the basic toxicity testing was not required. They did, however, reference two aquatic studies that had been submitted in 1980, Hydrotech Chemical Corporation, the producer. These studies used a variety of forms of BCDMH (which included 1-Bromo-1-chloro-5,5-dimethylhydantoin) as the test chemical and were classified as fulfilling the requirements. Other registrants have submitted avian toxicity data to fulfill the guidelines for registration BCDMH, but Great Lakes, apparently, did not receive permission to use the data on the active BCDMH. The other chemical, Trichloro-S-triazine trione has been published as a Registration Standard and is therefore public domain. In order for EEB to evaluate the product CN-501 Tablets, the registrant will need to receive permission from the companies who paid for the avian toxicity studies with BCDMH or failing that, submit new studies to satisfy the data requirements. These data requirements are:

1.) Acute oral toxicity with an avian species, either a bobwhite or mallard duck.

2.) Dietary exposure with a bobwhite and a mallard.
March 5, 1989

NOTE TO: Barbara Pringle, PM Team-32
       Antimicrobial Program Branch
       Registration Division (H7505C)

       As per your request last week, I have examined the file
       for Dantobrom and found that the six basic studies are available
       for each of the active ingredients listed on the attached label.
       You also indicated that the registrant has submitted
       estuarine/marine studies to support the proposed once-through
       cooling water systems use.

       To support the once-through use the estuarine/marine
       studies should be done on either the technical of each active
       ingredient or the end-use product (and residue analyses for
       active ingredients must be performed during the study(ies)). In
       addition, residue monitoring studies for freshwater and
       marine/estuarine use sites are required, and protocols for such
       studies must be approved by the Agency prior to study initiation.
       Also, further studies might be required, but this determination
       would be based on the results of the monitoring studies.

       Please note that the above is based on a "quick review"
       of EEB files.

       [Signature]
       Norm Cook
       RD Coordinator
       EEB, EFED
DIRECTIONS FOR USE
It is a violation of Federal Law to use this product in a manner inconsistent with the labeling.

RECIRCULATING COOLING WATER SYSTEMS
DANTOBROM™ RW acts in the control of bacterial, fungal and algal stress in evaporative condensers, heat exchangers, water towers, influent systems such as flow through filters, lagoon etc., industrial water scrubbing systems and brewery pasteurizers.
This product may be added to the system either continuously or intermittently or as needed. The frequency of feeding and duration of the treatment will depend upon the severity of the problem.
BADLY FOULED SYSTEMS must be cleaned before treatment is begun.

FOR CONTROL OF BACTERIA AND FUNGI

INTERMITTENT OR SLUG METHOD
INITIAL DOSE: When the system is noticeably fouled, add 0.1 to 1.0 lb. to 1000 gallons or 12 to 120 parts per million of water in the system. Repeat until control is achieved.
SUBSEQUENT DOSE: When microbial control is evident, add 0.1 to 0.10 lb. to 1000 gallons, daily or 12 to 80 parts per million daily or as needed to maintain control.

CONTINUOUS FEED METHOD
INITIAL DOSE: When the system is noticeably fouled, add 0.1 to 1.0 lb. to 1000 gallons or 12 to 120 parts per million of water in the system. Repeat until control is achieved.
SUBSEQUENT DOSE: When microbial control is evident, add 0.1 to 0.10 lb. to 1000 gallons, daily or 12 to 80 parts per million daily or as needed to maintain control.

STORAGE AND DISPOSAL
STORAGE: Keep container tightly closed. Store in a dry, cool, and dry place.
DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Pesticide waste is considered hazardous waste. Improper disposal of pesticide spray, air, or liquid may be a violation of Federal Law. The waste cannot be disposed of by use or according to the label instructions. Contact your County Landfill or environmental control agent or the hazardous waste representative at the nearest EPA regional office for guidance.
METAL AND PLASTIC CONTAINERS: Triple Threat (i.e., equivalent). Then offer for recycling or reconditioning to a designated facility.
FIBER DRUMS AND LINERS: Completely empty lin by shoveling and tapping sides and bottom to loosen drum and then dispose of in a sanitary landfill or creep or burn, if allowed by state and local authorities. If burned, stay out of smoke.

FOR INDUSTRIAL USE ONLY
Technical advice regarding specific problems is available from LONZA. A material data sheet is not file to the use of this product is also available upon request.

DANTOBROM™ RW
17-17 Route 208
Fair Lawn, NJ 07410
EMERGENCY TEL. NO. 309-697-5400

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER
HARMFUL IF SWALLOWED. HIGHLY CORROSIVE. 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, chemical goggles and 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 NPDES permit. For guidance, contact your Regional Office of the EPA.

KEEP OUT OF REACH OF CHILDREN
DANGER
STATEMENT OF PRACTICAL TREATMENT
For eyes contact, flush eyes with large amounts of running water for at least 15 minutes. Hold eyelids open to ensure flushing of entire surface of the eye and lid with water. If physician is not available, flush for additional 15 minutes. Get immediate medical attention.

For skin contact, immediately wipe away excess material with a dry cloth while removing contaminated clothing and shoes. Under a safety shower, wash affected area thoroughly with large amounts of water, soap, and water, for at least 15 minutes. Get immediate medical attention. Discontinue or discontinue use of contaminated clothing and shoes.

For oral exposure, wash the mouth immediately, get immediate medical attention. Do not give anything by mouth to an unconscious or convulsing person. Get immediate medical attention.

CONTROVERSY OF ALGAE
INTERMITTENT OR SLUG METHOD
INITIAL DOSE: When the system is noticeably fouled, add 0.1 to 1.0 lb. to 1000 gallons or 12 to 120 parts per million of water in the system. Repeat until control is achieved.
SUBSEQUENT DOSE: When algae control is evident, add 0.1 to 0.10 lb. to 1000 gallons, daily or 12 to 80 parts per million daily or as needed to maintain control.

CONTINUOUS FEED METHOD
INITIAL DOSE: When the system is noticeably fouled, add 0.1 to 1.0 lb. to 1000 gallons or 12 to 120 parts per million of water in the system. Repeat until control is achieved.
SUBSEQUENT DOSE: Continuously feed to maintain a dosage of 0.1 to 0.15 lb. to 1000 gallons or 12 to 80 parts per million of water in the system.

AIRWASHERS
For use only in industrial airwashers systems that maintain effective mist eliminating components. DANTOBROM™ RW controls slime forming bacteria, fungi and algae in industrial airwashers systems. Add DANTOBROM™ RW at the rate of 0.1 to 1.0 lb. (12 to 120 ppm) per 1000 gallons of water in the system, depending upon the severity of the contamination.

Control the application by measuring the free chlorine residual in the treated water. There is no need to exceed 1.0 ppm as free chlorine.

Badly fouled systems must be cleaned before treatment is begun.

INTERMITTENT OR SLUG METHOD
INITIAL DOSE: When system is noticeably fouled, add to airwasher or mist washer to prevent uniform mixing. Add 0.1 to 1.0 lb. to 1000 gallons or 12 to 120 parts per million of water.
SUBSEQUENT DOSE: When microbial control is evident add 0.1 to 0.10 lb. to 1000 gallons or 12 to 80 parts per million of water.

CONTINUOUS FEED METHOD
INITIAL DOSE: When system is noticeably fouled, add to airwasher or mist washer to prevent uniform mixing. Add 0.1 to 1.0 lb. to 1000 gallons or 12 to 120 parts per million of water.
SUBSEQUENT DOSE: When microbial control is evident add 0.1 to 0.10 lb. to 1000 gallons or 12 to 80 parts per million of water.

CONTINUOUS FEED METHOD
INITIAL DOSE: When system is noticeably fouled, add to airwasher or mist washer to prevent uniform mixing. Add 0.1 to 1.0 lb. to 1000 gallons or 12 to 120 parts per million of water.
SUBSEQUENT DOSE: When microbial control is evident add 0.1 to 0.10 lb. to 1000 gallons or 12 to 80 parts per million of water.

CONTINUOUS FEED METHOD
INITIAL DOSE: When system is noticeably fouled, add to airwasher or mist washer to prevent uniform mixing. Add 0.1 to 1.0 lb. to 1000 gallons or 12 to 120 parts per million of water.
SUBSEQUENT DOSE: When microbial control is evident add 0.1 to 0.10 lb. to 1000 gallons or 12 to 80 parts per million of water.

CONTINUOUS FEED METHOD
INITIAL DOSE: When system is noticeably fouled, add to airwasher or mist washer to prevent uniform mixing. Add 0.1 to 1.0 lb. to 1000 gallons or 12 to 120 parts per million of water.
MEMORANDUM

SUBJECT: Data Requirement for Dantobrom BTE

FROM: Curtis E. Laird, Fishery Biologist  
Ecological Effects Branch  
Hazard Evaluation Division (TS-769C)

THRU: Norman J. Cook, Head-Section 2  
Ecological Effects Branch  
Hazard Evaluation Division (TS-769C)  

TO: Jeff Kempter, PM 32  
Disinfectants Branch  
Registration Division (TS 767C)

Ecological Effects Branch (EEB) needs the following studies for recirculating cooling water systems and airwashers uses:

a. Hydrolysis (§161-1); and

b. Photolysis in water (laboratory) §161-2.

CC: Emil Regelman EAB/HED
MEMORANDUM

SUBJECT: Data Requirements for Dantobrom BTB

FROM: Emil Regelman, Head
Environmental Chemistry Review Section #3
Exposure Assessment Branch

TO: Brigid Lowery
Management Support Staff
Hazard Evaluation Division (TS-769c)

THRU: Paul Schuda, Chief
Exposure Assessment Branch
Hazard Evaluation Division (TS-769c)

Having reviewed the submitted package for Dantobrom BTB, I would like to summarize EAB's position relative to this submission and anticipated data requirements:

1. The Dantobrom BTB package contained no 'data' (studies) upon which to evaluate the environmental fate relative to the proposed Indirect Discharge use (cooling towers). Anecdotal information provided with the package suggests that the degradation of different substituted hydantoins may vary widely.

2. The registrant apparently wishes to rely on existing data for other hydantoins. Data previously have been submitted to support the swimming pool use of 'halogenated' 5,5-dimethylhydantoin, including:
   - 1-bromo-3-chloro-5,5-dimethylhydantoin
   - 1,3-dichloro-5,5-dimethylhydantoin
   - 1,3-dichloro-5-ethyl-5-methylhydantoin

Additionally, the following hydantoins were proposed for use in recirculating water treatment systems:
   - 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin
   - hydroxymethyl-5,5-dimethylhydantoin
3. The Registration Standard Science Chapter for Danthochlor was completed on June 18, 1985, assuming only the active ingredient 1,3-dichloro-5-ethyl-5-methylhydantoin. No data requirements were satisfied by that review.

4. The Confidential Statement of Formula shows four new chemicals, for which no chemical-specific data have yet been submitted. These are:
   - 1,3-dibromo-5-ethyl-5-methylhydantoin
   - 1-bromo-3-chloro-5-ethyl-5-methylhydantoin
   - 1,3-dibromodimethylhydantoin
   - 1-chloro-5-ethyl-5-methylhydantoin

5. The Confidential Statement of Formula fails to indicate the actual percentage composition of each a.i. component, as required.

6. The EAB review of May 12, 1987 identified the potential formation of highly toxic N-chloro-isopropylimine by the ring opening of bromochlorodimethylhydantoins in the presence of high chlorine levels.

Since the hydantoins are used primarily to 'deliver' bromine/chlorine at a controlled rate, EAB assumes that constant recharge of the cooling tower lagoon could result in the accumulation of significant quantities of a wide variety of degradates, which could subsequently be discharged into a holding area (pond).

To EAB, this burden of unknown levels of unknown components appears to be quite different from that conventionally seen for indirect discharge uses. Therefore, EAB cannot concur with the registrant's proposal to register Hydantoins as a 'class' of compounds. Rather, the following data will be required for each active ingredient; for use in cooling water towers:
   - 161-1 Hydrolysis (laboratory)
   - 161-2 Photolysis in Water (laboratory)
   - 162-3 Anaerobic Aquatic Metabolism (laboratory)
   - 162-4 Aerobic Aquatic Metabolism (laboratory)
   - 163-1 Adsorption/Desorption (laboratory, batch equilibrium) for both parent and major degradates
   - 164-2 Field Dissipation for Aquatic Impact Uses (dissipation from the outdoor holding pond following drainage of the cooling tower lagoon).
   - 165-4 Accumulation in Fish (laboratory)

CC: Curtis Laird, EEB/HED
    Albin Kocialski, TOX/HED
    Hank Jacoby, SIPS/HED
    Jeff Kempter, RD
    Lynn Bradley, RSERB/RD
    Files, EAB
MEMORANDUM

SUBJECT: Dantobrom BTB

FROM: Curtis E. Laird, Fishery Biologist
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)

THRU: Norman J. Cook, Head-Section 2
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)

and

James Akerman, Chief
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)

TO: Jeff Kempter, Project Manager 32
Disinfectants Branch
Registration Division (TS-767C)

The EEB has completed a new chemical screen for three new chemicals proposed for use in recirculating cooling water systems and airwashers:

(1) 1-Chloro-5-ethyl-5-methylhydantoin
(2) 1,3-Dibromo-5-ethyl-5-methylhydantoin
(3) 1-Bromo-3-chloro-5-ethyl-5-methylhydantoin.

In doing so, EEB determined the following:

(1) The registrant has referenced data for the three similar, apparently, previously registered, chemicals. These are:
   (a) 1-Bromo-3-chloro-5,5-dimethylhydantoin (Bromochlor)
   (b) 1,3-Dichloro-5,5-dimethylhydantoin (Dantochlor)
   (c) 1,3-Dibromo-5,5-dimethylhydantoin (Glychlor)
(2) EEB was able to locate acceptable data for (1)(a) and (1)(b) above (i.e. Bromochlor and Dantochlor, respectively). However, we were unable to locate data for (1)(c) above (i.e. Glychlor).

(3) In reviewing the files we also found acceptable data for: 1,3-Dichloro-5-ethyl-5-methylhydantoin. It appears these data are the registrant's, but said registrant did not reference them. Also, it appears this chemical is registered.

Relative to the above, EEB concludes the following:

(1) The Glychlor data must be submitted for review to EEB;

(2) If the registrant can, he should reference the data available for: 1,3-Dichloro-5-ethyl-5-methylhydantoin; and

(3) If (1) and, possibly, (2) can be met, it appears enough toxicity data are available for EEB to address acute toxicity and risk concerns for the three new chemicals. However, if the end-use products are intended for use in estuarine/marine environments then the following studies are required to support registration:

   a. The 96-hour LC₅₀ for sheepshead minnow; (§72-3)
   b. The 96-hour LC₅₀ for shrimp; (§72-3) and
   c. The 48-hour embryo-larvae or 96-hour shell deposition study for American Oyster. (§72-3)

Further, other studies may be required to support the proposed registration. This determination cannot be made until EEB has received and reviewed all the required acceptable data plus environmental fate data.