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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: Sodium Bromide - Company Response to Meeting of January 14, 1987.
Great Lakes Chemical Corporation. Record No. 189106/189107.
Caswell No. 750A Tox. Project No. 7-0392

To: Jeff Kempter/Olivia Laird
Product Manager #32
Disinfectants Branch/RD (TS-767C)

From: Judith W. Hauswirth, Ph.D. Judith W. Hauswirth 3/6/87
Acting Head, Section VI
Toxicology Branch/HED (TS-769C)

Thru: Theodore M. Farber, Ph.D., Chief 3/6/87
Toxicology Branch/HED (TS-769C)

Action Requested: Exemption from certain toxicology requirements for the use of Sodium Bromide in recirculating and once-through cooling systems.

Recommendation: The toxicology requirements for registration of sodium bromide for use in recirculating and once-through cooling systems are the following:

- o Acute oral LD_{50}
- o Acute dermal LD_{50}
- o Primary eye irritation
- o Primary dermal irritation.

The requested waivers for the following studies are granted.

- o 90-day subchronic feeding study
- o Teratology study
- o Battery of mutagenicity studies
- o Dermal LC_{50}
- o Acute inhalation LC_{50}

1 of 7

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Discussion:

The registrant has submitted the following information on the safety of sodium bromide.

> Sodium bromnide is known to be an innocuous chemical similar to sodium chlorde, a table salt. Existing food tolerances permit presence of inorganic bromides at level as high as 240 ppm on popcorn. A joint FAO/WHO group set an ADI of 1 mg/kg/day inorganic bromides.....based on the chronic studies in rats and dogs and the information derived over the years on human that 750 mg or 11 mg/kg/day inorganic bromide is a safe level provided that human is not unduely sensitive to inorganic bromide [summarized from a FDA review]...

They state that the intended uses of sodium bromide would not be expected to result in subchronic exposure to humans.

On the basis of the above considerations, in a meeting on January 14, 1987 the Toxicology Branch concurred with the registrant and waived the following toxicology requirements which were outlined in a letter to the registrant (September 29, 1986): 90-day subchronic feeding study, a teratology study and a battery of mutagenicity assays.

The registrant was also told that a dermal LC_{50} study was not required, since such a test does not exist although it was listed in the letter.

At the time of the meeting Toxicology Branch witheld comment on the requirement for an acute inhalation toxicity study. In their letter of January 29, 1987, addressing the issues discussed at the meeting on January 14, 1987, the registrant states that they believe the waiver request for this study is justified since there is no vapor hazard to sodium bromide. The marketed product contains sodium bromide in a 46% solution which should be completely ionized. The boiling point of pure sodium bromide is 1390°C. Toxicology Branch concurs with their waiver request based upon the above discussion and upon the proposed use for sodium bromide.

Toxicology Branch agrees with the registrant that the outstanding toxicology requirements for the registration of this product are as follows:

- o Acute oral toxicity in rats
- o Acute dermal toxicity
- o Primary eye irritation
- o Primary dermal irritation.

2