



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 2 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Review of (a) an Agency proposed decision and (b) response to a Chemical Manufacturers Association position paper on copper and zinc naphthenate.
EPA ID #'s 023102 and 088301; EPA Record #'s 202871 and 202872; Caswell #'s 245 and 919; Tox Branch Project No. 7-1054.

TO: Geraldine W. Werdig/Betty Crompton (PM-50)
Chief, Data Call-In Program,
Registration Division (TS-767)

FROM: Stephen C. Dapson, Ph.D. *Stephen C. Dapson*
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Toxicology Branch/HED (TS-769C)

THRU: Quang Q. Bui, Ph.D., D.A.B.T. *Quang Bui 11/20/87*
Acting Section Head, Review Section V
and
William Burnam, Deputy Chief
Toxicology Branch
Hazard Evaluation Division (TS-769C) *WLB 12/1/87*

Registrant: Naphthenate Program Panel of the Chemical Manufacturers Association.

Action Requested: Review (a) an Agency proposed decision and (b) response to a Chemical Manufacturers Association position paper on copper and zinc naphthenate.

Recommendations: The Toxicology Branch agrees in principle with the draft Agency proposed decision and response to the position paper: "No additional testing is required for EPA's special Data Call-In on Copper and Zinc Naphthenate" prepared by the Naphthenate Program Panel of the Chemical Manufacturers Association, dated March 26, 1985.

However, the Toxicology Branch believes a different toxicity testing requirement is necessary for these wood preservative alternatives (copper naphthenate and zinc naphthenate). Testing of these agents should follow the testing strategy illustrated in the Data Call-In Notice for subchronic and chronic toxicological data for antimicrobial pesticide active ingredients, signed by James W. Akerman, March 4, 1987.

Therefore, for each chemical the Agency requires the submission of the following studies:

Acute Toxicity Data
Subchronic Testing:
 90 Day Dermal Toxicity and/or
 90 Day Inhalation
Developmental Toxicity - Teratogenicity
 (one species, rat or rabbit)
Mutagenicity: Gene Mutations
 Structural chromosome aberrations
 Other genotoxic effects
Any available exposure information

Results of these studies will indicate if further testing is necessary.

Since the exposure is primarily dermal, a 90-day dermal toxicity study is necessary to fulfill the regulatory requirements of a subchronic study for this chemical.

A developmental toxicity - teratogenicity study is necessary since available evidence is lacking on the developmental toxicity of these compounds (copper naphthenate and zinc naphthenate). The reference stated in the CMA position paper, Hardin B.D. [et.al.], "Testing of Selected Workplace Chemicals for Teratogenic Potential" (Scandinavian Journal of Environmental Health: 7:6-75, 1981), is a screening study, which tested single doses of 19 chemicals at a "previously determined" maximum tolerated dose (MTD). This study does not contain adequate data and is therefore, not useful for regulatory purposes. Further, relative to the teratogenic potential of zinc naphthenate, one can not, "by implication" state that data from one chemical is justification for not conducting further studies with a second chemical. Available open literature sources state that high doses (and deficiencies) of the metal (copper or zinc) are possibly teratogenic.

Some studies have been submitted and are acceptable to fulfill some of the above mentioned regulatory requirements.

For Copper Naphthenate:

Acute Oral Toxicity - Rat (2% and 9.6%)*
Acute Oral Toxicity - Rabbit (2% and 9.6%)
Acute Dermal Toxicity - Rabbit (9.6%)
Primary Dermal Irritation - Rabbit (2% and 9.6%)
Primary Eye Irritation - Rabbit (2% and 9.6%)
Mutagenicity - rec assay (1%)
 other mutagenicity studies are conditionally acceptable

For Zinc Naphthenate:

Acute Oral Toxicity - Rat (2%, 7.5%, 8% and 60%)*
Acute Oral Toxicity - Rabbit (60%)
Acute Dermal Toxicity - Rabbit (2%, 7.5%, 8%, 55% and 60%)
Acute Dermal Irritation - Rabbit (2%, 7.5%, 8%, 55% and 60%)
Acute Dermal Sensitization - Guinea Pig (7.5% and 60%)
Acute Eye Irritation - Rabbit (2%, 7.5%, 8%, 55% and 60%)
Acute Inhalation Toxicity - Rat (7.5%, 8%, 55% and 60%)

* = indicates concentration of metal naphthenate tested