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

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

#923

MEMORANDUM

SUBJECT: **Zinc Omadine:** Purity Data for Three Mutagenicity Studies.

EPA ID# 088002-001258 DP Barcode D205707
Case No. 815252 PC CODE Chem. ID No. 088002

FROM: John E. Whalan, D.A.B.T., Toxicologist
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John E. Whalan 9-14-94

TO: Bruce Sidwell (PM Team # 53)
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THRU: Roger L. Gardner, Section Head Pamela M. Hurley 9/22/94
Section 1, Toxicology Branch I
Health Effects Division (7509C) for KB 9/23/94

I. Background:

The following three mutagenicity studies were classified **Unacceptable** because they failed to describe the test article. A TB-I memorandum (John E. Whalan, May 27, 1993), which contained the Detailed Evaluation Reports (DER's), stated that these studies could be upgraded upon receipt of acceptable purity data.

84-2a *Salmonella*/Mammalian-Microsome Plate Incorporation Mutagenicity Assay (Ames Test) with a Confirmatory Assay; Study No. T9153.501014; October 19, 1990; MRID No. 419065-02.

84-2b CHO/HGPRT Mutation Assay with Confirmation; Study No. T9153.332001; September 6, 1990; MRID No. 419065-03.

84-2c Micronucleus Cytogenetic Assay in Mice; Study No. T9153.122; October 22, 1990; MRID No. 419065-01.

Olin Corporation has submitted a report (MRID No. 432833-01) describing test article purity. Lot No. 9RC-290-109ZP, a 48% zinc omadine dispersion, was formulated from two batches of zinc Omadine cake — 9RC-279-P475 and 9RC-279-P476. The purities of these lots were 97.7% and 98.8%, respectively. Lot No. 9RC-290-109ZP was used in the CHO/HGPRT Mutation Assay and the Micronucleus Cytogenetic Assay. The lot number was not reported for the Ames Assay, but the test article was described as a white, milky, semi-viscous liquid — presumably the 48% aqueous dispersion.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

II. Recommendations:

HED Guidelines require mutagenicity studies be performed using the technical product. Although all preceding toxicity studies had been performed using the 95% powder, Olin chose to use the 48% aqueous dispersion for the mutagenicity studies and two developmental toxicity studies. No justification was offered for switching test articles.

A telephone call to the registrant revealed confusion as to which product is the technical product, and the reason for switching from the 95% product to the 48% product. It seems that a [redacted] to yield the 48% aqueous dispersion. Provided that [redacted] is not toxic, and considering that [redacted] is virtually non-toxic, the 48% product may be toxicologically equivalent to an aqueous dilution of the 95% powder. If this is the case, both the 95% and 48% products can be used interchangeably in all toxicity studies requiring a technical product.

Olin should submit a letter to the Agency describing the following:

1. The end-processing of the zinc omadine wet cake.
2. A declaration of which registered products are considered technicals and which are considered end-use products.
3. A justification for switching test articles from the 95% powder to the 48% aqueous dispersion.
4. A description of the toxicity of [redacted] and any other additives (other than [redacted] and water) in the 48% aqueous dispersion.
5. The lot number for the Ames Assay (Study No. T9153.501014).

A decision on the admissibility of all studies using the 48% aqueous dispersion is pending Olin's reply.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

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