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

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AUG 23 1989

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Subject: Dantobrom S; EPA ID# 6836-116; Record No 245107
MRID #(s) 410889-01, 02.

To: Jeffrey Kempter/Barbara Pringle PM# 32 Tox Chem No(s) 309C
Disinfectants Branch 114A
Registration Division (H7507C) 306
568E
366D

From: Joycelyn E. Stewart, Ph.D. 7/20/1989
Section II, Toxicology Branch I
Health Effects Division (H7509C) Proj. No. 9-1450

Thru: Marion Copley, D.V.M., Section Head Marion Copley 7/24/89
Section II, Toxicology Branch I KA 8/22/89
Health Effects Division (H7509C)

Registrant: Lonza, Inc
Fairlawn, New Jersey, 07410

Action Requested: Review 90 day rat oral toxicity study in response to Agency letter of 2/15/1989.

In addition to the data submitted for the 90 day rat study, the registrant has submitted four responses to ~~to~~ other concerns raised in Toxicology Branch's memorandum of 5/14/1987.

ITEMS 1 and 3

The registrant has submitted additional information on the purity of EMH and DMH requested in Toxicology Branch's memorandum:Stewart to Kempter/Douglas dated 3/10/1988. These organic moieties were administered to the test animals in the following studies (a) delayed hypersensitivity, SIB 3161.1.2 (b) rat teratology, t86m0006g, rabbit teratology, t86m0007g and (c) 90 day gavage rat study, t86m0023g.

The information indicated that the reference numbers represented individual batches of recrystallized EMH and DMH. Batches 1083.31 and 1083.46, represented EMH 98.9% and 99% respectively, while batches 1083.32 and 1083.45 represented 100% DMH. All of those batches were used in the subject studies.

The information provided adequately answers Toxicology Branch's concern. Consequently, the studies performed with DMH and EMH which have no other deficiencies are upgraded to to core-Minimum. These studies are: the delayed hypersensitivity studies, the rat teratology studies, the rabbit teratology

study using DMH. The 90 day rat studies for both EMH and DMH and the rabbit teratology using EMH remain core-Supplementary for other deficiencies. The purity and composition of EMH had been addressed in a previous submission.

ITEM 2

The registrant has supplied individual animal data as requested in Toxicology Branch's memorandum dated 3/10/1988. However, the data as presented are uninterpretable. In order for the data to be acceptable the registrant must do the following:

1. Indicate which animals were used as the control, DMH, and EMH treated groups respectively.

2. Clarify why all the clinical chemistry tests on rat blood were designated CANINE

3. Indicate the animals from which the organ weight data were taken.

4. Indicate which 5 animals/sex were sacrificed at 30 days, and which were carried to study termination at 90 days.

5. Explain why so many of the clinical chemistry results are designated out of range (or uninterpretable).

6. Supply gross and microscopic data for each animal.

7. Construct a summary incidence table of the significant findings.

ITEM 4

Toxicology Branch has no comment on the registrant's extension request. Based on the tier testing, the metabolism study may not have to be repeated for certain use patterns. However, the Antimicrobial Data Call-In Notice requires chronic testing for swimming pool and spa use. It is in this regard that the metabolism study may need to be repeated. The registrant should consult Subdivision F of the FIFRA Guidelines for instructions as to performance of the study.

ITEM 5

The rabbit teratology study on EMH must be repeated. The study was performed at a single dose level which did not show a definite NOEL for fetotoxicity.

Toxicology Branch calls to the registrant's attention, Toxicology Branch's memorandum dated 10/31/1985 regarding testing of the organic moieties of Dantobrom which states" considering the pre-

ponderance of DMH in the formulation (approximately 90%) and the close structural similarity between DMH and EMH, toxicology data on DMH might be adequate to determine ~~of~~ the safety of the compound. This certainly does not preclude the Agency requiring testing of EMH in the future.