Memorandum

Date: 16 June 1983

Subject: EPA Reg. No. 3125-326 LAB AUDIT REPORT ON AMAZE

From: B. T. Backus
IRB/TSS

To: Mr. William Miller
Product Manager 16

Registrant: Mobay Chemical Corp.
17745 S. Metcalf
Stilwell, KS 66085

Background:

A laboratory audit has raised questions regarding oral LD_{50} and inhalation LC_{50} studies conducted at a test facility of this corporation. The original studies are apparently in Acc. 243557. The conclusions of this reviewer are based entirely upon the investigational report based on an inspection which was made from 3-17-83 to 3-21-83. The oral study was, according to this report, conducted between June 19 and July 3, 1979. The acute inhalation LC_{50} study was conducted in May, 1980.

Comments and Recommendations:

1. According to the investigational report there is raw data for only six dosage levels in the acute oral LD_{50} study. However, the copies of the raw data with this investigational report are for only 4 dosage levels; 323, 475, 698 and 1027 mg/kg. These indicate the following mortalities:

Dosage Level	Mortalities/Animals Dosed	
	M	F
323	0/10	0/10
475	1/10	2/10
698	1/10	8/10
1027	7/10	10/10

From these data, an oral LD_{50} for males is suggested which is in the range of 698-1027 mg/kg, while that for females is in the range of 475-698 mg/kg. This indicates a toxicity category III hazard for this product by this exposure route.

Although questions have been raised on a number of points (the reporting of congested lungs as having been caused by carbon dioxide suffocation, a non-existing dosage level group at a dosage level of 3263 mg/kg) toxicity categorization is based on mortality, and it appears that, unless more substantial discrepancies can be shown, the study is acceptable.

2. With respect to the acute inhalation LC_{50} study, the situation is considerably different. Under current guidelines, a study which did not report information as to actual (as opposed to nominal) concentrations of product and/or active(s), as well as particle size data, would be classified as supplementary data. In this particular case, even the "nominal concentration" is a suspect figure.

If the apparatus used for inhalation LC_{50} studies was a modified 55-gallon drum as described then not only this study but all studies run using this type of exposure system would be inadequate.

This strongly suggests an expanded review of all inhalation LC_{50} studies which were conducted by this laboratory until such time as more adequate inhalation exposure equipment was put into operation.

Byron T Backus 06/16/83

Byron T. Backus
IRB/TSS

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