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SUBJECT: Reconsideration of Reg./File No 10707-9. Acrolein.
EAB review of March 7, 1983.
8/30/83 Meeting of EAB/HED, HRB/RD, & Magna Corporation Representatives.

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1.0 INTRODUCTION

This is submitted in response to the 8/30/83 meeting with RD (R. Mountfort) and the representatives from Magna Corporation. The purpose of this meeting was to discuss the EAB review of the application for amending the currently registered label for the aquatic herbicide Magnacide H (acrolein, as a. i).

During the meeting, the EAB request for recovery data was discussed.

As agreed, EAB will try to clarify the distinction between "calibration curve" and "recovery data":

1.1 A calibration curve is generated using standrad solutions of known concentrations of highly pure acrolein dissloved in reagent (highly pure) water and plotting the reponse (peak height, in this case) versus the concentration on a graph.

The range where the response is linear with concentration is the optimum operating range of the method. When analyzing samples of unknown concentrations, those outside the optimum linear range should be diluted or concentrated so that the response is within the linear range.

A calibration curve can be considered as a measure of the precision of the method when conducted under the most standardized conditions. This provides for evaluating the reproducibility by other investigators.

1.2 Recovery data, on the other hand, are generated (in the case of acrolein) by adding known amounts of acrolein to a blank sample matrix [untreated canal water (in this case)] to give solutions of known concentrations. These "spiked" samples are then analyzed. After analysis is carried out, the concentration is determined by reading the response (peak height) from the calibration curve. The percent recovery is then the comparison of the value for the concentration as measured with the original known concentration.

Soil, sediment, plant material can also be examples of the sample matrix.

Recovery data can be considered a measure of the accuracy (efficiency) of the method in detecting all the acrolien present.

Note: A calibration curve generated in the presence of the sample matrix is not acceptable. There is no assurance that the method is measuring 100 percent recovery (efficiency). It would be only assumed. For example, such a calibration curve can be generated and plotted but it may be only measuring a small percentage of the compound actually present. Thus, the concentration of unknown samples would be consistently under-reported.

1.3 Re-review of the previously submitted methodology in Tab 2, "Determination of Acrolein in Aqueous Solutions by Differential Pulse Polarography. John L. Brady and Charles L. Kissel. Magna Corporation," reports that untreated water collected from the system to be tested is to be used in preparation of the calibration curves.

It should be noted that the report by L. H. Howe, "Differential Pulse Polarographic Determination of Acrolein in Water Samples," previously sumbitted also in Tab 2 mentions that the calibration solutions be made up with reagent water. EAB interprets this to mean reagent grade or highly pure water.

1.4 Calibration curves submitted in the individual studies are labeled in the "y" axis as "Corrected Peak Height." This term should be explained.

2.0 EXECUTIVE SUMMARY

2.1 Upon reconsideration, EAB concludes that the method previously reviewed (submitted in Tab 2) is inadequate for determining residues of acrolein in the field dissipation studies. Calibration curves must be based on using reagent grade water in preparing the standard concentrations. Untreated field ("sample") water should not be used.

2.2 Also, recovery data, as a measure of the efficiency of the method to detect acrolein in the sample matrix, must also be included.

2.3 Until the registrant submits an adequate method and recovery data, EAB considers the results of the field monitoring studies previously submitted to be incomplete.

3.0 RECOMMENDATION

3.1 As agreed, the above interpretations of "calibration curve" and "recovery data" should be forwarded to the registrant, Magna Corp.

3.2 The registrant should be informed that, based on re-review, the previously submitted procedure is inadequate because it calls for using untreated sample water in developing the calibration curve. Reagent grade (highly pure) water should be used.

3.2.1 The procedure is also inadequate in that no recovery data were presented in the report. Untreated field water should be used.

3.3 The heading of the "y" axes in several of the calibration curves submitted in the individual monitoring studies are entitled "Corrected Peak Height." This term should be explained.

3.4 Until the points in 3.2 and 3.3, above are resolved, EAB considers the data submitted in the individual monitoring studies to be incomplete.

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