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

JAN 13 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

Subject: Reregistration of Monosodium Methanearsonate. ISK-Biotech Corp. Product Chemistry. DP Barcode D171424. MRID Nos. 42081200, 42081201 CBRS No. 8931.

From: Stephen Funk, Ph.D., Chemist
Special Review Section I
Chemistry Branch II - Reregistration Support
Health Effects Division (H7509C)

Through: Andrew Rathman, Section Head
Special Review Section I
Chemistry Branch II - Reregistration Support
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To: Betty M. Crompton
Reregistration Section 1
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Reregistration Division (H7508W)

Background

ISK Biotech Corporation (formerly Fermenta ASC Corporation) has submitted manufacturing data for monosodium methanearsonate (MSMA, chemical no. 13803). The Phase 4 Review noted that temperatures and pressures were not given in the description of the manufacturing process.

Discussion

The submission (MRID No. 42081201, Document Number PC-90-DGL-001-01-01) provides detailed information on the manufacture of MSMA and the starting materials used in that process. The description is complete and fulfills the requirements of Guideline 61-2. Details are provided in Confidential Appendix A.

Conclusion and Recommendation

The data gap identified under Guideline 61-2 in the Phase 4 Review is satisfied. No additional action is required for description of the manufacturing process. The registrant should note that the Phase 4 Review identified other product chemistry deficiencies.

cc without Confidential Appendix: circ.

cc with Confidential Appendix: List B Methanarsonates File, RF, S. Funk, C.Furlow (PIB, FOD).

RDI: A. Rathman:01/08/92: D.Edwards:01/08/92: E. Zager:01/08/92:

H7509C:CBRS:S.Funk:305-5430:CM#2:RM803-A:SF(1191.13):12/19/91.

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Page_____ is not included in this copy.

Pages 3 through 4 are not included.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

✓ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.