



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

JAN 13 1992

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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 *S. A. Funk*
Special Review Section I
Chemistry Branch II - Reregistration Support
Health Effects Division (H7509C)

Through: Andrew Rathman, Section Head *AR*
Special Review Section I
Chemistry Branch II - Reregistration Support
Health Effects Division (H7509C)

To: Betty M. Crompton
Reregistration Section 1
Accelerated Reregistration Branch
Special Review and
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.



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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 2 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.
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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.
