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

FEB 25 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Monosodium methanearsonate (MSMA) Reregistration: a List B Chemical. APC Holdings, Inc. Response to MSMA (Case No. 2395, Chemical No. 013803) Reregistration Product Chemistry Data Requirements (Regarding Guideline # 61-2 & 62-1).
(MRID # 417020-01, 424741-01)
CBRS # 10622; DP BARCODE: D182871

FROM: Freshteh Toghrol, Ph.D., Chemist *F. Toghrol*
Reregistration Section II
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

THRU: William J. Hazel, Ph.D., Section Head *W. J. Hazel*
Reregistration Section II
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

To: Barbara Briscoe, PM 51
Accelerated Reregistration Branch
Special Review and Reregistration Division (H7508W)

Attached is a Phase 5 Review of the APC Holdings 51.3% MSMA (EPA Reg. No. 63239-13) product chemistry data. These data (MRID Nos 417020-01, 424741-01) were considered by The MSMA Phase 4 Review (dated 3/28/91) candidates to fulfil Phase 5 data requirements for Guideline Nos 61-2 and 62-1 respectively. These data were reviewed by Dynamac Corporation under the supervision of Chemistry Branch II: Reregistration Support, Health Effects Division (CBRS, HED).

This Dynamac review has undergone secondary review in CBRS and has been revised to reflect the Branch policies.

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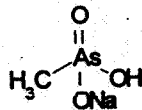


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Summary of Conclusions:

The 51.3% MSMA product chemistry data gaps regarding Guidelines description of starting materials and manufacturing process (Guideline 61-2) and preliminary analysis (Guideline 62-1) are resolved.

The structure of MSMA is shown below:

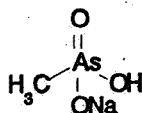


Attachment: MSMA: Registrants Response to Product Chemistry Data Requirement.

cc: MSMA S.F., R.F., F. Toghrol, List B File, Dynamac.
RDI: W. Hazel (2/22/93): M. Metzger (2/24/93): E. Zager (2/24/93)
H7509C:CBRS:F.Toghrol:F.T.:RM:804B:CM#2:(703)305-7887:2/16/93.

See the index of Studies Attached to this Summary Report

MSMA



Shaughnessy No. 013803

(CBRS No. 10622; DP Barcode D182871; Case 2395)

Task 4

PHASE V - PRODUCT CHEMISTRY REREGISTRATION REVIEW

BACKGROUND

In response to the Methanearsonic Acid and Salts (MSMA) Phase IV Review dated 3/28/91 by C. Olinger, APC Holdings, Inc. has submitted a single volume of supplemental product chemistry data (CBRS No. 10622; 1992; MRID 42474101) for the TGAI of MSMA. APC Holdings does not have any registered manufacturing-use products (MPs); the APC Holdings 51.3% end-use product (EP; EPA Reg. No. 63239-13) is produced by an integrated process.

The MSMA Phase IV Review dated 3/28/91 concludes that two submissions by APC Holdings (1990; MRIDs 41702001 and 41702002) are candidates to fulfill Phase V data requirements for Guideline Reference Nos. 61-2 and 62-1, respectively. Accordingly, these submissions are reviewed here for adequacy in fulfilling data requirements.

The submitted data and our conclusions are discussed below.

61-1. Product Identity and Disclosure of Ingredients

Although data concerning the product identity of the MSMA TGAI or EPs are not required at this time (61-1 is a product specific requirement), APC Holdings has submitted (1990 and 1992; MRIDs 41702001 and 42474101) information and a Confidential Statement of Formula (CSF) dated 9/10/92 for the 51.3% EP (EPA Reg. No. 63239-13). These data are presented in the Confidential Appendix for informational purposes only.

61-2. Description of Starting Materials and Manufacturing Process

The MSMA Phase IV Review dated 3/28/91 indicates that a submission previously received from APC Holdings (1990; MRID 41702001) is a candidate to fulfill the Phase V data requirements concerning the starting materials and manufacturing process of the TGAI of MSMA. This information is presented in the Confidential Appendix and satisfies the requirements of 40 CFR §158.160 and §158.162 (Guideline Reference No. 61-2) regarding the starting materials and production process of the TGAI of MSMA. No additional information is required; however, we note that if the manufacturing process/site or sources/purities of starting materials change, the registrant must submit information concerning the starting materials and manufacturing process, and preliminary analysis data (Guideline Reference Nos. 61-2 and 62-1, respectively) to confirm that the MSMA TGAI produced at the new site/via the new process has not changed.

61-3. Discussion of Formation of Impurities

The MSMA Phase IV Review dated 3/28/91 requires additional information pertaining to the discussion of formation of impurities for the TGAI of MSMA. In response, APC Holdings has submitted (1992; MRID 42474101) a revised discussion of impurities formed during the production of the TGAI. This information is presented in the Confidential Appendix and satisfies the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) regarding discussion of formation of impurities in the TGAI of MSMA. No additional data are required.

62-1. Preliminary Analysis

MSMA Phase IV Review dated 3/28/91 indicates that a submission previously received from APC Holdings (1990; MRID 41702002) is a candidate to fulfill the Phase V data requirements concerning the preliminary analysis of the TGAI of MSMA. In addition, APC Holdings has submitted (1992; MRID 42474101) supplemental information concerning the analytical methods used to quantitate the active ingredient and its impurities. These data are presented in the Confidential Appendix and satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) regarding preliminary analysis for the MSMA TGAI.

62-2. Certification of Limits

Although data concerning the certified limits of the MSMA TGAI and EPs are not required at this time (62-2 is a product specific requirement), APC Holdings has submitted (1992; MRID 42370201) a CSF dated 9/10/92 for the 51.3% EP (EPA Reg. No. 63239-13). These data are presented in the Confidential Appendix for informational purposes only.

MASTER RECORD IDENTIFICATION NUMBERS

Citations for the MRID documents referred to in this review are presented below.

41702001 Haefele, Louis R. (1990) Product Identity and Composition - MSMA 660. Unpublished compilation prepared by APC Holdings, Inc. 24 p.

41702002 Haefele, Louis R. (1990) Analysis and Certification of Ingredient Limits - MSMA 660. Unpublished study prepared by APC Holdings, Inc. 18 p.

42474101 Haefele, Louis R. (1992) Supplemental To Product Chemistry - MSMA 660. Unpublished compilation prepared by APC Holdings, Inc. 11 p.

Case No. 2395
Chemical No. 013803

Case Name: MSMA
Registrant: APC Holdings, Inc.
Product(s): TGAI of MSMA

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? *	MRID Number
61-1	Product Identity and Disclosure of Ingredients	N/A ^b	
61-2	Starting Materials and Manufacturing Process	Y	41702001
61-3	Discussion of Formation of Impurities	Y	42474101
62-1	Preliminary Analysis	Y	41702002 42474101
62-2	Certification of Ingredient Limits	N/A ^b	
62-3	Analytical Methods to Verify the Certified Limits	N/A ^b	
63-2	Color	N	
63-3	Physical State	N	
63-4	Odor	N	
63-5	Melting Point	N	
63-6	Boiling Point	N	
63-7	Density, Bulk Density or Specific Gravity	N	
63-8	Solubility	N	
63-9	Vapor Pressure	N	
63-10	Dissociation Constant	N	
63-11	Octanol/Water Partition Coefficient	N	
63-12	pH	Y	42378601
63-13	Stability	Y	42378601

* Y = Yes; N = No; N/A = Not Applicable. Data were submitted in response to the MSMA Phase IV Review dated 3/28/91 by C. Olinger. Data requirements followed by MRID citations reflect conclusions determined in this document (CBRS No. 10622).

^b Data concerning this guideline are not required for the TGAI.

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