

6/1/92

MEMORANDUM

SUBJECT: Reregistration of Sodium methyldithiocarbamate. ICI Americas Product Chemistry Considerations. Rereg. case# 2390; Chemical# 39003. MRID#s 422771-01 & 02. CBRS# 9757. Action: 627 Generic Data Submission # S416315. DP Barcode D177132.

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Special Review Section I
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THRU: A.R. Rathman, Head
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TO: L. De Luise / T. Myers, PM Team 52
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Introduction

Metam sodium [sodium *N*-methyldithiocarbamate], a List B chemical, is registered as a soil fumigant. The Agency has concluded that all product chemistry requirements are applicable to metam sodium, with the possible exception of 63-6 Boiling point and 63-10 Dissociation constant. The Registrant committed to provide appropriate data. Requirements 63-6 and 63-10 are reserved, pending submission of melting point information and proof that the TGAI is totally dissociated in water. This memo will discuss ICI's product chemistry considerations for the reregistration of their pesticide product containing metam sodium as active ingredient.

61-2 - Discussion of the Beginning Materials and Manufacturing Process

The Registrant has submitted the names and addresses of the suppliers of the beginning materials, and a detailed manufacturing process for "VAPAM® Soil Fumigant (metam sodium)" [MRID Nos. 422771-01 and 422771-02].

A summary of the manufacturing process is given in Confidential Appendix A.

No additional information is required on this topic.

62-1 - Preliminary Analyses of Product Samples

The Registrant claims that, "these data for the TGAI, an aqueous solution of metam sodium, were reported previously". The "report" was not identified further [MRID No. 422771-01].

Additional information is required on this topic, **see** footnote 3 Phase 4 review dated 5/13/91 by C. Olinger. That footnote states:

Individual results for the determination of the a.i. in five or more lots are required, in addition to the reported range. The TGAI as well as the reported EP must be analyzed for active ingredient and all impurities > 0.1% (w/w). Alternatively, the registrant may analyze the MP (five lots) with methods of demonstrated sufficient sensitivity to detect impurities > 0.03% w/w (0.1% w/w corrected for water dilution in the MP).

62-3 - Analytical Methods to Verify Certified Limits

The Registrant has not submitted the required data to demonstrate the accuracy of the a.i. determination. The Registrant, "feels quite strongly that the methodology incorporated in the a.i. method (acid hydrolysis to liberate carbon disulfide followed by iodine titration for the carbon-disulfide-derived xanthate) is accurate". By reference, the Registrant stated that, "the accuracy of the titration method is supported by the fact that material closure reported in RRC-84-87

for the six production samples range between 97.7-99.4 w/w%". Raw data and the method description were not provided. The "25+ year-old" methodology was referenced as depicted below:

- "1. Raizman, P., and Thompson, Q.E., in Karchner, J.H., Editor, "Analytical Chemistry of Sulfur and its Compounds," Part II, Wiley, NY, 1972, pp. 623-633.
- "2. Bontoyan, W.R., "Analysis of Dithiocarbamates by CS₂ Evolution," JOAC, 1965, 48, p 562.
- "3. Gray, R.A., in Zweig, G., Editor, "Analytical Methods for Pesticides, Plant Growth Regulators, and Food Additives", Vol. III "Fungicides, Nematocides and Soil Fumigants, Rodenticides, and Food and Feed Additives," Academic Press, NY, 1964, pp 177-183.

But, the current manufacturing procedure [MRID No. 422771-02] states that, "the a.i. assay was measured using an FT-IR spectrometer".

Additional information is required under this topic.

Conclusion

Except for 61-1, 61-2, 61-3, and 62-2 all other product chemistry requirements for sodium methyldithiocarbamate [metam sodium; 39003] remain unsatisfied.

Attachments:

Appendix A [CONFIDENTIAL, 1 page]

Table A: Product Chemistry Data Supporting Guideline Requirements for Reregistration of Metam sodium.

cc with Attachments: K. Dockter (CBRS), RF, SF, FIFRA '88

File, E. Saito, C. Furlow/J. Burrell
(PIB/FOD).

cc without Confidential Attachment: Circulation (7).

RDI:ARRathman:5/28/92:EZager:6/1/92
H7509C:CBRS:CM#2:RM804B:3057886:KD/Kd:6/1/92
308C.M[METAM_SO]

Table A

Product Chemistry Data Supporting Guideline Requirements for
Reregistration of Sodium methylthiocarbamate

Requirement	Requirement Fulfilled	Citation
61-1	Chemical Identity	Yes 92098001
61-2	Beginning Materials and Manufacturing Process	Yes 92098001 42277101 42277102
61-3	Discussion of the Formation of Impurities	Yes 92098001
62-1	Product Analysis	No ^a 92098002 42277101
62-2	Certification of Limits	Yes 92098002
62-3	Methods to Verify Limits	No ^b 92098002 42277101
63-2	Color	No ^c 92098003
63-3	Physical State	No ^c 92098003
63-4	Odor	No ^c 92098003
63-5	Melting Point	No ^d NP
63-6	Boiling Point	No ^e NP
63-7	Density	No ^c 92098003
63-8	Solubility	No ^d NP
63-9	Vapor Pressure	No ^f NP
63-10	Dissociation Constant	No ^g NP
63-11	Octanol/Water Partition Coefficient	No ^h NP
63-12	pH	No ^c 92098003
63-13	Stability	No ^d NP

NP = Not provided.

^a Individual results are required, see footnote 3 Phase 4 review dated 5/13/92 by C. Olinger. ^b The AI assay accuracy must be demonstrated. ^c Required for both the MP/EP [reported] and the TGAI. ^d Required for the TGAI, not for the MP/EP [as reported]. ^e Required for the TGAI, not for the EP [as reported]; reserved, see footnote 7 of aforesaid review. ^f Waiver requested; reserved see footnote 9 of aforesaid review. ^g Waiver requested; reserved see footnote 10 of aforesaid review. ^h Required for the PAI, not for the MP/EP. Cannot ascertain if registrant used the PAI or the MP [registrant-designated "TGAI"].

PRODUCT CHEMISTRY

Case No.: 2390 Case Name: Sodium methyldithiocarbamate

Chemical No(s): 39003

Chemical Name(s): Metam sodium

Registrant: ICI Americas

Guide- line #	Is require- ment appli- cable?	Does summary/avail- able information indicate that MRID is a candidate for Phase 5 review?	Are additional data required?	MRID
61-1	Y	Y	N	92098001
61-2	Y	Y	N	92098001 42277101 42277102
61-3	Y	Y	N	92098001
62-1	Y	N	Y ^a	92098002 42277101
62-2	Y	Y	N	92098002
62-3	Y	N	Y ^b	92098002 42277101
63-2	Y	N	Y ^c	92098003
63-3	Y	N	Y ^c	92098003
63-4	Y	N	Y ^c	92098003
63-5	Y	N	Y ^d	NP
63-6	I	N	Y ^e	NP
63-7	Y	N	Y ^c	92098003
63-8	Y	N	Y ^d	NP
63-9	I	N	Y ^f	NP
63-10	Y	N	Y ^g	NP
63-11	Y	N	Y ^h	NP
63-12	Y	N	Y ^c	92098003
63-13	Y	N	Y ^d	NP

Key: Y=yes; I=a decision cannot be made at this time; N=no.

^a Individual results are required, see footnote 3 Phase 4 review dated 5/13/92 by C. Olinger. ^b The AI assay accuracy must be demonstrated. ^c Required for both the MP/EP [reported] and the TGAI. ^d Required for the TGAI, not for the MP/EP [as

reported]. ^e Required for the TGAI, not for the EP [as reported]; reserved, see footnote 7 of aforescited review. ^f Waiver requested; reserved see footnote 9 of aforescited review. ^g Waiver requested; reserved see footnote 10 of aforescited review. ^h Required for the PAI, not for the MP/EP. Cannot ascertain if registrant used the PAI or the MP [registrant-designated "TGAI"].