

US EPA ARCHIVE DOCUMENT



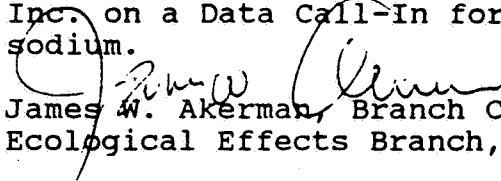
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MAR 20 1989

MEMORANDUM

SUBJECT: Review of comments on waiver request from Transbas, Inc. on a Data Call-In for the herbicide metam sodium.

FROM:  James W. Akerman, Branch Chief,  
Ecological Effects Branch, EFED

TO: Geraldine Werdig, (PM-50)  
Herbicides Branch, RD

We are in receipt of a request from your office to evaluate the waiver requests from the registrant Transbas, Inc. for a herbicide, metam sodium. In the response from the registrant to the DCI, they indicated that the required "data has already been supplied or is being supplied with this submission". Neither statement is true as far as we in EEB know. Our files do not contain any of the required studies and we did not receive any studies with this submission package. Therefore we can neither concur nor deny the waiver requests from the registrant.

*Handwritten note:* 1/11/89

238732  
RECORD NO.

039003  
SHAUGHNESSY NO.

\_\_\_\_\_  
REVIEW NO.

EEB REVIEW

DATE: IN 1-31-89

DATE: OUT 3-21-89

FILE OR REG. NO. 039003

PETITION OR EXP. NO. \_\_\_\_\_

DATE OF SUBMISSION 12-23-88

DATE RECEIVED BY HED 1-27-89

RD REQUESTED COMPLETION DATE 3-20-89

EEB ESTIMATED COMPLETION DATE 3-20-89

RD ACTION CODE 400

TYPE OF PRODUCT(S) : I,D,H,F,N,R,S HERBICIDE

DATA ACCESSION NO(S). \_\_\_\_\_

PRODUCT MANAGER (NO.) G. WERDIE (50)

PRODUCT NAME(S) METAM SODIUM

COMPANY NAME METAM SODIUM TASKFORCE (TRANSBAS, INC.)

SUBMISSION PURPOSE REGISTRANT RESPONSE CONCERNING DCI

NOTICE OF 7/21/88

SHAUGHNESSY NO.	CHEMICAL & FORMULATION(S)	% A.I.
_____	_____	_____
_____	_____	_____
_____	_____	_____

Date Received 7 5 2 7  
1/27/87

OFFICE OF PESTICIDE PROGRAMS DATA REVIEW RECORD

ATTACHMENT 1

Confidential Business Information-Does Not Contain National Security Information(E.O. 12065)  
This form is to be used for individual studies and for submission of pesticide applications

1. PRODUCT NAME <b>Metam Sodium</b>		CHEMICAL NAME	
2. IDENTIFYING NUMBER <b>039003</b>	3. RECORD NUMBER <b>238732</b>	4. ACTION CODE <b>4001</b>	5. MRID/ACCESSION NUMBER
7. REFERENCE NUMBER	8. DATE RECEIVED (EPA) <b>12/29/86</b>	9. PRODUCT/REVIEW MANAGER/DCI <b>UCT</b>	10. PM/RM TEAM NUMBER <b>50</b>
12. PROJECTED RETURN DATE <b>3/20/87</b>	13. DATE RETURNED TO (RD/SRRD)	11. DATE SENT TO (HED/EFED/RD/BEAD) <b>1/25/87</b>	
INSTRUCTIONS: <b>Response to Metam Sodium Data Call Jan. of 7/12/86</b>			

*Do you concur with the waiver  
submitted from Task Force*

(THIS SECTION APPLIES TO REVIEW OF STUDIES ONLY)

14. CHECK APPLICABLE BOX:

- ADVERSE 6(a)(2) DATA (405)
- SPECIAL REVIEW DATA (870)
- GENERIC DATA (REREGISTRATION) (660)

15. NUMBER OF INDIVIDUAL STUDIES SUBMITTED

- PRODUCT SPECIFIC DATA (655) (REREGISTRATION)

16. HAVE ANY OF THE ABOVE STUDIES (in whole or in part) BEEN PREVIOUSLY SUBMITTED FOR REVIEW? (circle: yes or no) IF YES, PLEASE IDENTIFY THE STUDY(IES):

17. RELATED ACTIONS:

18.	TO	TYPE OF REVIEW	19. REVIEWERS ALSO SENT TO
HED	<input checked="" type="checkbox"/>	SCIENCE ANALYSIS & COORD.	SAC
	<input checked="" type="checkbox"/>	TOXICOLOGY/HFA	TOX/HFA
	<input type="checkbox"/>	TOXICOLOGY/IR	TOX/IR
EF ED	<input type="checkbox"/>	DIETARY EXPOSURE	DEB
	<input type="checkbox"/>	NON-DIETARY EXPOSURE	NDE
	<input checked="" type="checkbox"/>	ECOLOGICAL EFFECTS	EEB
SRRD	<input checked="" type="checkbox"/>	ENVIRONMENTAL FATE & GROUND H2O	EFGWB
	<input type="checkbox"/>	SPECIAL REVIEW	SR
	<input type="checkbox"/>	REREGISTRATION	RER
RD	<input type="checkbox"/>	GENERIC CHEMICAL SUPPORT	GSC
	<input type="checkbox"/>	INSECTICIDE-RODENTICIDE	IR
	<input type="checkbox"/>	FUNGICIDE-HERBICIDE	FH
HEAD	<input checked="" type="checkbox"/>	ANTIMICROBIAL	AM
	<input type="checkbox"/>	PRODUCT CHEMISTRY	
	<input type="checkbox"/>	PRECAUTIONARY LABELING	
		ECONOMIC ANALYSIS	
		ANALYTICAL CHEMISTRY	
		BIOLOGICAL ANALYSIS	

20. DATA REVIEW CRITERIA
- A. Policy Note #31
- 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria
  - 2 = data of particular concern from registration standard
  - 3 = data necessary to determine tiered testing requirements
- B. Section 18
- 1 = data in support of section 3 in lieu of section 18
- C. Inert Ingredients
- 1 = data in support of continued use of List 1 inert

- CONFIDENTIAL STATEMENT OF FORMULA (TRADE SECRETS)
- LABEL ATTACHED

White - Data Coordinator  
Yellow - Data Review Section  
Green - Return with completed review  
Pink - PM/RM/DCI

Include original + two (2) copies with each submission



December 02, 1988

TO: Geraldine W. Werdig, Chief  
Data Call In Program  
Registration Division (TS-767C)  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
401 M Street, S.W.  
Washington, DC 20460

SUBJECT: Comprehensive Data Call In  
Notice for Data on Metam Sodium

Dear Ms. Werdig:

Please find attached our 135 - Day Call In Summary Sheets for our Metam Sodium product. EPA Registration No. 37507-1. We are current members of the Metam Sodium Task Force and it is through this consortium we will be submitting the data required by the data call in notice for Metam Sodium.

Sincerely,

Randy Bodley

A handwritten signature in cursive script that reads "Randy Bodley".

RB/lls

WAIVER REQUESTS - METAM SODIUM

Requests for waivers for certain data requested under the Data Call-In Notice dated July 12, 1988 have been made on the 135 day data call-in summary sheets. The explanations for these requests are made by cross reference to the footnotes contained on the summary sheets.

FOOTNOTE 1- The technical grade active ingredient is an aqueous solution.

FOOTNOTE 2- The technical grade active ingredient is a sodium salt and has no further ionizable functions.

FOOTNOTE 3- The TGAI and the manufacturing use product are identical. Therefore the data has already been supplied or is being supplied with this submission.

FOOTNOTE 4- The necessity of this study can only be assessed after the plant metabolism of the material is defined. This product is a soil fumigant, once applied it rapidly breaks down to methylisothiocyanate (MITC) which acts as the sterilant. Crops can only be planted after the active sterilant is dissipated or the plants do not survive. Recent plant metabolism studies have shown that neither metam sodium nor MITC are present as terminal residues in plant material after being grown in soil treated with metam sodium. The data clearly indicate that the material is extensively metabolized and probably enters into the carbon pool.

FOOTNOTE 5- The necessity of this study can only be assessed after the soil dissipation data required under 164-1 are reviewed.

FOOTNOTE 6- The necessity of this study can only be assessed after review of the data required by 165-1 are reviewed.

FOOTNOTE 7- The TGAI and the manufacturing use product are identical, therefore the data has already been supplied or is being supplied with this submission.

FOOTNOTE 8- As plant metabolism has shown that there is no dietary exposure to metam sodium, it is unnecessary to conduct chronic or subchronic feeding studies.

FOOTNOTE 9- Since it is clear that MITC is the material of interest when addressing worker exposure by the inhalation route it is proposed that the inhalation subchronic testing be conducted with MITC.

FOOTNOTE 10- The necessity of this study can not be assessed until the questions of dermal and inhalation toxicity are answered.

FOOTNOTE 11- The necessity of this study cannot be assessed until the data required by 72-1 and 72-2 are reviewed.

FOOTNOTE 12- Metam sodium is a soil sterilant, it is quite clear and expected that severe phytotoxic effects will be manifested until the sterilant, MITC is dissipated.

TABULATION SHEET FOR THE 135-DAY DATA CALL IN SUMMARY SHEETS

If you selected option C on the 90-day Data Call In Summary Sheet, check the various options you selected on the following 135-day summary sheets for complying with the requirements of this Notice. Submit this sheet with the 135-day summary sheets. If you selected the same options for all your products, submit only one set of 135-day summary sheets.

Name of Registrant and EPA Registration No.: Transbas Inc. 37507-1  
 Date of Data Call-In Notice: July 12, 1988 of products containing Metam-sodium as an active ingredient.

Options for complying with the requirements of this Notice.	Check Option(s) Selected
1. I am submitting existing data for one or more of the data requirements identified on the following sheets. A coversheet (Attachment G) is attached which summarizes each study submitted.	
2. I will generate and submit data for one or more of the data requirements identified on the following sheets. I will submit semiannual progress reports according to the schedule on the Summary Sheets. These data will be generated according to the Pesticide Assessment Guidelines <input type="checkbox"/> , OECD protocols <input type="checkbox"/> , or other protocols <input type="checkbox"/> .	
3. I have entered into an agreement under FIFRA §3(c)(2)(B)(ii) with one or more other registrants to share the burdens of generating and submitting data and progress reports for one or more of the data requirements identified on the following sheets, according to the schedule on those sheets. A copy of the agreement is attached and the name and address of the registrant to submit each test is specified.	✓
4. I have been unsuccessful in entering into any agreement to develop data with other registrants. Attached are copies of the offers I have made regarding one or more of the data requirements on the following sheets. Also attached is proof of receipt of the offer(s).	
5. I enclose a completed application to amend my registration(s) by deleting one or more of its currently registered uses. Once this amendment is approved, I believe the data requirements, identified on the following sheets, will not apply to my product.	
6. I request a waiver from the obligation to arrange to submit data for one or more of the data requirements on the attached sheets because the active ingredient in my registered pesticide product is a low volume/minor use chemical. Attached, are supporting documents according to Section III.	
7. I contend that I am not obliged to comply with this Notice because the uses of my registered pesticide product(s) are such that, under the Pesticide Registration Data Requirements regulation, these data requirements do not apply to my product. Attached is my explanation together with a current and accurate Confidential Statement of Formula for my pesticide product(s).	

(406) 245-4171  
 Phone No. + area code

Randy Bodley  
 Signature of Authorized Representative

Randy Bodley  
 Signature (Typed or printed)

\_\_\_\_\_  
 Address (If different from mailing address)



135-DAY DATA CALL IN SUMMARY SHEET  
 GENERIC DATA REQUIREMENTS FOR METAM SODIUM

Data Requirement	Compo- sition To Be Tested a/	Time Frame For Submit- ting Data	Use Pattern Miere Appli- cable b/	Data Deter- mined To Be "R" or "CR" c/	Reglatriants Response d/
<u>\$158.190 PRODUCT CHEMISTRY (previously 158.120)</u>					
<u>Product Identity and Composition:</u>					
61-1 - Product Identity and Dis- closure of Ingredients	TGAI	6 months	--	R	①2,3,4,5,6,7
61-2 - Description of Beginning Materials and Manufac- turing Process	TGAI	6 months	--	R g/	①2,3,4,5,6,7
61-3 - Discussion of Formation of Impurities	TGAI	6 months	--	R f/	①2,3,4,5,6,7
<u>Analysis and Certification of Product Ingredients</u>					
62-1 - Preliminary Analysis of Product Samples	TGAI	12 months	--	R g/	①2,3,4,5,6,7
62-2 - Certification of Ingre- dient Limit	TGAI	12 months	--	R h/	①2,3,4,5,6,7
62-3 - Analytical Methods to Verify Certified Limits .....	TGAI	12 months	--	R i/	①2,3,4,5,6,7

12-2-88  
 \_\_\_\_\_  
 DATE

*L. J. New*  
 \_\_\_\_\_  
 SIGNATURE OF REGISTRANT

135-DAY DATA CALL IN SUMMARY SHEET

GENERIC DATA REQUIREMENTS FOR METAM SODIUM

Data Requirement	Compo- sition To Be Tested a/	Time Frame For Submit- ting Data	Use Pattern Where Appli- cable b/	Data Deter- mined To Be "R" or "CR" c/	Registrants Response d/
<u>5158.190 PRODUCT CHEMISTRY - continued</u>					
<u>Physical and Chemical Characteristics</u>					
63-2 - Color	TGAI	6 months	--	R <input checked="" type="checkbox"/>	①2,3,4,5,6,7
63-3 - Physical State	TGAI	6 months	--	R <input checked="" type="checkbox"/>	①2,3,4,5,6,7
63-4 - Odor	TGAI	6 months	--	R <input checked="" type="checkbox"/>	①2,3,4,5,6,7
63-5 - Melting Point	PAI	6 months	--	R <input checked="" type="checkbox"/>	1,2,3,4,5,6,7 <sup>1</sup>
63-6 - Boiling Point	PAI	6 months	--	R <input checked="" type="checkbox"/>	①2,3,4,5,6,7
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	6 months	--	R <input checked="" type="checkbox"/>	①2,3,4,5,6,7
63-8 - Solubility	TGAI or PAI	6 months	--	R <input checked="" type="checkbox"/>	①2,3,4,5,6,7
63-9 - Vapor Pressure	TGAI or PAI	6 months	--	R <input checked="" type="checkbox"/>	①2,3,4,5,6,7

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12-2-88  
DATE

*L. A. ...*  
SIGNATURE OF REGISTRANT

135-DAY DATA CALL IN SUMMARY SHEET

GENERIC DATA REQUIREMENTS FOR METAM SODIUM

Data Requirement	Compo- sition To Be Tested a/	Time Frame For Submit- ting Data	Use Pattern Where Appli- cable b/	Inta- deter- mined To Be "R" or "CR" c/	Registrants Resubmit d/
<b>§158.190 PRODUCT CHEMISTRY - continued</b>					
<b>Physical and Chemical Characteristics (Continued)</b>					
63-10 - Dissociation Constant	TGAI or PAI	6 months	--	R <input checked="" type="checkbox"/>	1,2,3,4,5,6,7 <sup>2</sup>
63-11 - Octanol/Water Partition Coefficient	PAI	6 months	--	R <input checked="" type="checkbox"/> k/	① 2,3,4,5,6,7
63-12 - pH	TGAI	6 months	--	R <input checked="" type="checkbox"/>	① 2,3,4,5,6,7
63-13 - Stability	TGAI	6 months	--	R <input checked="" type="checkbox"/>	① 2,3,4,5,6,7
<b>Other Requirements:</b>					
64-1 - Submittal of samples	CHOICE	6 months	--	R	1,2,3,4,5,6,7

**FOOTNOTES:**

- a/ Test Substance: TGAI = Technical Grade of the Active Ingredient; PAI = Pure Active Ingredient; HHP = Manufacturing-Use Product.
- b/ The use patterns are coded as follows: TF=Terrestrial, Food Crop; TN=Terrestrial, Non-Food; AF=Aquatic, Food Crop; AN=Aquatic, Non-Food; GF=Greenhouse, Food Crop; GN=Greenhouse, Non-Food; F=Forestry; DD=Domestic Outdoor; I=Indoor; ALL=All uses.
- c/ The Agency has reviewed records of registered use patterns for this chemical and determined that the following studies or data are either required (R) or conditionally required (CR) to be submitted. The footnotes explain under what conditions the conditionally required studies are required. Refer to the attached copy of the Federal Register Part 158 Data Requirements for Pesticide Registration Final Rule for an explanation of the conditions under which this study is required. If the registrant does not believe the conditions apply, they may submit their rationale and select the option on Inapplic-able data requirement.

12-2-88  
DATE

*L. J. ...*  
SIGNATURE OF REGISTRANT

135-DAY DATA CALL IN SUMMARY SHEET

GENERIC DATA REQUIREMENTS FOR METAM SODIUM

Data Requirement	Compo- sition To Be Tested	Time Frame For Submit- ting Data	Use Pattern Where Appli- cable	Data Deter- mined To Be "R" or "CR"	Registrants Response
\$158.190			b/	c/	d/

FOOTNOTES (Continued)

- d/ Indicate which allowable option you have selected by circling the appropriate number above, corresponding to the way in which you will fulfill this data requirement: (1) An submitting existing certified data with these tables and am submitting a signed certification as to the adequacy of each study submitted (Submitting); (2) Will generate and submit data within specified timeframes (Generate); (3) Have entered into an agreement (Agreement); (4) Have made offers to pay (Offer); (5) Will amend registration to delete uses (Amendment); (6) Have requested a low volume/minor use waiver (Minor); or (7) I contend the data requirement does not apply to my product (Inapplicable). Those allowable options are exactly the same as those included and explained in the IXI notice and the Tabulation of the 135-day Data Call In Summary Sheet. Sign and date the bottom of each page.
- e/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, a flow chart with chemical equations for each intended chemical reaction, equipment used to produce the product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material.
- f/ A detailed discussion of all impurities that are or may be present at >0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.
- g/ Five or more representative samples of each product must be analyzed for the amount of active ingredient and each impurity present at >0.1% (w/w). Complete validation data (accuracy, precision) for each analytical method used must be submitted.
- h/ Upper and lower limits for the active ingredient and upper limits for each impurity present at >0.1% (w/w) must be provided, certified, and validated using analytical procedures for which accuracy and precision data have been provided. Certifications must be submitted on EPA form 8570 Rev. 2-85.

12-2-88  
DATE

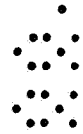
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SIGNATURE OF REGISTRANT

135-DAY DATA CALL IN SUMMARY SHEET

GENERIC DATA REQUIREMENTS FOR METAM SODIUM

Data Requirement	Composition To Be Tested a/	Time Frame For Submitting Data	Use Pattern Where Applicable b/	Data Determined To Be "R" or "CR" c/	Registrants Resubmit d/
§158.190 FOOTNOTES (Continued)					

- j/ Analytical methods are required to determine the active ingredient and each toxicologically significant impurity for which a certified limit is required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.
- k/ Physical/chemical characteristics (color, physical state, odor, melting point, specific gravity, solubility, vapor pressure, dissociation constant, Kow, pH, and stability) as required in 49 FR No. 207, p. 42890 (Sec. 158.190, previously 158.120) and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.
- l/ The Agency acknowledges that there are existing data which pertain to this data requirement. If you wish to rely on such data to fill the data requirement, you must certify that it meets the criteria for submitting existing data as explained in Section III-C-3 of the Notice, Submitting Existing Data or select another option.



12-2-88  
DATE

*L. J. [Signature]*  
SIGNATURE OF REGISTRANT

135-DAY DATA CALL IN SUMMARY SHEET

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS CONTAINING METAM SODIUM

Data Requirement	Compo- sition To Be Tested a/ c/	Time Frame For Submit- ting Data	Use Pattern Micro Appli- cable b/ c/	Data Deter- mined To Be "R" or "C" c/	Registrants Response d/ e/
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\$158.190 PRODUCT CHEMISTRY (previously 158.120)

Product Identity

61-1 - Product Identity and Dis- closure of Ingredients	MP	6 months	--	R	1,2,3,4,5,6 <sup>3</sup> 7
61-2 - Description of Beginning Materials and Manufacturing Process	MP	6 months	--	R	1,2,3,4,5,6 <sup>3</sup> 7
61-3 - Discussion of Formation of Impurities	MP	6 months	--	R	1,2,3,4,5,6 <sup>3</sup> 7

Analysis and Certification of  
Product Ingredients:

62-2 - Certification of Ingredient Limits	MP	12 months	--	R	1,2,3,4,5,6 <sup>3</sup> 7
62-3 - Analytical Methods to Verify Enforcement Limits	MP	12 months	--	R	1,2,3,4,5,6 <sup>3</sup> 7

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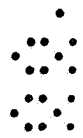
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*L. J. ...*  
SIGNATURE OF REGISTRANT

135-DAY DATA CALL IN SUMMARY SHEET

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING METAM SODIUM

Data Requirement	Composition To Be Tested a/	Time Frame For Submitting Data	Use Pattern Where Applicable b/	Data Determined To Be "R" or "CR" c/	Registrants Response d/
<u>S158.190 PRODUCT CHEMISTRY - continued</u>					
<u>Physical and Chemical Characteristics</u>					
63-2 - Color	MP	6 months	--	R 1/	1,2,3,4,5,6,7 <sup>3</sup>
63-3 - Physical State	MP	6 months	--	R 1/	1,2,3,4,5,6,7 <sup>3</sup>
63-4 - Odor	MP	6 months	--	R 1/	1,2,3,4,5,6,7 <sup>3</sup>
63-7 - Density, Bulk Density, or Specific Gravity	MP	6 months	--	R 1/	1,2,3,4,5,6,7 <sup>3</sup>
63-12 - pH	MP	6 months	--	R 1/	1,2,3,4,5,6,7 <sup>3</sup>
63-16 - Explodability	MP	6 months	--	R 1/	1,2,3,4,5,6,7 <sup>3</sup>
63-17 - Storage Stability	MP	15 months	--	R 1/	1,2,3,4,5,6,7 <sup>3</sup>
63-20 - Corrosion Characteristics	MP	15 months	--	R 1/	1,2,3,4,5,6,7 <sup>3</sup>
<u>Other Requirements</u>					
64-1 - Submittal of Samples	Choice	6 months	--	R	1,2,3,4,5,6,7 <sup>3</sup>



12.2.88

DATE

*L. J. ...*

SIGNATURE OF REGISTRANT

135-DAY DATA CALL IN SUMMARY SHEET

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING METHAM SODIUM

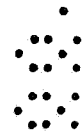
Data Requirement	Compo- sition To Be Tested a/	Time Frame For Submit- ting Data	Use Pattern Where Appli- cable b/	Data Deter- mined To Be "R" or "CR" c/	Registrants Response d/
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§159.190  
EXEMPTIONS:

- a/ Test Substance: TGA1 = Technical Grade of Active Ingredient; PAI = Pure Active Ingredient; Choice = Choice of several test substances determined on a case-by-case basis; MP = Manufacturing Use Product. The use patterns are coded as follows: TF-Terrestrial, Food Crop; TN-Terrestrial, Non-Food; AF-Aquatic, Food Crop; AI-Aquatic, Non-Food; GF-Greenhouse, Food Crop; GN-Greenhouse, Non-Food; F-Forestry; IN-Indoestic (Indoor; I-Indoor); ALL-All Uses.
- b/ The Agency has reviewed records of registered use patterns for this chemical and determined that the following studies are either required (R) or conditionally required (CR). Refer to the attached copy of the Federal Register Part 158 Data Requirements for Pesticide Registration; Final Rule for an explanation of the conditions under which these studies are required. If the registrant does not believe the conditions apply, they may submit their rationale and select the option on inapplicable data requirement.
- c/ Indicate which allowable option you have selected by circling the appropriate number above, corresponding to the way in which you will fulfill this data requirement: (1) An submitting existing certified data with these tables and am submitting a signed certification as to the adequacy of each study submitted (Submitting); (2) Will generate and submit data within specified timeframe (Generate); (3) Have entered into an agreement (Agreement); (4) Have made offers to pay (Offer); (5) Will amend registration to delete uses (Amendment); (6) Have requested a low volume/minor chemical waiver (Minor); or (7) I claim the data requirement does not apply to my product (Inapplicable). These allowable options are the same as those included and explained in the ICI notice and the Tabulation of the 135-Day Data Call In Summary Sheet. Sign and date the bottom of each page.
- d/

12-2-88  
 \_\_\_\_\_  
 DATE

*L. P. ...*  
 \_\_\_\_\_  
 SIGNATURE OF REGISTRANT





PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING METAM SODIUM

Data Requirement	Composition To Be Tested <sup>a/</sup>	Time Frame For Submitting Data	Use Where Applicable <sup>b/</sup>	Data Determined To Be "R" or "CR" <sup>c/</sup>	Registrants Resipwise <sup>d/</sup>

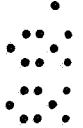
§158.190

FOOTNOTES (Cont Inued)

- e/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, a flow chart with chemical equations for each intended chemical reaction, equipment used to produce the product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material.
- f/ A detailed discussion of all impurities that are or may be present at >0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.
- g/ Upper and lower limits for the active ingredient and upper limits for each impurity present at >0.1% (w/w) must be provided, certified, and validated using analytical procedures for which accuracy and precision data have been provided. Certifications must be submitted on EPA form 8570 Rev. 2-85.
- h/ Analytical methods are required to determine the active ingredient and each toxicologically significant impurity for which a certified limit is required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.
- i/ Physical/chemical characteristics (color, physical state, odor, melting point, specific gravity, solubility, vapor pressure, dissociation constant, K<sub>ow</sub>, pH, and stability) as required in 49 FR No. 207, p. 42090 (Sec 158.120 previously 158.190) and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

12 2 88  
DATE

*L. Peter Ward*  
SIGNATURE OF REGISTRANT



135-DAY DATA CALL, IN SUMMARY SHEET

GENERIC DATA REQUIREMENTS FOR METAM SODIUM

Data Requirement	Composition To Be Tested	Time Frame For Submitting Data	Use Pattern Where Applicable	Data Determined To Be "R" or "CR" or "C"	Registrants Response
<b>\$158.240 RESIDUE CHEMISTRY (previously 158.125)</b>					
171-2 Chemical Identity	TCGI	6 months	TP, TN, AF, AV, F, DO, I	R	①2,3,4,5,6,7
171-3 Directions for Use Information	—	6 months	TP, TN, AF, AV, F, DO, I	R	①2,3,4,5,6,7
171-4 Nature of the residue (Metabolism, including storage stability data)					
- Plants	PAIRA	18 months	TP, AF	R	①2,3,4,5,6,7
- Livestock	PAIRA	18 months	TP, AF	CR	1,2,3,4,5,6,7 <sup>4</sup>
171-4 Residue analytical methods (plant and animal residues)	TCGI and Metabolites	15 months	TP, AF	R	①2,3,4,5,6,7
171-4 Storage stability data	TEP or PAI and Metabolites	15 months	TP, AF	R	①2,3,4,5,6,7
171-4 Magnitude of the Residue (including storage stability data)					
- Crop field trials					
o Growing Crops	EP, TEP	18 months	TP, AF	R	①2,3,4,5,6,7
o Studies					

12-2-88

DATE

*[Signature]*  
SIGNATURE OF REGISTRANT

135-DAY DATA CALL IN SUMMARY SHEET  
 GENERIC DATA REQUIREMENTS FOR METAM SODIUM

Data Requirement	Composition To Be Tested a/	Time Frame For Submitting Data	Use Pattern Where Applicable b/	Data Determined To Be "R" or "CR" c/	Registrants Response d/ e/
<b>158.240 RESIDUE CHEMISTRY - continued</b>					
Magnitude of the Residue (Continued) (including storage stability data)					
- Processed Food/ Feed Studies (Processing Studies)	EP	24 months f/	TP, AP	R	1, 2, 3, 4, 5, 6, 7 4
- Meat/Milk/Poultry/ Eggs (Animal/Livestock feeding studies)					
o Conventional ruminant and poultry feeding studies	TGAI or plant metabolites	18 months f/	TP, AP	R	1, 2, 3, 4, 5, 6, 7 4
<b>171-4 Aquatic Use Sites</b>					
- Water Residue Studies	EP	15 months	AP	R	1, 2, 3, 4, 5, 6, 7
- Fish and Shellfish Residue Studies	EP	15 months	AP	R	1, 2, 3, 4, 5, 6, 7
- Irrigated Crop Residue Studies	EP	18 months	AP, AN	R	1, 2, 3, 4, 5, 6, 7

12.2.88  
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 SIGNATURE OF REGISTRANT

135-DAY DATA CALL IN SUMMARY SHEET

GENERIC DATA REQUIREMENTS FOR METAM SODIUM

Data Requirement	Composition To Be Tested	Time Frame For Submitting Data	Use Pattern Where Applicable	Data Determined To Be "R" or "CR"	Registrants Response
	a/		b/	c/	d/ e/

\$158.240

FOOTNOTES:

- a/ Test Substances: TCAI = Technical Grade of the Active Ingredient; PAIRA = Pure Active Ingredient, RADIOLabeled; TEP = Typical End-use Product; EP = End-use Product; PAI = Pure Active Ingredient.
- b/ The use patterns are coded as follows: TP=Terrestrial, Food Crop; TN=Terrestrial, Non-Food; AP=Aquatic, Food Crop; AN=Aquatic, Non-Food; GP=Greenhouse, Food Crop; GN=Greenhouse, Non-Food; P=Forestry; ID=Domestic Outdoor; and I=Indoor; ALL=All Uses.
- c/ The Agency has reviewed records of registered use patterns for this chemical and determined that the following studies are either required (R) or conditionally required (CR) to be submitted. Refer to the attached copy of the Federal Register Part 158, Data Requirements for Pesticide Registrations; also be expressed in a footnote. If the registrant does not believe the conditions apply they may submit their rationale and select the option on inapplicable data requirement.
- d/ Indicate which allowable option you have selected by circling the appropriate number above corresponding to the way in which you will fulfill this data requirement: (1) An submitting existing certified data with these tables and am submitting a signed certification as to the adequacy of each study submitted (Submitting); (2) Will generate and submit data within specified timeframes (Generate); (3) Have entered into an agreement (Agreement); (4) Have made offers to pay (Offer); (5) Will amend registration to delete uses (Amendment); (6) Have requested a low volume/minor use waiver (Minor); or (7) I contend the data requirement does not apply to my product (Inapplicable). These allowable options are the same as those included and explained in the DCI notice and the Tabulation of the 135-day Data Call In Summary Sheet. Sign and date the bottom of each page.
- e/ The registrant(s) who select: option 1 or 2 must list those uses/crops for which data will be generated or are being submitted or, in other words, the registrant(s) must submit a list of those uses/crops which they intend to continue to support.
- f/ The time frame listed is the standard elapsed time frame. It does not in any way supercede any deadlines established by previous Data Call Ins.

12-2-88

DATE

*L. J. ...*  
SIGNATURE OF REGISTRANT

135-DAY DATA CALL IN SUMMARY SHEET

GENERIC DATA REQUIREMENTS FOR METAM SODIUM

Data Requirement	Compo- sition To Be Tested a/	Time Frame For Submit- ting Data	Use Pattern Where Appli- cable b/	Data Deter- mined To Be "R" or "CR" c/	Registrants Response d/ e/

15R.240

FOOTNOTES (Continued)

- g/ **Plant Metabolism Studies** - The uptake, distribution and metabolism of active ingredient must be studied in registered field crops following soil, foliar or other appropriate treatment at rates sufficiently high to permit complete characterization of <sup>14</sup>C-residues. The identities and quantities of residues in or on mature plant parts must be determined in order to elucidate terminal residues. Residue identities must be confirmed by a method such as GC, HPLC, and/or mass spectrometry. Data reflecting solvent extraction efficiency must be represented. Representative samples from these tests must also be analyzed by analytical methods proposed for enforcement to ascertain that the methods are capable of adequately recovering and quantifying all residues of concern. Prior to initiation of residue field trials and processing studies, the registrant should complete and submit all plant metabolism data to the Agency for review to determine among other things, the metabolites of concern.
- h/ **Livestock Metabolism Studies** - Metabolism studies using ruminants and poultry must be submitted. Animals must be dosed for at least 3 days with <sup>14</sup>C-labelled ingredient at a level sufficiently high to permit complete identification and quantifications of <sup>14</sup>C-residues. Milk and eggs must be collected twice daily during the dosing period. Animals must be sacrificed within 24 hours of the final dose. The distribution and characterization of residue must be determined in milk, eggs, liver, kidney, muscle and fat. Samples from these studies must also be analyzed using analytical methods proposed for enforcement to ascertain that the methods are capable of adequately recovering and quantifying all residues of concern. [It should be noted that if metabolism in ruminants or poultry is found to differ significantly from that in rats, additional metabolism data for swine may be required.]
- i/ **Residue Analytical Methods** - Residues of active ingredient and any other residues of concern discovered in the required plant metabolism studies in or on crop samples must be subjected to analysis by multi-residue method PCTCOO's I-IV, available from NTIS under order No. PB203734/AS. If it is determined that tolerances must be established for residues of active ingredient in animal commodities, these data will also be required for representative animal commodities.
- j/ **Residue Analytical Methods** - All residue data required in this Notice must be accompanied by a complete description of all analytical methods used in data collection along with complete method validation data (accuracy, precision, and sensitivity) for each residue in/on each commodity.
- k/ **Storage Stability Studies** - To support crop residue data, storage stability studies must be conducted generally on both weathered samples and fortified frozen samples of at least one representative crop

12-2-88

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*L. J. [Signature]*  
SIGNATURE OF REGISTRANT

GENERIC DATA REQUIREMENTS FOR METAM SODIUM

Data Requirement	Compo- sition To Be Tested a/	Time Frame For Submi- ting Data	Use Pattern Where Appli- cable b/	Data Deter- mined To Be "R" or "CR" c/	Registrants Response d/ e/
S158.240					

FOOTNOTES ( k/ continued)

from each crop grouping (40 CFR 180.34) on which registered uses of the active ingredient exist. Analyses of each crop must be conducted over a time period that includes the time interval that the raw agricultural commodity is held in frozen storage prior to the crop residue analysis. To support residue data on processed commodities, fortified storage stability data are required for all processing studies submitted to the Agency. Analyses to processing and each processed commodity prior to the residue analysis. Protocols for these storage stability studies must be submitted to and approved by the Agency prior to initiating the studies.

- (1) Storage stability data using weathered samples. Data are required on the parent compound in which crop samples field treated with a typical end use product are frozen immediately upon harvesting. The integrity of the samples must be maintained by freezing. The samples must be analyzed for the active ingredient on the day they arrive at the analytical laboratory, and then stored frozen and analyzed periodically for the active ingredient during the time intervals specified in the Agency approved protocol.
- (2) Storage stability data using fortified samples. Data are required on the active ingredient and metabolites in which a group of untreated samples of raw agricultural commodities and processed crops are fortified (spiked) with the pure active ingredient and other groups are fortified individually with each additional metabolite. Immediately after fortification, the samples fortified with the active ingredient must be analyzed and samples fortified with other metabolites must be analyzed for only the metabolite with which the sample was fortified. Sample integrity must be maintained by freezing, and analyses for active ingredient and metabolites must be conducted periodically during the time intervals specified in the Agency approved protocol.
- (3) Storage stability data for livestock/poultry feeding studies. Fortified storage stability studies are required on all animal commodities (i.e., tissues, milk and eggs) for which residue data are submitted to the Agency. Analyses must be conducted over a time period that includes the time interval that each commodity is held in frozen storage prior to residue analyses.

1/ Growing Crops Studies - Data must be submitted depicting active ingredient and other residues of concern in or on crops. Tests must represent all major geographic production regions for each crop according to the most recent edition of Agricultural Statistics (USDA). If residues are found to concentrate in any processed products, appropriate food/feed additive tolerances must be proposed. Generally, a maximum permissible seasonal application rate or number of applications must be proposed and reflected in the submitted data. This does not supersede prior requirements; these studies are to be submitted by December 1, 1988 in accordance with a previous issued Data Call In Notice.

m/ This does not supersede prior requirement; this study is due to the Agency.

12.2.88  
DATE

SIGNATURE OF REGISTRANT

135-DAY DATA CALL IN SUMMARY SHEET  
 GENERIC DATA REQUIREMENTS FOR NET/AM SODIUM

Data Requirement	Completion To Be Tested	Time Frame For Submitting Data	Use Pattern Here Available by	Inter-Related To Be "R" or "C"	Regulants Removable (Y/N)
<b>S150.290 ENVIRONMENTAL FAIE (previously 158.130)</b>					
<b>ILLUMINATION STUDIES-LAB:</b>					
161-1 - Hydrolysis	TGAI or PAIRA	9 months	TF, TN, AF, AN, DO, F	R <input checked="" type="checkbox"/>	① 2, 3, 4, 5, 6, 7
<u>Photodegradation</u>					
161-2 - In Water	TGAI or PAIRA	9 months	TF, TN, AF, AN, F	R <input checked="" type="checkbox"/>	① 2, 3, 4, 5, 6, 7
161-3 - On Soil	TGAI or PAIRA	9 months	TF, TN, F	R <input checked="" type="checkbox"/>	① 2, 3, 4, 5, 6, 7
<b>FINANCIAL STUDIES-LAB:</b>					
162-1 - Aerobic Soil	TGAI or PAIRA	27 months	TF, TN, DO, F	R <input checked="" type="checkbox"/>	1, 2, 3, 4, 5, 6, 7
162-2 - Anaerobic Soil	TGAI or PAIRA	27 months	TF	R <input checked="" type="checkbox"/>	① 2, 3, 4, 5, 6, 7
162-4 - Aerobic Aquatic	TGAI or PAIRA	27 months	AF, AN	R	1, 2, 3, 4, ⑤ 6, 7
<b>MOBILITY STUDIES:</b>					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	12 months	TF, TN, AF, AN, DO, F, I	R <input checked="" type="checkbox"/>	① 2, 3, 4, 5, 6, 7

12-2-88  
 DATE

*L. J. ...*  
 SIGNATURE OF REGISTRANT

135-DAY DATA CALL IN SUMMARY SHEET

GENERIC DATA REQUIREMENTS FOR METAM SODIUM

Data Requirement	Compo- sition To Be Tested a/	Time Frame for Submit- ting Data	Use Pattern Where Appli- cable b/	Data Deter- mined To Be "R" or "CR" c/	Registrants Response d/ e/
<u>§158.290 ENVIRONMENTAL FATE - continued</u>					
<u>DISSIPATION STUDIES-FIELDS:</u>					
164-1 - Soil	TEP	27 months	TF, TN, DO	R E/	① 2,3,4,5,6,7
164-2 - Aquatic (Sediment)	TEP	27 months	AF, NI	R	1,2,3,4⑤6,7
164-3 - Forestry	TEP	27 months	F	CR	1,2,3,4,5,6⑦ 5
164-5 - Soil, Long-Term	TEP	50 months	TF, AF	CR	1,2,3,4,5,6⑦ 5
<u>ACCUMULATION STUDIES:</u>					
165-1 - Rotational Crops (Confined) PAIRA	TEP	39 months	TF, AF	R	1,2③4,5,6,7
165-2 - Rotational Crops (Field)	TEP	50 months	TF, AF	CR	1,2,3,4,5,6⑦ 6
165-3 - Irrigated Crops	TEP	39 months	AF, AN	CR	1,2,3,4⑤6,7
165-4 - Accumulation In Fish	TGAI or PAIRA	12 months	TF, TN, AF, AN, F	R	1,2③4,5,6,7

12-2-88  
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SIGNATURE OF REGISTRANT



135-DAY DATA CALL IN SUMMARY SHEET

GENERIC DATA REQUIREMENTS FOR METAM SODIUM

Data Requirement	Compo- sition To Be Tested a/	Time Frame For Submit- ting Data	Use Pattern Where Appli- cable b/	Data Deter- mined To Re- "R" or "CR" c/	Registrants Response d/ e/
\$158.290					

FOOTNOTES:

- a/ Test Substance: TCAl = Technical Grade of Active Ingredient; PAI = Pure Active Ingredient; PAIRA = Pure Active Ingredient Radiolabeled; TEP=Typical End-use Product; Choice= Choice of several test substances determined on a case-by-case basis.
- b/ The use patterns are coded as follows: TP=Terrestrial, Food Crop; TN=Terrestrial, Non-Food; AP=Aquatic, Food Crop; AN=Aquatic, Non-Food; GP=Greenhouse, Food Crop; GN=Greenhouse, Non-Food; AF=Aquatic, DO=Domestic Outdoor; I=Indoor; ALL=All Uses.
- c/ The Agency has reviewed records of registered use patterns for this chemical and determined that the following studies are either required (R) or conditionally required (CR). Refer to the attached copy of the Federal Register Part 158 Data Requirements for Pesticide Registration; Final Rule for an explanation of the conditions under which this study is required. If the registrant does not believe the conditions apply, they may submit their rationale and select the option on inapplicable data requirement.
- d/ Indicate which allowable option you have selected by circling the appropriate number above, corresponding to the way in which you will fulfill this data requirement: (1) An submitting existing certified data with these tables and am submitting a signed certification as to the adequacy of each study submitted (Submitting); (2) Will generate and submit data within specified timeframe (Generate); (3) Have entered into an agreement (Agreement); (4) Have made offers to pay (Offer); (5) Will amend registration to delete uses (Amendment); (6) Have requested a low volume/minor chemical waiver (Minor); or (7) I contend the data requirement does not apply to my product (Inapplicable). These allowable options are the same as those included and explained in the DCI notice and the Tabulation of the 135-Day Data Call In Summary Sheet. Sign and date the bottom of the sheet.
- e/ The registrant who selects option 1 or option 2 must list those uses/crops for which data will be generated or are being submitted, or in other words, the registrant(s) must submit a list of those uses/crops which they intend to continue to support.
- f/ The Agency acknowledges that there are existing data which pertain to this data requirement. If you wish to rely on such data to fill the data requirement, you must certify that it meets the criteria for submitting existing data as explained in Section III-C-3 of the Notice, Submitting Existing Data or select another option.

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DATE

*L. J. ...*  
SIGNATURE OF REGISTRANT

135-DAY DATA CALL IN SUMMARY SHEET

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING METAM SODIUM

Data Requirement	Compo- sition To Be Tested a/	Time Frame For Submitt- ing Data	Use Pattern Where Appli- cable b/	Data Deter- mined To Be "R" or "CR" c/	Registrants Response d/
<u>\$158.340 TOXICOLOGY DATA REQUIREMENTS (previously 158.135)</u>					
<u>ACUTE TESTING</u>					
81-1 - Acute Oral Toxicity - Rat	MP	9 months	TP, TN, AF, AN, DO, F, I	R	1, 2, 3, 4, 5, 6, 7
81-2 - Acute Dermal Toxicity - Rabbit	MP	9 months	TP, TN, AF, AN, DO, F, I	R	1, 2, 3, 4, 5, 6, 7
81-3 - Acute Inhalation Toxicity - Rat	MP	9 months	TP, TN, AF, AN, DO, F, I	R	1, 2, 3, 4, 5, 6, 7
81-4 - Primary Eye Irritation Rabbit	MP	9 months	TP, TN, AF, AN, DO, F, I	R	1, 2, 3, 4, 5, 6, 7
81-5 - Primary Dermal Irritation Rabbit	MP	9 months	TP, TN, AF, AN, DO, F, I	R	1, 2, 3, 4, 5, 6, 7
81-6 - Dermal Sensitization Guinea Pig	MP	9 months	TP, TN, AF, AN, DO, F, I	R	1, 2, 3, 4, 5, 6, 7

FOOTNOTES:

- a/ Test Substance: TCAI - Technical Grade of Active Ingredient; PAI - Pure Active Ingredient; Choice - Choice of several test substances determined on a case-by-case basis; MP - Manufacturing Use Product.
- b/ The use patterns are coded as follows: TP-Terrestrial, Food Crop; TN-Terrestrial, Non-Food; AF-Aquatic, Food Crop; AN-Aquatic, Non-Food; CR-Greenhouse, Food Crop; GN-Greenhouse, Non-Food; F-Forestry; I-Indoor; ALL-All Uses.

12-2-88  
DATE

SIGNATURE OF REGISTRANT

135-DAY DATA CALL IN SUMMARY SHEET

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING METAM SODIUM

Data Requirement	Compo- sition To Be Tested a/	Time Frame for Submit- ting Data	Use Pattern Where Appli- cable b/	Data Deter- mined To Be "R" or "CR" c/	Registrants Response d/

§15A.340

FOOTNOTES (Continued)

c/ The Agency has reviewed records of registered use patterns for this chemical and determined that the following studies are either required (R) or conditionally required (CR). These footnotes explain under what condition(s) the conditionally required studies are required. Refer to the attached copy of the Federal Register Part 158 Data Requirements for Pesticide Registration; Final Rule for an explanation of the conditions under which these studies are required. If the registrant does not believe the conditions apply, they may submit their rationale and select the option on inapplicable data requirement.

d/ Indicate which allowable option you have selected by circling the appropriate number above, corresponding to the way in which you will fulfill this data requirement: (1) Am submitting existing data with these tables and am submitting a signed certification as to the adequacy of each study submitted (Submitting); (2) Will generate and submit data within specified timeframe (Generate); (3) Have entered into an agreement (Agreement); (4) Have made offers to pay (Offer); (5) Will amend registration to delete uses (Amendment); (6) Have requested a low volume/minor chemical waiver (Minor); or (7) I claim the data requirement does not apply to my product (Inapplicable). These allowable options are the same as those in the DCI notice and the Tabulation of the 135-Day Data Call in Summary Sheet. Sign and date the bottom of each page.

e/ The Agency acknowledges that there are existing data which pertain to this data requirement. If you wish to rely on such data to fill the data requirement, you must certify that it meets the criteria for submitting existing data as explained in Section III-C-3 of the Notice, Submitting Existing Data or select another option.



12.2.88  
DATE

*L. James M...*  
SIGNATURE OF REGISTRANT

GENERIC DATA REQUIREMENTS FOR METAM SODIUM

Data Requirement	Composition To Be Tested <u>a/</u>	Time Frame For Submitting Data	Use Pattern Where Applicable <u>b/</u>	Data Determined To Be "R" or "CR" <u>c/</u>	Registrants Response <u>d/ e/</u>
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S158.340 TOXICOLOGY (previously 158.135)

ACUTE TESTING:

81-1 - Acute Oral LD <sub>50</sub> - Rat	TGAI	9 months	<u>f/</u> TP, TN, AF, AN, F, DO, I R	R	① 2, 3, 4, 5, 6, 7
81-2 - Acute Dermal LD <sub>50</sub> - Rabbit	TGAI	9 months	<u>f/</u> TP, TN, AF, AN, F, DO, I R	R	① 2, 3, 4, 5, 6, 7
81-3 - Acute Inhalation LD <sub>50</sub> - Rat	TGAI	9 months	<u>f/</u> TP, TN, AF, AN, F, DO, I R	R	① 2, 3, 4, 5, 6, 7

SUBCHRONIC TESTING:

82-1 - 90-Day Feeding					
- Rodent	TGAI	15 months	TF, AF	R	1, 2, 3, 4, 5, 6, 7, 8
- Non-Rodent	TGAI	18 months	TF, AF	R	1, 2, 3, 4, 5, 6, 7, 8
82-2 - 21-Day Dermal - Rabbit	TGAI	12 months	TP, TN, AF, AN, F, DO, I R	R	1, 2, ③ 4, 5, 6, 7
82-4 - 90-Day Inhalation - Rat	TGAI	15 months	TP, TN, AF, AN, F, DO, I R	R <u>g/</u>	1, 2, ③ 4, 5, 6, 7, 9

12-2-88  
DATE

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SIGNATURE OF REGISTRANT

135-DAY DATA CALL IN SUMMARY SHEET

GENERIC DATA REQUIREMENTS FOR METAM SODIUM

Data Requirement	Composition To Be Tested	Time Frame For Submitting Data	Use Pattern Where Applicable	Data Determined To Be "R" or "CR"	Registrant Response d/e/
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S158.340 TOXICOLOGY - continued

Subchronic Testing (Continued)

82-5 - 90-Day Neurotoxicity

- Ilen

- Mammal

CHRONIC TESTING:

83-1 - Chronic Feeding - Rodent

83-1 - Chronic Feeding - Non-Rodent

83-2 - Oncogenicity - Rat

83-2 - Oncogenicity - Mouse (preferred)

83-3 - Teratogenicity - Rat (preferred)

83-3 - Teratogenicity - Rabbit (preferred)

83-4 - Reproduction - Rat (2-generation)

MUTAGENICITY TESTING

84-2 - Gen's Mutation

TCGI	15 months	TP, TN, AF, AN, F, DO, I	CR	1, 2, 3, 4, 5, 6, 7 <sup>8</sup>
TCGI	15 months	TP, TN, AF, AN, F, DO, I	CR	1, 2, 3, 4, 5, 6, 7 <sup>8</sup>
TCGI	50 months	TP, AF	R	1, 2, 3, 4, 5, 6, 7 <sup>8</sup>
TCGI	50 months	TP, AF	R	1, 2, 3, 4, 5, 6, 7 <sup>8</sup>
TCGI	50 months	TP, AF	R	1, 2, 3, 4, 5, 6, 7 <sup>8</sup>
TCGI	50 months	TP, AF	R	1, 2, 3, 4, 5, 6, 7 <sup>8</sup>
TCGI	15 months	TP, AF	R	1, 2, 3, 4, 5, 6, 7
TCGI	15 months	TP, AF	R	1, 2, 3, 4, 5, 6, 7
TCGI	39 months	TP, AF	R	1, 2, 3, 4, 5, 6, 7 <sup>8</sup>

TCGI	9 months	TP, TN, AF, AN, F, DO, I	R	1, 2, 3, 4, 5, 6, 7
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12-2-88  
DATE

*L. J. ...*  
SIGNATURE OF REGISTRANT

135-DAY DATA CALL IN SUMMARY SHEET

GENERIC DATA REQUIREMENTS FOR METAM SODIUM

Data Requirement	Compo- sition To Be Tested a/	Time Frame For Submit- ting Data	Use Pattern Where Appli- cable b/	Data Deter- mined To Be "R" or "CR" c/	Registrants Responses d/ e/
<u>\$158.340 TOXICOLOGY - continued</u>					
<u>Mutagenicity Testing (Continued)</u>					
84-2 - Chromosomal Aberration	TGAI	12 months	TF, TN, AF, AN, F, DO, I	R ✓	① 2, 3, 4, 5, 6, 7
84-4 - Other Mechanisms of Mutagenicity	TGAI	12 months	TF, TN, AF, AN, F, DO, I	R ✓	① 2, 3, 4, 5, 6, 7
<u>SPECIAL TESTING</u>					
85-1 - General Metabolism	PAI or PAIRA	24 months	E/ AF	R	① 2, 3, 4, 5, 6, 7

FOOTNOTES:

- a/ Test Substance: TGAI=Technical Grade of Active Ingredient; PAI=Pure Active Ingredient; PAIRA=Pure Active Ingredient, Radiolabeled; Choice=Choice of several test substances determined on a case-by-case basis.
- b/ The use patterns are coded as follows: TF=Terrestrial, Food Crop; TN=Terrestrial, Non-Food; AF=Aquatic, Food Crop; AN=Aquatic, Non-Food; GF=Greenhouse, Food Crop; GN=Greenhouse, Non-Food; F=Forestry; DO=Domestic/Outdoors; I=Indoors; ALL=All uses.
- c/ The Agency has reviewed records of registered use patterns for this chemical and determined that the following studies are either required (R) or conditionally required (CR). Refer to the attached copy of the Federal Register Part 158 Data Requirements for Pesticide Registration; Final Rule for an explanation of the conditions under which these studies are required. If the registrant does not believe the conditions apply, they may submit their rationale and select the option on inapplicable data requirement.

12.2.88  
DATE

*L. J. ...*  
SIGNATURE OF REGISTRANT

135-DAY DATA CALL IN SUMMARY SHEET

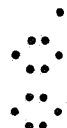
GENERIC DATA REQUIREMENTS FOR METAM SODIUM

Data Requirement	Composition To Be Tested	Time Frame For Submitting Data	Use Pattern Where Applicable	Data Determined To Be "R" or "CR"	Registrants Response
	a/		b/	c/	d/ e/

\$158,340

FOOTNOTES (Continued)

- d/ Indicate which allowable option you have selected by circling the appropriate number above, corresponding to the way in which you will fulfill this data requirement: (1) An submitting existing certified data with these tables and am submitting a signed certification as to the adequacy of each study submitted (Submitting); (2) Will generate and submit data within specified timeframe (Generate); (3) Have entered into an agreement (Agreement); (4) Have made offers to pay (Offer); (5) Will amend registration to delete uses (Amendment); (6) Have requested a low volume/minor chemical waiver (Minor); or (7) I claim the data requirement does not apply to my product (Inapplicable). These allowable options are the same as those included and explained in the DCI notice and the Tabulation of the 135-Day Data Call In Summary Sheet. Sign and date the bottom of each page.
- e/ The registrant who selects option 1 or option 2 must submit a list of those uses/crops for which data will be generated or are being submitted, or in other words, the registrant(s) must submit a list of those uses/crops which they intend to continue to support.
- f/ The timeframe listed is the standard elapsed time frame. It does not in any way supersede any deadlines established by prior Data Call In Notices.
- g/ Required if repeated inhalation exposure expected to be toxic.
- h/ Depends on results of acute neurotoxicity study.
- i/ Data requirement deferred pending evaluation of other data required by previous Data Call In.
- j/ The Agency acknowledges that there are existing data which pertain to this data requirement. If you wish to rely on such data to fill the data requirement, you must certify that it meets the criteria for submitting existing data as explained in Section III-C-3 of the Notice, Submitting Existing Data or select another option.



12.2.88

DATE

*L. J. ...*

SIGNATURE OF REGISTRANT

135-DAY DATA CALL IN SUMMARY SHEET

GENERIC DATA REQUIREMENTS FOR METAM SODIUM

Data Requirement	Compo- sition To Be Tested a/	Time Frame For Submit- ting Data	Use Pattern Where Appli- cable b/	Data Inter- mined To Be "R" or "CR" c/	Registrants Response d/ g/
<u>§158.390 - REENTRY PROTECTION (previously 158.140)</u>					
132-1 - Foliar Dissipation	TEP	27 months	TP, TN, AF, AN, F	CR <u>g/</u>	1, 2, 3, 4, 5, 6, 7 <sup>10</sup>
132-1 - Soil Dissipation	TEP	27 months	TP, TN, AF, AN, F	CR <u>g/</u>	1, 2, 3, 4, 5, 6, 7 <sup>10</sup>
133-3 - Dermal Exposure	TEP	27 months	TP, TN, AF, AN, F	CR <u>h/</u>	1, 2, 3, 4, 5, 6, 7 <sup>10</sup>
133-4 - Inhalation Exposure	TEP	27 months	TP, AN, AF, AN, F	CR <u>h/</u>	1, 2, 3, 4, 5, 6, 7 <sup>10</sup>

FOOTNOTES:

- a/ Test Substance: TAI = Technical Grade of Active Ingredient; PAI = Pure Active Ingredient; Choice = Choice of several test substances determined on a case-by-case basis; TEP = Typical End-use Product.
- b/ The use patterns are coded as follows: TP-Terrestrial, Food Crop; TN-Terrestrial, Non-Food; AF-Aquatic, Food Crop; AN-Aquatic, Non-Food; F-Forestry; I-Indoor; ALL-All uses.
- c/ The Agency has reviewed records of registered use patterns for this chemical and determined that the following studies are either required (R) or conditionally required (CR). Refer to the attached copy of the Federal Register Part 158 Data Requirements for Pesticide Registration Final Rule for an explanation of the conditions under which this study is required. If the registrant does not believe the conditions apply, they may submit their rationale and select the option on inapplicable data requirement.
- d/ Indicate which allowable option you have selected by circling the appropriate number above, corresponding to the way in which you will fulfill this data requirement: (1) An submitting existing certified data with these tables and an submitting a signed certification as to the adequacy of each study submitted (Submitting); (2) Will generate and submit data within specified timeframe (Generate); (3) Have entered into an agreement (Agreement); (4) Have made offers to pay (Offer); (5) Will amend registration to delete uses (Amendment); (6) Have requested a low volume/minor chemical waiver (Minor); or (7) I claim the data requirement does not apply to my product (Inapplicable). These allowable options are the same as those included and explained in the RLI notice and the Tabulation of the 135-Day Data Call in Summary Sheet. Sign and date the bottom of each page.

12.2.88  
DATE

*L. J. Fusa*  
SIGNATURE OF REGISTRANT



135-DAY DATA CALL IN SUMMARY SHEET

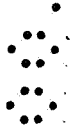
GENERIC DATA REQUIREMENTS FOR METAM SODIUM

Data Requirement	Compo- sition To Be Tested a/	Time Frame For Submit- ting Data	Use Pattern Where Appli- cable b/	Data Inter- mined To Be "R" or "CR" c/	Registrants Response d/ e/
S158.390					
<b>FOOTNOTES (Cont Inued)</b>					

- e/ The registrant(s) who select option 1 or option 2 must submit a list of those uses/crops for which data will be generated or are being submitted, or in other words, the registrant(s) must submit a list of those uses/crops which they intend to support.
- f/ For each end-use, the registrant is required to propose an acceptable reentry interval based either upon data; (a) on dissipation of residues (decline curve), on human exposure to those residues, and on toxicity of the residues; or (b) on determination of that time beyond which there are no detectable dislodgeable or inhalable residues remaining in the worker environment. If the registrant has reason to believe that an end-use will not cause exposure to residues, a request for waiver from this data requirement should be submitted.
- g/ Soil dissipation data are required only for uses where workers will be exposed directly to substantial quantities of soil during their work, e.g., for use on potatoes where hand harvesting will be performed.
- h/ Human-exposure monitoring data may be submitted if the registrant wishes to use the "allowable exposure method" of determining reentry intervals. The data submitted are limited to foliar and soil dislodgeable residues (132-1 and 132-2 above). Human exposure and reentry intervals would be estimated from submitted both dermal exposure (133-3) and inhalation exposure (133-4) must be submitted.

12-2-88  
DATE

*L. J. ...*  
SIGNATURE OF REGISTRANT



135-DAY DATA CALL IN SUMMARY SHEET

GENERIC DATA REQUIREMENTS FOR METAM SODIUM

Data Requirement	Composition To Be Tested a/	Time Frame For Submitting Data	Use Pattern Where Applicable b/	Data Determined To Be "R" or "CR" c/	Registrants Response d/ e/
<b>§158.490 WILDLIFE AND AQUATIC ORGANISMS (Previously 158.145)</b>					
<b>AQUATIC ORGANISM TESTING</b>					
72-1 Freshwater Fish Toxicity					
- Warmwater Fish	TGAI	9 months	TF, TN, AF, AN, DO, F	R	1, 2, 3, 4, 5, 6, 7
72-2 Acute Toxicity to Freshwater Invertebrates	TGAI	9 months	TF, TN, AF, AN, DO, F	R	1, 2, 3, 4, 5, 6, 7
72-4 Aquatic Life-Cycle					
- Fish (Early Life Stage)	TGAI	15 months	TF, TN, AF, AN, DO, F	CR E/	1, 2, 3, 4, 5, 6, 7 11
- Invertebrate Life-Cycle (Freshwater and Estuarine)	TGAI	15 months	TF, TN, AF, AN, DO, F	CR E/	1, 2, 3, 4, 5, 6, 7 11

FOOTNOTES

- a/ Test Substance: TGAI = Technical Grade of Active Ingredient; PAI = Pure Active Ingredient; Choice = Choice of several test substances determined on a case-by-case basis; TEP= Typical End-Use Product.
- b/ The use patterns are coded as follows: TF-Terrestrial, Food Crop; TN-Terrestrial, Non-Food; AF-Aquatic, Food Crop; AN-Aquatic, Non-Food; GP-Greenhouse, Food Crop; GN-Greenhouse, Non-Food; AF-Aquatic, Domestic Outdoor; I-Indoor; ALL-All Uses.
- c/ The Agency has reviewed records of registered use patterns for this chemical and determined that the following studies are either required (R) or conditionally required (CR). Refer to the attached copy of the Federal Register Part 158 Data Requirements for Pesticide Registration/ Final Rule for an explanation of the conditions under which the studies are required. If the registrant does not believe the conditions apply, they may submit their rationale and select the option on inapplicable data requirement.

12-2-88

*L. J. Hines, M.D.*

DATE

SIGNATURE OF REGISTRANT

135-DAY DATA CALL IN SUMMARY SHEET

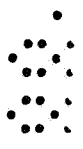
GENERIC DATA REQUIREMENTS FOR METAM SODIUM

Data Requirement	Composition To Be Tested	Time Frame for Submitting Data	Use Pattern Where Applicable	Data Determined To Be "R" or "CR"	Registrants Response
	a/		b/	c/	d/ e/

S158.490

FOOTNOTES (continued)

- d/ Indicate which allowable option you have selected by circling the appropriate number above, corresponding to the way in which you will fulfill this data requirement: (1) Am submitting existing certified data with these tables and am submitting a signed certification as to the adequacy of each study submitted (Submitting); (2) Will generate and submit data within specified timeframe (Generate); (3) Have entered into an agreement (Agreement); (4) Have made offers to pay (Offer); (5) Will amend (Minor); or (7) I claim the data requirement does not apply to my product (Inapplicable). These allowable options are the same as those included and explained in the DCI notice and the Tabulation of the 135-Day Data Call In Summary Sheet. Sign and date the bottom of each page.
- e/ The registrant(s) who select option 1 or 2 must submit a list of those uses/crops for which data will be generated or are being submitted, or in other words, the registrant(s) must submit a list of those uses/crops which they intend to continue to support.
- f/ Requirement is conditioned on outcome of acute aquatic testing and appropriate fate data (leaching).



12-2-68

DATE

*L. Alan Muesel*

SIGNATURE OF REGISTRANT

135-DAY DATA CALL IN SUMMARY SHEET

GENERIC DATA REQUIREMENTS FOR METAM SODIUM

Data Requirement	Compo- sition To Be Tested a/	Time Frame For Submit- ting Data	Use Pattern Where Appli- cable b/	Data Deter- mined To Be "R" or "CR" c/	Registrants Responses d/ e/
<u>§158.540 PLANT PROTECTION (previously 158.150)</u> <u>Non-target Area Phytotoxicity - Tier I</u>					
122-1 - Seed germination seedling/emergence	TGAI	9 months	TN,AN,P	R	1,2,3,4,5,6,7 12
122-1 - Vegetative Vigor	TGAI	9 months	TN,AN,P	R	1,2,3,4,5,6,7 12
122-2 - Aquatic Plant Growth	TGAI	9 months	TN,AN,P	R	1,2,3,4,5,6,7 12

FOOTNOTES:

- a/ Test Substances: TGAI = Technical Grade of Active Ingredient; PAI = Pure Active Ingredient; Choice = Choice of several test substances determined on a case-by-case basis.
- b/ The use patterns are coded as follows: TF-Terrestrial, Food Crop; TN-Terrestrial, Non-Food; AF-Aquatic, Food Crop; AN-Aquatic, Non-Food; GF-Greenhouse, Food Crop; GN-Greenhouse, Non-Food; F-Forestry; IO-Domestic Outdoor; I-Indoor; ALL-All uses.
- c/ The Agency has reviewed records of registered use patterns for this chemical and determined that the following studies are either required (R) or conditionally required (CR). Refer to the attached copy of the Federal Register Part 158 Data Requirements for Pesticide Registration/Final Rule for an explanation of the conditions under which these studies are required. If the registrant does not believe the conditions apply, they may submit their rationale and select the option on inapplicable data requirement.
- d/ Indicate which allowable option you have selected by circling the appropriate number above, corresponding to the way in which you will fulfill this data requirement: (1) An submitting existing certified data with these tables and an submitting a signed certification as to the adequacy of each study submitted (Submitting); (2) Will generate and submit data within specified timeframe (Generate); (3) Have entered into an agreement (Agreement); (4) Have made offers to pay (Offer); (5) Will amend registration to delete uses (Amendment); (6) Have requested a low volume/minor chemical waiver (Minor); or (7) I claim the data requirement does not apply to my product (Inapplicable). These allowable options are the same as those included and explained in the DCI notice and the Tabulation of the 135-Day Data Call In Summary Sheet. Signifying data the bottom of each sheet.
- e/ The registrant(s) who select option 1 or 2 must submit a list of those uses/crops for which data will be generated or are being submitted, or in other words, the registrant(s) must submit a list of those uses/crops which they intend to continue to support.

12.2.88

DATE

*L. J. ...*  
SIGNATURE OF REGISTRANT

SUBJECT: Transmittal of Material From a Registrant About Studies on Chemical Van Metam-sodium In Response to Data Call In Notice.

TO: The Files & For Transmittal to Office of Compliance Monitoring

Attached is a copy of material concerning the generation of data in response to the subject 3c2B notice. Please disregard any other statements in the attached documents which do not relate to the specific material checked below. The attached documents consist of:

- Data Call In Summary Sheet indicating commitments
- Letter commitment to conduct studies
- Coversheet identifying the studies for which commitments have been received or existing studies submitted.
- Progress report on studies underway.
- Transmittal letter submitting final report.
- Agency decision on commitments to submit data
- Agency decision on waiver requests
- Agency decision on requests for extension of data for submitting data
- Agency decision on acceptability of protocols
- Data Call In Notice
- Other

Studies/data involved  
135 day summary sheets  
with options & waiver requests

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*Am Lenz*  
for Geraldine Werdig, Chief  
Data Call In Program