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CONFIDENTIAL



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

JUL 21 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Amitraz Registration Standard

ID NO(S). 45639-51
RCB NO(S). 3975
MRID NO(S). 406507-00 TO -07

FROM: H. Fonouni, Ph.D., Chemist *H. C. Fonouni*
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

TO: Dennis Edwards (PM-12)
Insecticide/Rodenticide Branch
Registration Division (TS-767C)

THRU: William J. Boodee, Section Head *WJB*
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

In response to the Amitraz Registration Standard (Guidance Document, October, 1987 and Task 1, October 5, 1984), Nor-Am Chemical Company has forwarded product chemistry information/data on the technical chemical. It should be noted that, the composition of the technical product for which the current information has been provided differs from the stabilized technical chemical, EPA Registration No. 45639-51, as reflected in the Task 1.

The information/data submitted and our conclusions are discussed below. In addition, revised Tables A and B have been included to reflect the remaining product chemistry data requirements.

61-2 Description of Beginning Materials and Manufacturing Process

MRID NO(S): 406507-01

The information/data provided appears in Confidential Appendix A.

(2)

The information/data provided satisfy the requirements for this topic.

61-3 Discussion of Formation of Impurities

MRID NO: 406507-01

The information provided appears in Confidential Appendix A.

The information provided satisfies the requirements for this topic.

62-1 Preliminary Analysis of Product Samples

MRID NO: 406507-02

The information/data provided appears in Confidential Appendix B.

The information/data provided satisfies the requirements for this topic.

62-2 Certification of Ingredient Limits

MRID NO: 406507-03

The information/data provided appears in Confidential Appendix C.

The information/data provided satisfy the requirements for this topic.

62-3 Analytical Methods to Verify Certified Limits

MRID NO: 406507-04 to -06

The information/data provided appears in Confidential Appendix D.

The information/data provided satisfy the requirements for this topic

63 Physical and Chemical Characteristics

MRID NO: 406507-07

The information/data provided is presented below.

63-2 Color: White/Pale yellow

63-3 Physical State: Powder

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- 63-4 Odor: Slight amine odor
- 63-5 Melting Point (solids): 86.1 Degree C
- 63-6 Boiling Point (liquids): N/A
- 63-7 Density, Bulk Density or
Specific Gravity: 1.128 g/ml at 20 Degree C
- 63-8 Solubility: 9.3×10^{-5} g/l of water at 25.5 Degree C; the product is not stable in water, as a result the concentration of at least one of the degradation products formed is reportedly higher than that of the product.
- 63-9 Vapor Pressure: 3.4×10^{-4} pa at 25 degree C (pure form)
- 63-11 Octanol/water Partition
Coefficient: 3.0×10^5 at 25 Degree C (pH = 5.8)
- 63-12 pH: N/A; the product has a low solubility, and decomposes in water.

N/A = Not Applicable

Information/data gaps remain on this topic. Additional Data must be provided on solubility of the product in organic solvents (63-8); dissociation constant (63-10); and stability (63-13), of the product, including thermal stability, sensitivity to sun light, metals and metal ions.

Attachment I - Tables A (2 pages) and B (1 page)

cc: Amitraz Registration Standard File, SF, Reviewer
(H. Fonouni), RBP, TOX (R. Coberly), PMSD/ISB (E. Eldredge),
PM 12 (D. Edwards)

Attachment II - Confidential Appendix A (2 pages)
Attachment III - Confidential Appendix B (1 page)
Attachment IV - Confidential Appendix C (2 pages)
Attachment V - Confidential Appendix D (3 pages)

cc: Amitraz Registration Standard File, SF, Reviewer
(H. Fonouni), RBP, TOX (R. Coberly), PMSD/ISB (E. Eldredge),
PM 12 (D. Edwards).

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cc: Amitraz Registration Standard File, SF, RF, Reviewer
(H. Fonouni), RBP, TOX (R. Coberly), PMSD/ISB (E. Eldredge),
PM 21 (D. Edwards), Circu.

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TABLE A
GENERIC DATA REQUIREMENTS FOR THE TECHNICAL ANTIRAZ, NOR-AM CHEMICAL COMPANY

Guideline Citation and Name of Test	Test ¹ Substance	Guidelines Status	Are Additional Data Required?		Reference Citation (MTRD No.)
			[Yes]	[No]	
<u>40 CFR 158.120 Product Chemistry</u>					
Product Identity and Composition					
61-1 - Identity of Ingredients	TGAI	R		X	406507-01 406507-01 406507-01
61-2 - Materials and Process	TGAI	R		X	
61-3 - Formation of Impurities	TGAI	R		X	
<u>Analysis and Certification of Product Ingredients</u>					
62-1 - Preliminary Analysis	TGAI	R		X	406059-02
62-2 - Certification of Ingredient Limits	TGAI	R		X	406059-03
62-3 - Analytical Methods to Verify Certified Limits	TGAI	R		X	406059-04 to -6
<u>Physical and Chemical Characteristics</u>					
63-2 - Color	TGAI	R		X	406059-07
63-3 - Physical State	TGAI	R		X	
63-4 - Odor	TGAI	R		X	
63-5 - Melting Point	TGAI	R		X	
63-6 - Boiling Point	TGAI	N/A ²		X	
63-7 - Bulk Density	TGAI	R		X	
63-8 - Solubility	TGAI or PAI	R	X		
63-9 - Vapor Pressure	PAI	R		X	
63-10 - Dissociation Constant	PAI	R	X		
63-11 - Octanol/Water Partition Coefficient	PAI	R		X	
63-12 - PH	TGAI	N/A ³		X	

(Continued, footnotes follow)

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TABLE A
GENERIC DATA REQUIREMENTS FOR THE TECHNICAL AMITRAZ, NOR-AM CHEMICAL COMPANY

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Additional Data Required?		Reference Citation (MTRD No.)
			[Yes]	[No]	
<u>158.120 Product Chemistry (Cont'd)</u>					
<u>Physical and Chemical Characteristics</u>					
63-13- Stability	TGAI	R	X		
<u>Other Requirements</u>					
64-1 - Submittal of Samples	TGAI and PAI	CR ⁴		X	

TGAI = Technical Grade Active Ingredient (Technical Chemical); PAI = Purified Active Ingredient; R = Required; CR = Conditionally Required; N/A = Not Applicable.

1/ The technical chemical also serves as a manufacturing-use product.

2/ Not applicable, since the product is a solid at room temperature.

3/ Not applicable, since the product is only slightly soluble and decomposes in water.

4/ If samples are needed, the Agency will request them.

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TABLE B

DATA REQUIREMENTS FOR THE MANUFACTURING-USE PRODUCT CONTAINING AMITRAZ¹, NOR-AM CHEMICAL COMPANY

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Additional Data Required? [Yes] [No]	Reference Citation (MTRD No.)
<u>40 CFR 158.120 Product Chemistry</u>				
<u>Product Identity and Composition</u>				
61-1 - Identity of Ingredients	MP	R	X	
61-2 - Materials and Process	MP	R	X	406507-01
61-3 - Formation of Impurities	MP	R	X	406507-01
<u>Analysis and Certification of Product Ingredients</u>				
62-1 - Preliminary Analysis	MP	R	X	406507-02
62-2 - Certification of Ingredient Limits	MP	R	X	406507-03
62-3 - Analytical Methods to Verify Certified Limits	MP	R	X	406507-04 to -06
<u>Physical and Chemical Characteristics²</u>				
				406507-07
<u>Other Requirements</u>				
64-1 - Submittal of Samples	MP	CR ³		

MP = Manufacturing-Use Product; N/A = Not Applicable; CR = Conditionally Required

1/ The technical chemical also serves as a manufacturing-use product.

2/ As requested by the Registration Division, The Residue Chemistry Branch no longer reviews the physical/chemical properties of manufacturing-use products.

3/ If samples are needed, the Agency will request them.

Amitraz residue chemistry review

Page _____ is not included in this copy.

Pages 8 through 15 are not included in this copy.

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 product 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.
