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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

October 28, 1999

MEMORANDUM

Subject: Reregistration of **Molinate:** Product and Residue Chemistry Chapters to the Rereregistration Eligibility Decision; Chemical No. 41402; DP Barcode: D249755

From: Christine L. Olinger, Chemist
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and

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and

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Special Review Branch
Special Review and Reregistration Division (7508W)

Attached are the Product and Residue Chemistry Chapters to the Molinate Reregistration Eligibility Decision. Data gaps and highlights of each chapter are listed below.

Product Chemistry Considerations

The product chemistry database is substantially complete; the registrant must submit additional studies as described below before all guideline requirements can be considered fulfilled.

- A revised Confidential Statement of Formula (Form 8570-4; the most recent one is dated 11/87).
- The identity and source of a catalyst used in the production is required.
- An explanation on how the upper certified limits for certain impurities were derived.
- Quantitative data demonstrating the stability of the TGAI upon exposure to metals and metal ions are required.
- Data pertaining to the UV/visible absorption of the PAI are required (GLN 830.7050).

Residue Chemistry Considerations

Most residue chemistry guideline studies have been submitted; all that are necessary for the dietary exposure assessment are available. Anticipated residues have been estimated and are included in the residue chemistry chapter. Studies which are outstanding are listed below.

- Multiresidue method testing for molinate, 4-hydroxymolinate, and molinate acid.
- Data on residues in irrigated crops for molinate, 4-hydroxymolinate, and molinate acid, molinate sulfoxide, and molinate sulfone.

cc: COlinger, Reg. Std. File, RF
7509C:RRB1:CLOlinger:clo:CM#2:Rm 722J:305-5406: 10/25/99
RDI: CSwartz: 4/15/99 ExpoTeam: 4/15/99 ChemSAC: 4/22/99 WPhang: 10/26/99

MOLINATE

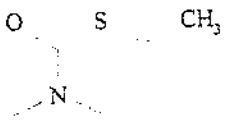
REREGISTRATION ELIGIBILITY DECISION:

PRODUCT CHEMISTRY CONSIDERATIONS

PC Code No. 041402; Case No. 2435

DESCRIPTION OF CHEMICAL

Molinate [S-ethyl hexahydro-1H-azepine-1-carbothioate] is a selective herbicide used primarily for control of watergrass in rice.



Empirical Formula:	$C_9H_{17}NOS$
Molecular Weight:	187.3
CAS Registry No.:	2212-67-1
Shaughnessy No.:	041402

IDENTIFICATION OF ACTIVE INGREDIENT

Molinate is an amber liquid with a boiling point of 136.5 C at 10 torr, specific gravity of 1.0663 at 20 C, octanol/water partition coefficient (K_{ow}) of 756 at 25 C, and vapor pressure of 5.3 x 10^{-3} mm Hg at 25 C. Molinate is soluble in water at 970 mg/L at 25 C, and is miscible with acetone, chlorobenzene, ethanol, kerosene, n-octanol, and xylenes.

MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 5/18/98 identified a single molinate manufacturing-use product (MP) registered under Shaughnessy No. 041402; the Zeneca AG Products (formerly ICI Americas) 96% T (EPA Reg. No. 10182-275). Only the registered 96% T/TGAI is subject to a reregistration eligibility decision.

REGULATORY BACKGROUND

The Molinate Phase 4 Review dated 2/21/91 by C. Olinger determined that the available product chemistry data met the acceptance criteria for Phase 5 review; no additional product chemistry data were required. The current status of the product chemistry data requirements for the molinate manufacturing-use product is presented in the attached data summary table. Refer to this table for a listing of the outstanding product chemistry data requirements.

CONCLUSIONS

Pertinent product chemistry data requirements remain unfulfilled for the Zeneca 96% T/TGAI. Additional data are required concerning OPPTS 830.1550, 1600, 1750, 1800, 6313, 7050, and 7840. Provided that the registrant submits the data required in the attached data summary table for the 96% T/TGAI, and either certifies that the suppliers of beginning materials and the manufacturing process for the molinate technical product have not changed since the last comprehensive product chemistry review or submits a complete updated product chemistry data package, CBRS has no objections to the reregistration of molinate with respect to product chemistry data requirements.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

DP Barcode(s):	D254972
Subject:	Product Chemistry Data Reviewed in Support of the Zeneca 96% T.
From:	C. Olinger
To:	W. Livingston/R. McNally
Dated:	10/27/99
MRID(s):	00149370, 40237201-40237203, 40593304, and 40739801

PRODUCT CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

References (cited):

00149370 Lee, K.; Bartell, L. (1984) Hydrolysis and Solubility Studies of Molinate: Report No. RRC 84-51. Unpublished study prepared by Stauffer Chemical Company. 10 p.

40237201 Javdani, K. (1987) Description of Beginning Materials and Manufacturing Process and Discussion of the Formation of Impurities for Ordram Technical: Laboratory Project ID: RRC 87-58. Unpublished study prepared by Stauffer Chemical Co. 51 p.

40237202 Farina, L. (1987) Analysis and Certification of Product Ingredients in Ordram Selective Herbicide: Laboratory Project ID: RRC-87-57. Unpublished study prepared by Stauffer Chemical Co. 174 p.

40237203 Myers, H. (1987) Molinate - Physical Properties: Laboratory Project ID: RRC 87-55. Unpublished study prepared by Stauffer Chemical Co. 52 p.

40593304 Riggs, R. (1987) Molinate - The Density, Vapor Pressure, Octanol/ Water Partition Coefficient, and Henry's Law Constant: Laboratory Project ID RRC 87-100. Unpublished study prepared by Stauffer Chemical Co. 64 p.

40739801 Myers, H. (1988) Molinate: Oxidizing or Reducing Action, Flammability, Explodability, Storage Stability, Viscosity, Miscibility, and Corrosion Characteristics: Study No. ENV-001: Report No. RRC 88-33. Unpublished study prepared by ICI Americas, Inc. 23 p.

Case No. 2435
Chemical No. 041402

Case Name: Molinate
Registrant: Zeneca AG Products
Product(s): 96% T (EPA Reg No. 10182-275)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [1]	MRID Number [2]
830.1550	Product identity and composition	N [3]	CSF 11/16/87
830.1600	Description of materials used to produce the product	N [4]	40237201
830.1620	Description of production process	Y	40237201
830.1670	Discussion of formation of impurities	Y	40237201
830.1700	Preliminary analysis	Y	40237202
830.1750	Certified limits	N [3]	40237202, CSF 11/16/87
830.1800	Enforcement analytical method	Y	40237202
830.6302	Color	Y	40237203
830.6303	Physical state	Y	40237203
830.6304	Odor	Y	40237203
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	N [5]	40237203
830.7000	pH	Y	40237203
830.7050	UV/Visible absorption	N [6]	
830.7100	Viscosity	Y	40739801
830.7200	Melting point/melting range	N/A [7]	
830.7220	Boiling point/boiling range	Y	40237203
830.7300	Density/relative density/bulk density	Y	40237203, 40593304
830.7370	Dissociation constants in water	N/A [8]	
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	40593304
830.7840	Water solubility: column elution method; shake flask method	Y	00149370, 40739801
830.7950	Vapor pressure	Y	40593304

[1] Y = Yes; N = No; N/A = Not Applicable.

[2] All references are from C. Olinger, DP Barcode D254972, 10/27/99.

[3] A revised CSF must be submitted on EPA Form 8570-4, including proper identification of the registrant, producer, and EPA registration number, and nominal concentrations and certified limits for the ai and impurities present in any sample of the technical product at ≥0.1%. In addition, an explanation is required concerning how upper certified limits were established for several impurities which were not resolved by preliminary analysis.

[4] The identity and source of a catalyst used in the production process is required.

[5] Quantitative data demonstrating the stability of the TGAI upon exposure to metals and metal ions are required.

[6] The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI

[7] Data are not required because the T/TGAI is a liquid at room temperature.

[8] Data are not required because the TGAI is not an acid or base.

MOLINATE

REREGISTRATION ELIGIBILITY DECISION

RESIDUE CHEMISTRY CONSIDERATIONS

PC Code No. 041402; Case 2435

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MOLINATE

REREGISTRATION ELIGIBILITY DECISION

RESIDUE CHEMISTRY CONSIDERATIONS

PC Code No. 041402; Case 2435

INTRODUCTION

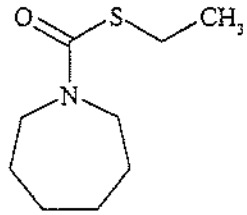
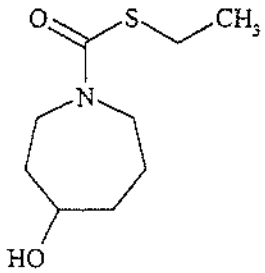
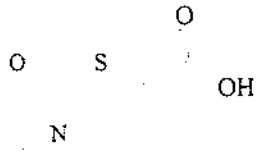
Molinate (*S*-ethyl hexahydro-1*H*-azepine-1-carbothioate) is a herbicide registered for use on rice. Molinate is manufactured by Zeneca, Inc., the basic producer, under the trade names Ordram® and Arrosolo®. Emulsifiable concentrate (EC) and granular (G) formulations may be applied to rice preemergence and/or postemergence using ground and aerial equipment.

REGULATORY BACKGROUND

Molinate is a list B reregistration chemical and was the subject of a Phase 4 Review dated 2/21/91. This document summarized regulatory conclusions on the available residue chemistry data and specified that additional data were required for reregistration purposes. Several submissions of data have been received since the Phase 4 Review was issued. The information contained in this document outlines the current Residue Chemistry Science Assessments with respect to the reregistration of molinate.

Tolerances are established (40 CFR §180.228) for residues of molinate *per se* in/on rice and rice straw each at 0.1 ppm. The HED Metabolism Committee (C. Olinger, 3/2/94 and 4/25/94) has determined that the residues to be regulated in plants include molinate and its metabolites 4-hydroxymolinate (*S*-ethyl hexahydro-4-hydroxy-1*H*-azepine-1-carbothioate) and molinate acid [*S*-(carboxymethyl)-hexahydro-1*H*-azepine-1-carbothioate]. Residues of molinate and its metabolites of concern are not expected to transfer to edible livestock commodities at the maximum dietary burden. The chemical names and molecular structures of molinate and metabolites of concern are depicted in Figure A.

Figure A. Chemical names and molecular structures of molinate and its metabolites of concern in plants.

Chemical Name **Common Name**	Structure
s-ethyl hexahydro-1*H*-azepine-1-carbothioate **Molinate**	
s-ethyl hexahydro-4-hydroxy-1*H*-azepine-1-carbothioate **4-Hydroxymolinate**	
s-(carboxymethyl)-hexahydro-1*H*-azepine-1-carbothioate **Molinate acid**	

SUMMARY OF SCIENCE FINDINGS

OPPTS GLN 860.1200: Directions for Use

A search of the Agency's Reference Files System conducted in 3/99 indicates that there are six molinate end-use products (EPs) with food/feed uses registered to Zeneca Ag Products. These EPs are presented below.

EPA Reg No.	Label Acceptance Date	Formulation Class	Product Name
10182-171	3/10/94	6 lb/gal EC	Ordram ® 6E
10182-174	9/25/96	10% G	Ordram ® 10-G
10182-204	12/20/96	8 lb/gal EC	Ordram ® 8-E
10182-260	4/29/96	3 lb/gal EC	Arrosolo® 3-3E
10182-274	1/25/94	15% G	Ordram ® 15-G
10182-420	4/1/97	15% G	Ordram ® 15-GM

The registrant has proposed revising the molinate labels, which have been reviewed by HED (DP Barcodes D199140, D199148, D208046, 3/13/95, C. Olinger) and judged to be adequate. The sequential application program of the EC and G formulations is presented in Table A. As of 3/99, the modifications had not been made to the registrant's labels. Restrictions applicable to all modified labels are as follows:

- Do not apply molinate at more than 9 lb ai/acre per season regardless of the formulation
- Do not make any application within 45 days of harvest.
- Do not apply ORDRAM 15-G in areas where fish, crayfish, or mollusks are commercially cultivated.
- Hold flood water a minimum of 4 days after application.
- Observe a minimum retreatment interval of 7 or 14 days between applications (depending upon product or treatment program).
- Rotated crops may not be planted for a least six months after the final application.

A tabular summary of the residue chemistry science assessments for reregistration of molinate is presented in Table B. The conclusions listed in Table B regarding the reregistration eligibility of molinate food/feed uses are based on the use patterns registered by the basic producer, Zeneca Ag Products. When end-use product DCIs are developed (e.g., at issuance of the RED), RD should require that all end-use product labels (e.g., MAI labels, SLNs, and

products subject to the generic data exemption) be amended such that they are consistent with the basic producer's labels.

Table A. Sequential Application Programs for Molinate on Rice

Products in Sequence of Application	Timing of Application	Maximum Use Rate per Application (lb ai/A)	Minimum Retreatment Interval (days)
Arrosolo Arrosolo Ordram Granular	post-emergence/preflood post-emergence/preflood post-emergence/postflood	3 3 3	7 7
Arrosolo Ordram Granular	post-emergence/preflood post-emergence/postflood	4 5	14
Ordram 8E or Granular Ordram Granular or 8E	pre-plant incorporated post-emergence/postflood	4 5	14
Ordram Granular Arrosolo or Ordram 8E	postflood/preplant post-emergence/preflood	4 5	14
Ordram Granular Ordram Granular	postflood/preplant post-emergence/postflood	4 5	14

OPPTS GLN 860.1300: Nature of the Residue in Plants

The qualitative nature of the residue in rice is adequately understood. In rice treated with [^{14}C]molinate at a 1x rate the parent molinate was detected in rice grain and straw at <0.01 ppm and 0.06 ppm, respectively, representing 0.2% of the total radioactive residue (TRR) in each raw agricultural commodity. 4-Hydroxymolinate accounted for 0.7% of the TRR in grain (0.02 ppm) and 15.3% in straw (3.64 ppm). Molinate acid accounted for 3.6% TRR in grain (0.13 ppm) and 7.1% in straw (1.69 ppm). In grain 48.8% TRR (1.76 ppm) was incorporated into starch. The residues of concern in plants are molinate, 4-hydroxymolinate, and molinate acid.

OPPTS GLN 860.1300: Nature of the Residue in Livestock

The qualitative nature of the residue in livestock is adequately understood based upon acceptable ruminant and poultry metabolism studies. None of the residues of concern in plant commodities, including molinate, 4-hydroxymolinate, and molinate acid, were found in livestock tissues, eggs, or milk at dosing levels greater than 10 times the maximum dietary burden. The major residue found was hexamethyleneimime (HMI), which is not of concern at

the levels expected in livestock commodities. Tolerances in livestock commodities are not needed at this time, as this is considered to be Category 3 of 180.6, that residues of concern in livestock are not expected.

OPPTS GLN 860.1340: Residue Analytical Methods

Data from analysis of residues in rice matrices have been collected using a gas chromatography (GC)/nitrogen-phosphorus detection (NPD) method for molinate and a GC/mass-selective detection (MSD) method for 4-hydroxymolinate and molinate acid. The GC/NPD method for molinate involves direct extraction; the validated limit of quantitation (LOQ) is 0.05 ppm. PAM, Vol. II includes a GC/NPD method for molinate in rice commodities that includes extraction by steam distillation. The GC/MSD method for the metabolites includes extraction and hydrolysis, paralleling procedures used in the rice metabolism study; the LOQ is 0.05 ppm for each analyte. This method has undergone successful independent laboratory validation and will be validated by the Agency for use in tolerance enforcement. The registrant has reported the limit of detection (LOD) as 0.003-0.004 ppm for all methods and matrices, but this LOD has not been confirmed by the Agency laboratory.

As no residues of concern have been identified in livestock tissues, analytical methods and tolerances for molinate residues in livestock commodities are not required.

OPPTS GLN 860.1360: Multiresidue Method Testing

The FDA PESTDATA database does not contain information regarding the recovery of molinate through FDA Multiresidue protocols. These data were required in the Phase IV review and remain outstanding. Multiresidue method testing is required for molinate, molinate acid, and 4-hydroxymolinate.

OPPTS GLN 860.1380: Storage Stability Data

The Molinate Phase 4 Review cited data indicating that molinate *per se* is stable in a variety of commodities, including alfalfa hay, almond nutmeat, soybeans, wheat grain and wheat straw at -20 C for 3 years. Recently submitted data indicate that field incurred residues of 4-hydroxymolinate and molinate acid were stable in rice grain and straw during a period from the initial analysis ~200 days after harvest through an additional year in storage. Both residues were stable in grain stored for ~4 years after the initial analysis. After 4 years, there was no decline in molinate acid in straw, but there was a 40% decline in 4-hydroxymolinate in straw. No additional storage stability data are required to support the existing magnitude of residue studies.

OPPTS GLN 860.1500: Magnitude of the Residue in Crop Plants

For purposes of reregistration, requirements for magnitude of the residue in plants are fulfilled for rice grain and straw, pending required label amendments. Geographic representation is adequate and a sufficient number of trials reflecting representative formulation classes were conducted. Combined residues of molinate, 4-hydroxymolinate, and molinate acid were <0.15-0.73 ppm in grain and <0.49-<6.27 ppm in straw from 14 field trials conducted in Arkansas, Texas, Louisiana, Mississippi, and California.

OPPTS GLN 860.1520: Magnitude of the Residue in Processed Food/Feed

The reregistration requirements for magnitude of the residue in processed food/feed commodities are fulfilled for rice grain. Combined residues of molinate, 4-hydroxymolinate, and molinate acid concentrated 3.2x in rice hulls and 2.3x in rice bran. Based on the available processing studies, tolerances for residues in rice hulls and bran are required. The combined residues are reduced by a factor of 0.3x in polished rice.

OPPTS GLN 860.1480: Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

The maximum theoretical dietary intake of molinate by cattle, calculated using reassessed tolerances, is approximately 1.8 ppm based on a diet of 40% rice grain, 15% rice bran, 10% rice hulls, and 10% rice straw. The maximum theoretical dietary burden for poultry is 1.4 ppm based on a diet of 60% rice grain, 25% rice bran, and 15% rice hulls. The maximum theoretical dietary burden for swine is 0.8 ppm based on a diet of 65% rice grain and 15% rice bran. The livestock metabolism studies indicate that molinate residues of concern are not present in tissues, milk, or eggs from animals dosed with molinate at levels greater than the theoretical maximum dietary exposure. These diets are exaggerated and represent the maximum dietary exposure assuming all rice is treated and bears residues at the tolerance level. Tolerances for molinate residues in livestock commodities are not required.

OPPTS GLN 860.1400: Magnitude of the Residue in Water, Fish, Irrigated Crops

Adequate potable water studies are available. The data indicate that residues decrease to <0.01 ppm in water 29 days after treatment of flooded rice fields. The registrant has reported previously that the water holding period of 14 days currently on the labels is not practical. Therefore, the use of molinate on rice will be considered an aquatic use and additional data are required under this guideline. Studies on the magnitude of residue in fish are not required provided the registrant adds an aquaculture restriction on all product labels. Data must be submitted depicting molinate, 4-hydroxymolinate, and molinate acid in irrigated crops exposed to molinate residues in irrigation water. Data on irrigated crops were submitted for Phase 4

review; however, the analyses included the parent compound and did not include 4-hydroxymolinate or molinate acid. If significant residues of molinate sulfoxide or sulfone are found in the irrigation water used in the study, then residues of the sulfoxide and sulfone should be sought in the crops as well. Residues of molinate *per se* are not generally found in the primary crop. The registrant should initially conduct irrigated crop studies for the representative crops of the crop groups most commonly rotated with rice. If residues are non-detectable for all tests, then further testing with representative crops of other crop groups will not be required. These data are considered confirmatory.

OPPTS GLN 860.1460: Magnitude of the Residue in Food-Handling Establishments

Molinate is not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

OPPTS GLN 860.1850: Confined Accumulation in Rotational Crops

An adequate confined rotational crop study has been reviewed by EFED. The study indicates that residues of concern are not expected in rotational crops at plant-back intervals of six months or more. Rotational crop studies at intervals less than six months were not provided. Accordingly registrants should amend their product labels to include a plant-back interval of six months; if a shorter interval is desired, then an additional study is required.

OPPTS GLN 860.1900: Field Accumulation in Rotational Crops

Additional data on rotational crops are not required.

Table B. Residue Chemistry Science Assessments for Reregistration of Molinate.

OPPTS GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References[1]
860.1200: Directions for Use	N/A	Yes [2]	Table A
860.1300: Nature of the Residue			
- Plants	N/A	No	41827702[3] 42432201[4] 43110201[5] 43111202[5]
- Livestock	N/A	No	42798601[6] 42798602[6] 43276302[7] 43276303[7] 43743302[8]
860.1340: Residue Analytical Methods	N/A	No	00094720 00152310 42824601[9] 43276301[7] 44104701[10] 44306902[11] 44655301[12] 44655302[12] 44765006[13]
860.1360: Multiresidue Method	N/A	Yes [14]	
860.1380: Storage Stability	N/A	No	40980201 41421803[15] 41421804[15] 43743301[16] 44306903[17]
860.1500: Magnitude of the Residue in Crop Plants			
Cereal Grains Group			
- Rice, grain	0.1 [§180.228]	No	42881201[9]
Forage and Straw of Cereal Grains Group			
- Rice, Straw	0.1 [§180.228]	No	42881201[9]
860.1520: Magnitude of the Residue in Processed Food/Feed			
- Rice, bran	None established	No	44306901[17]
- Rice, hulls	None established	No	44306901[17]
860.1480: Magnitude of the Residue in Meat, Milk, Poultry, and Eggs	None established		
860.1400: Magnitude of the Residue in water, fish, and irrigated crops	None established	Yes [18]	40651303[15] 40651307[15] 40651309[15] 40651311[15] 41407501 41421803[15] 41421804[15] 42268803[15] 43284801[15]
860.1460: Magnitude of the Residue in Food Handling Establishments	N/A	No	
860.1850: Confined Accumulation in Rotational Crops	N/A	No	41867901[19]
860.1900: Field Accumulation in Rotational Crops	None	No	

1. Non-annotated references were reviewed for the Molinate Phase 4 Review dated 2/91. Other references were reviewed as noted.

2. The recommended label amendments are listed in the SUMMARY OF SCIENCE FINDINGS, under OPPTS GLN 860.1200: Directions for Use.

3. DP Barcode D166831, 4/16/92, C. Olinger.

4. DP Barcode D181576, 09/21/92, C. Olinger.

5. DP Barcode D200185, 11/29/94, C. Olinger.

6. DP Barcode D192392, 3/7/94, C. Olinger.

7. DP Barcode D204824, 1/30/95, C. Olinger.

8. DP Barcode D219712, 07/08/98, C. Olinger.

9. DP Barcodes D192476/D194363, 3/14/95, C. Olinger.

10. DP Barcode D230158, 04/16/98, C. Andreasen.

11. DP Barcode D237181, 04/16/98, C. Andreasen.

12. DP Barcode D249975, 03/04/99, C. Olinger.

13. DP Barcode D253987, 04/19/99, C. Olinger.

14. Multiresidue method testing for molinate, molinate acid, and 4-hydroxymolinate are required.

15. DP Barcode D177192 and D205052, 8/2/95, C. Eiden.

16. DP Barcode D219717, 07/31/97, C. Olinger.

17. DP Barcode D245269, 07/08/98, C. Olinger.

18. Data are required depicting molinate residues of concern in crops irrigated with water from treated rice fields.

19. DP Barcode D166828, 04/29/92, E. Regelman.

TOLERANCE REASSESSMENT SUMMARY

Tolerances for residues of molinate in/on plant RACs are currently expressed in terms of molinate *per se*. The Agency has determined that the residues to be regulated in plant commodities are molinate and the metabolites 4-hydroxymolinate and molinate acid. Therefore, the tolerance definition in 40 CFR §180.228 should be amended to include all residues to be regulated.

A summary of the molinate tolerance reassessment and recommended modifications in commodity definitions are presented in Table C.

Tolerances Listed Under 40 CFR §180.228:

Sufficient data are available to ascertain the adequacy of the established tolerances for molinate residues in/on rice grain and rice straw. The tolerance for residues in/on rice grain should be increased to 0.75 ppm based on combined residues of <0.73 ppm in/on grain from field trials. The tolerance for residues in/on rice straw should be increased to 7.0 ppm based on combined residues of <6.27 ppm in/in straw from field trials. Molinate *per se* was <0.05 ppm (<LOQ) in/on rice grain and straw from all field trials.

New Tolerances Needed Under 40 CFR §180.228(a):

An adequate processing study indicated that residues concentrated in hulls and bran processed from molinate-treated rice grain; tolerances of 3.0 and 2.0 ppm, respectively, are required.

Table C. Tolerance Reassessment Summary for Molinate.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 40 CFR §180.228:			
Rice	0.1	0.75	*Rice, grain*
Rice straw	0.1	7	*Rice, straw*
Tolerances needed under 40 CFR §180.228:			
Rice, bran	none	2	
Rice, hulls	none	3	

DIETARY EXPOSURE ASSESSMENT SUMMARY

Adequate plant and animal metabolism data are available for reregistration and risk assessment purposes. Adequate magnitude of the residue data and processing studies are available, pending submission of appropriately amended labels. Anticipated residues have been calculated for molinate using an average from crop field trials and processing factors and are presented in Table D.

Table D. Molinate (Chemical # 041402)--Anticipated Residues for Rice Commodities Derived from Field Trial Studies [1]

Commodity	Average Residue [2], ppm	Processing Factor	Average Percent crop Treated [3]	Likely Maximum Percent Crop Treated [3]	Anticipated Residue for Acute Analysis, ppm [4]	Anticipated Residue for Chronic Analysis, ppm [4]
Polished Rice	0.15	0.32	40	54	0.03	0.02
Brown Rice	0.15	0.54	40	54	0.04	0.03
Rice Bran	0.15	2.3	40	54	0.19	0.14

[1] Residue values are the combined residues of molinate, 4-hydroxymolinate, and molinate acid.
[2] Residue reported in these columns are for the raw agricultural commodity, rice grain, which is not consumed. Note that HED is recommending for a reassessed tolerance of 0.75 ppm.
[3] From Quantitative Usage Analysis, J. Alsadek, 3/31/99.
[4] Derived by multiplying the average residue by the percent crop treated and the processing factor. The estimated maximum percent crop treated was used for the acute analysis, and the average percent crop treated was used for the chronic analysis.

CODEX HARMONIZATION

The Codex Alimentarius Commission has not established or proposed maximum residue limits (MRLs) for molinate residues. Therefore, there are no issues regarding compatibility of U.S. tolerances with Codex MRLs.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No.	8447
DP Barcode:	D166831
Subject:	Molinate: Rice Metabolism Study
From:	C. Olinger
To:	E. Dobbins/L. Deluise
Date:	04/16/92
MRID(s):	41827701, 41827702

CBRS No.	None
DP Barcode:	D166828
Subject:	Aged Leaching and Confined Rotational Crop Studies
From:	E. Regelman
To:	E. Dobbins
Date:	04/29/92
MRID(s):	41867901

CBRS No.	10404
DP Barcode:	D181576
Subject:	Reregistration of Molinate: Plant Metabolism
From:	C. Olinger
To:	E. Dobbins
Date:	09/21/94
MRID(s):	42432201

CBRS No.	12093
DP Barcode:	D192392
Subject:	Reregistration of Molinate: Animal Metabolism Data
From:	C. Olinger
To:	P. Parsons
Date:	03/07/94
MRID(s):	42798601, 42798602

CBRS No.	None
DP Barcode:	None
Subject:	Reregistration of Molinate: HED Metabolism Committee Decision
From:	C. Olinger
To:	P. Parsons
Date:	04/25/94
MRID(s):	None

CBRS No. 13333

DP Barcode:	D200185
Subject:	Molinate Rice Metabolism
From:	C. Olinger
To:	P. Parsons
Date:	11/23/94
MRID(s):	431102011, 43110202

CBRS No.	13928
DP Barcode:	D204824
Subject:	Reregistration of Molinate: Animal Metabolism and Plant Residue Analytical Method
From:	C. Olinger
To:	P. Parsons
Date:	01/26/95
MRID(s):	43276301, 43276302, 43276303

CBRS No.	13227, 13226, 14483
DP Barcode:	D199140, D199148, D208406
Subject:	Reregistration of Molinate: Proposed Label Modifications
From:	C. Olinger
To:	J. Miller/P. Parsons
Date:	03/13/95
MRID(s):	None

CBRS No.	12147, 12448
DP Barcode:	D192746, D194363
Subject:	Reregistration of Molinate: Residue Analytical Method and Rice Field Trial
From:	C. Olinger
To:	P. Parsons
Date:	03/14/95
MRID(s):	42824601, 42881201

CBRS No.	9779, 13962
DP Barcode:	D177192, D205052
Subject:	Molinate: Potable Water Study
From:	C. Eiden
To:	P. Parsons
Date:	08/02/95
MRID(s):	40651303, 40651307, 40651311, 43284801

CBRS No.	16301
DP Barcode:	D219717
Subject:	Reregistration of Molinate: Storage Stability Studies
From:	C. Olinger
To:	W. Livingston
Date:	07/08/97
MRID(s):	43743301

CBRS No.	None
DP Barcode:	D230158
Subject:	Molinate Reregistration Action: Independent Laboratory Validation of Analytical Method
From:	C. Andreasen
To:	R. McNally/W. Livingston
Date:	04/16/98
MRID(s):	44104701

CBRS No.	None
DP Barcode:	D237181
Subject:	Molinate Reregistration Action: Analytical Method for Metabolites
From:	C. Andreasen
To:	R. McNally/W. Livingston
Date:	04/16/98
MRID(s):	44306902

CBRS No.	None
DP Barcode:	D245269
Subject:	Reregistration of Molinate: Storage Stability Studies and Rice Processing Study
From:	C. Olinger
To:	W. Livingston
Date:	07/08/98
MRID(s):	44306901, 44306903

CBRS No.	None
DP Barcode:	D219712
Subject:	Reregistration of Molinate: Poultry Metabolism Upgrade
From:	C. Olinger
To:	W. Livingston
Date:	07/08/98
MRID(s):	43743302

CBRS No.	None
DP Barcode:	D249975
Subject:	Reregistration of Molinate: Residue Analytical Method Upgrade
From:	C. Olinger
To:	W. Livingston
Date:	03/04/99
MRID(s):	446553-01 and -02

CBRS No.	None
DP Barcode:	D253987
Subject:	Reregistration of Molinate: Anticipated Residue Assessment
From:	C. Olinger
To:	W. Livingston
Date:	04/19/99
MRID(s):	44765006

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