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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

11/14/96

MEMORANDUM

SUBJECT: Pyrimidinone. Case 2585. Chemical 118401. Product and Residue Chemistry Chapters for the Reregistration Eligibility Decision (RED). CB 17638. DP Barcode: D217434.

FROM: K. Dockter, Chemist
Special Review Section I
Chemistry Branch II - Reregistration Support
Health Effects Division(7509C)

THROUGH: Randolph B. Perfetti, Ph.D., Acting Chief
Chemistry Branch II - Reregistration Support
Health Effects Division(7509C)

TO: Jane Smith
Risk Characterization & Analysis Branch
Health Effects Division(7509C)

Attached are the Product and Residue Chemistry chapters for the pyrimidinone RED. The chapters were assembled by Dynamac Corporation under the supervision of CBRS, HED. The data assessment has undergone secondary review in the branch and has been revised to reflect Agency policies.

Product Chemistry

All pertinent generic and product-specific product chemistry data requirements are satisfied for the American Cyanamid 95% T, except for a new data requirement (GLN 830.7050; UV/visible absorption for the PAI). Provided that the registrant submits the data required in the attached data summary table for the 95% T, and either certifies that the suppliers of beginning materials and the manufacturing process for the pyrimidinone TGAI have not changed since the last comprehensive product chemistry reviews or submits a complete updated product chemistry data package, CBRS has no objections to the reregistration of pyrimidinone with respect to product chemistry data requirements.

Residue Chemistry

Additional information and data required are given below.

- The following label revisions are required for the purposes of reregistration: (i) delete rangeland as a site; (ii) amend the use pattern to that for which adequate data are available for pasture grasses [i.e., maximum application rate of 0.019 lb ai/A for broadcast treatment, maximum of three broadcast treatments per year from June to October with retreatment intervals of 48-58 days, PHI/PGI of 3 days for treated grass forage, and a 7-day baling interval for treated grass hay]; (iii) restrict use of pyrimidinone as a fire ant bait on pasture grasses to the following states: AL, AR, LA, FL, MS, NC, OK, SC, TN, TX, and VA, and (iv) restrict against harvesting of food/feed within one year of application on non-bearing nursery stocks.

- Should the registrant wish to add rangeland as a site to pyrimidinone EP labels in the future, additional field trial data on rangeland grass forage and hay will be required. The required field trials for rangeland grass commodities should be conducted in CA, CO/KS, ID/OR/WA, IL, and NE, and should reflect a 0-day PHI following applications of a representative granular formulation according to the maximum use patterns recommended for pastures. The current Agency policy is to set tolerances for grass forage and hay grown in rangelands at the residue level obtained on the day of application (0-day PHI).

- The registrant should propose new tolerances of 0.5 ppm for pasture grass forage and 0.2 ppm for pasture grass hay.

- American Cyanamid has submitted a petition, PP#2F2609, for the establishment of a tolerance for residues of pyrimidinone *per se* in/on pineapples at 0.05 ppm. This petition has been pending since 1982 and is currently in reject status.

Dietary Exposure/Risk Assessment

A DRES run was conducted in 1996 for meat and milk exposure using worse case scenarios assuming total radioactive residues were present entirely as parent and incorporating an uncertainty factor of 1000. The TMRC and %RfD for the U.S. population are 0.008 ug/kg/dy and 2.8%, respectively. The TMRC was also estimated for 22 populations subgroups. The results of this worse case scenario DRES analysis were sufficiently low that further DRES runs for residues of pyrimidinone were not performed.

Attachment - Reregistration Eligibility Decision: Product and Residue Chemistry Considerations
cc(without attachment): RF.
cc(with Attachment): Circ, List B File, Dockter, SRRD.

RD/I ARRathman 11/12/96; RBPerfetti 11/13/96
7509C:CBRS:CM#2:RM804S:3057886:KD/kd:November 13, 1996
PYRIMIDI.RED[638.R01]

PYRIMIDINONE (HYDRAMETHYLNON)

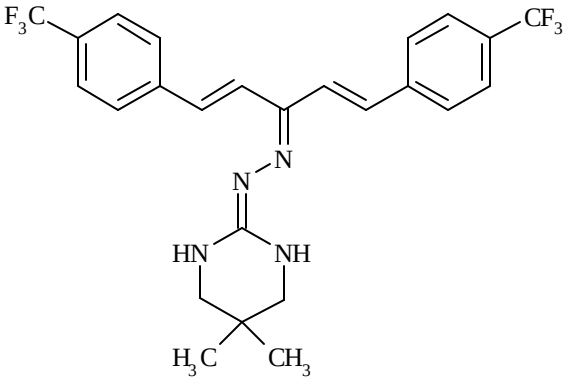
REREGISTRATION ELIGIBILITY DECISION:

PRODUCT CHEMISTRY CONSIDERATIONS

Shaughnessy No. 118401; Case No. 2585

DESCRIPTION OF CHEMICAL

Pyrimidinone [hydramethylnon; tetrahydro-5,5-dimethyl-2(1H)-pyrimidinone (3-(4-(trifluoromethyl)phenyl)-1-(2-(4-(trifluoromethyl)phenyl)ethenyl)-2-propenylidene)hydrazone] is primarily used as a formicide (leafcutting, bigheaded, harvester, and fire ants), but also is used in indoor nonfood use areas for cockroach control.



Empirical Formula:	$C_{25}H_{24}F_6N_4$
Molecular Weight:	494.50
CAS Registry No.:	67485-29-4
Shaughnessy No.:	118401

IDENTIFICATION OF ACTIVE INGREDIENT

Pyrimidinone is a yellow to tan crystalline solid with a characteristic vegetable oil odor and melting point of 189-191 C. Pyrimidinone is insoluble in water, slightly soluble in alcohols, and soluble in acetone, chlorobenzene, and 1,2-dichloroethane.

A search of the Reference Files System (REFS) conducted 9/9/96 identified a single pyrimidinone manufacturing-use product (MP) registered under Shaughnessy No. 118401: the American Cyanamid Company 95% technical (T; EPA Reg. No. 241-270). Only the 95% T/TGAI is subject to a reregistration eligibility decision.

REGULATORY BACKGROUND

The Pyrimidinone Phase IV Review dated 1/8/91 by C. Olinger determined that the available data concerning GLN 830.7950 met the acceptance criteria for Phase V review; American Cyanamid committed to conduct studies for the remaining GLNs.

The current status of the product chemistry data requirements for the pyrimidinone technical product is presented in the attached data summary table.

CONCLUSIONS

All pertinent generic and product-specific product chemistry data requirements are satisfied for the American Cyanamid 95% T, except for a new data requirement (GLN 830.7050; UV/visible absorption for the PAI). Provided that the registrant submits the data required in the attached data summary table for the 95% T, and either certifies that the suppliers of beginning materials and the manufacturing process for the pyrimidinone TGAI have not changed since the last comprehensive product chemistry reviews or submits a complete updated product chemistry data package, CBRS has no objections to the reregistration of pyrimidinone with respect to product chemistry data requirements.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No(s).:	None; RD Memorandum
Subject:	Product Chemistry Review on New Chemicals, EPA File Symbol 241-ETN.
From:	T. Alston
To:	G. LaRocca
Dated:	4/6/89
MRID(s):	40582501 and 40582502

CBRS No(s).: None; RD Memorandum
Subject: Product Chemistry Review of Amdro Technical (EPA File Symbol 241-ETN).
From: A. Smith
To: R. Richards
Dated: 3/22/91
MRID(s): 41612501 and 41612502

CBRS No(s).: 11622
DP Barcode(s): D189463
Subject: Hydramethylnon Reregistration: List B Chemical (Chemical No. 118401; Case No. 2585). American Cyanamid Company: Response to the Hydramethylnon Product Chemistry Data Requirements Regarding Dissociation Constant (Guideline No. 63-10).
From: F. Toghrol
To: J. Ellenberger/K. Davis
Dated: 5/6/93
MRID(s): 41612500

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

References (cited):

00106033 Kim, D. (1982) Amdro Fire Ant Insecticide (Cl 217,300): Determination of the Vapor Pressure of Cl 217,300 by the Gas-saturation Technique: Report No. PD-A 18-1: 1-10. (Unpublished study received Jun 23, 1982 under 241-267; submitted by American Cyanamid Co., Princeton, NJ; CDL:247831-A)

40582501 American Cyanamid Co. (1987) Product Identity and Disclosure of Ingredients: Amdro and Maxforce Technical. Unpublished study. 9 p.

40582502 Cardaciotto, S.; Conley, J. (1987) Product Chemistry Preliminary Analysis, Certification of Limits, and Analytical Methods to Verify Certified Limits. Unpublished compilation prepared by American Cyanamid Co. 76 p.

41612500 American Cyanamid Co. (1990) Submission of Data To Support Registration of AMDRO Technical Insecticide: Product Chemistry and Toxicology Studies. Transmittal of 6 studies.

41612501 Long, D.; Cardaciotto, S.; Conley, J. (1990) Product Identity, Description of Manufacturing Process and Discussion of Impurities for Technical AMDRO. Unpublished study prepared by American Cyanamid Co. 151 p.

41612502 Long, D.; Teeter, J.; Mangels, G. (1990) EPA Pesticide Assessment Guidelines, Subdivision D-Product Chemistry, Physical and Chemical Characteristics of the Technical/ Manufacturing Use Product:Technical AMDRO: Lab Project Number: CHDVVOLUME30/REPORT. Unpublished study prepared by American Cyanamid Co. 180 p.

Case No. 2585
Chemical No. 118401

Case Name: Pyrimidinone
Registrant: American Cyanamid Company
Product(s): 95% T (EPA Reg. No. 241-270)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [a]	MRID Number [b]
830.1550	Product Identity and Disclosure of Ingredients	Y	**40582501**
830.1600	Description of materials to produce the product	Y	**40582501**
830.1620	Description of production process	Y	41612501
830.1670	Discussion of Formation of Impurities	Y	**40582501**, 41612501
830.1700	Preliminary Analysis	Y	**40582502**
830.1750	Certification of Ingredient Limits	Y	**40582502**
830.1800	Analytical Methods to Verify the Certified Limits	Y	**40582502**
830.6302	Color	Y	41612502
830.6303	Physical State	Y	41612502
830.6304	Odor	Y	41612502
830.6313	Stability	Y	41612502
830.7000	pH	N/A [c]	
830.7050	UV/Visible Absorption	N [d]	
830.7200	Melting Point/Melting Range	Y	41612502
830.7220	Boiling Point/Boiling Range	N/A [e]	
830.7300	Density/Relative Density/Bulk Density	Y	41612502
830.7370	Dissociation Constant in Water	N/A [f]	41612500 [g]
830.7550	Partition Coefficient (Octanol/Water), shake flask	Y	41612502
830.7840	Water Solubility: column elution, shake flask	Y	41612502
830.7950	Vapor Pressure	Y	00106033 [h], 41612502

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

[b] **Bolded** references were reviewed by the Registration Division (RD Memorandum, 4/6/89, T. Alston; underlined references were also reviewed by RD (RD Memorandum, 3/22/91, A. Smith); and all other references were reviewed as noted.

[c] Data are not required because the TGAI is insoluble in water.

[d] The GLN 830.7050 requireS data pertaining to UV/visible absorption for the PAI.

[e] Data are not required because the TGAI is a solid at room temperature.

[f] Data are not required because the TGAI/PAI is not an acid or a base and does not dissociate in water or any solvent system.

[g] CBRS No. 11622, D189463, 5/6/93, F. Toghrol.

[h] Pyrimidinone Phase IV Review, 1/8/91, C. Olinger.

PYRIMIDINONE (HYDRAMETHYLNON)

REREGISTRATION ELIGIBILITY DECISION

RESIDUE CHEMISTRY CONSIDERATIONS

Shaughnessy No. 118401; Case 2585

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INTRODUCTION

Pyrimidinone [tetrahydro-5,5-dimethyl-2(1H)-pyrimidinone(3-(4-(trifluoromethyl)phenyl)-1-(2-(4-(trifluoromethyl)phenyl)ethenyl)-2-propenylidene)hydrazone] is a slow-acting insecticide registered for the control of ants (big-headed, fire, and harvester) in pastures, rangelands, and other noncrop lands such as lawns, turfs, and non-bearing nursery stocks. It is also registered for the control of household ants and cockroaches in nonfood use areas in domestic dwellings and commercial establishments. Pyrimidinone is sold in the United States by the basic producer, American Cyanamid Company, under the trade name Amdro®. For the control of ants, the registered granular (G) formulation may be applied via broadcast or individual mound treatment. For the control of household ants and cockroaches, the impregnated (Impr) formulation may be applied as a bait.

REGULATORY BACKGROUND

Pyrimidinone is a List B reregistration chemical. The Chemistry Branch completed the List B Inventory of Pyrimidinone Residue Chemistry Data on 6/29/90 and the Pyrimidinone Phase 4 Review on 1/8/91. Pyrimidinone Data-Call-In (DCI) Notices were issued 4/12/91 and 7/12/91. The Branch has conducted Phase 5 Review of several residue chemistry studies that were submitted in response to the Pyrimidinone Phase 4. The information contained in this document outlines the Residue Chemistry Science Assessments with respect to the reregistration of pyrimidinone.

Tolerances for residues of pyrimidinone in/on plant commodities are established under 40 CFR §180.395 and are expressed in terms of pyrimidinone *per se*. Tolerances are established at 0.05 ppm for grass and grass hay. There are no tolerances established for residues of pyrimidinone in animal commodities. Adequate methods are available for the enforcement of established tolerances for plant commodities. No Codex MRLs have been established for pyrimidinone; therefore, there are no issues of compatibility with respect to U.S. tolerances and Codex MRLs.

The Food Quality Protection Act (FQPA) of 1996 has amended and strengthened the standard for establishing tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). The Office of Pesticide Programs (OPP) is still assessing the full impact of this change in the law on the tolerance-setting process, and plans to issue guidelines concerning the establishment and reassessment of tolerances under the amended statute. All future tolerance petitions as well as reassessment of established tolerances must meet the requirements of the FFDCA as amended by the FQPA. OPP may require additional data to determine if the terms of the amended statute have been met.

SUMMARY OF SCIENCE FINDINGS

GLN 860.1200: Directions for Use

The reregistration of pyrimidinone in the United States is being supported by American Cyanamid Company. A REFs search conducted 9/9/96 identified five pyrimidinone end-use products (EPs) with food/feed uses registered to American Cyanamid Company. These EPs are presented below in Table A-1.

Table A-1. Pyrimidinone end-use products (EPs) with food/feed uses registered to American Cyanamid Company.

EPA Reg. No. [1]	Acceptance Date	Formulation	Product Name
241-260	04/25/94	0.88% G	Amdro® Granular Insecticide
241-261	04/25/94	0.88% G	Amdro® 20 Fire Ant Insecticide
241-322	04/25/94	0.73% G	Amdro® Granular Insecticide
241-357	04/25/94	0.73% G	Amdro® Insecticide Bait
241-358	04/25/94	0.88% G [2]	Amdro® Insecticide Ant Bait

[1] There are no active pyrimidinone Special Local Need (SLN) registrations.

[2] The REFs classifies EPA Reg. No. 241-358 as a pelleted/tableted (P/T) formulation. Based on examination of ingredients and use pattern, this product should be classified as a granular formulation.

The sole pyrimidinone food site being supported for reregistration is pasture grass. The registered use patterns for grasses grown in pastures are presented in Table A-2. American Cyanamid Company has indicated that it will not support pyrimidinone uses on grasses grown in rangelands. The application of pyrimidinone as a bait in domestic dwellings and commercial establishments has been determined to be a non-food use.

CBRS has examined the registered use patterns of EPs listed in Table A-1 and reevaluated the available residue chemistry database for adequacy in supporting the use patterns for grasses grown in pastures. The following label revisions are required for the purposes of reregistration: (i) delete rangeland as a site; (ii) amend the use pattern to that for which adequate data are available for pasture grasses [i.e., maximum application rate of 0.019 lb ai/A for broadcast treatment, maximum of three broadcast treatments per year from June to October with retreatment intervals of 48-58 days, preharvest/pregrazing intervals (PHI/PGI) of 3 days for treated grass forage, and a 7-day baling interval for treated grass hay]; (iii) restrict use of pyrimidinone as a fire ant bait on pasture grasses to the following states: AL, AR, LA, FL, MS, NC, OK, SC, TN, TX, and VA, and (iv) restrict against harvesting of food/feed within one year of application on non-bearing nursery stocks.

A tabular summary of the residue chemistry science assessments for reregistration of pyrimidinone is presented in Table B. The conclusions listed in Table B regarding the reregistration eligibility of pyrimidinone food/feed uses are based on the use patterns registered by the basic producer, American Cyanamid Company. When EP DCIs are developed (e.g., at issuance of the RED), RD should require that all EP labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the American Cyanamid Company labels.

Table A-2. Registered Food/Feed Use Patterns Of Pyrimidinone (Case 2585).

Site Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate	Maximum Number of Applications	Minimum Retreatment Interval (Days)	Use Limitations
Grasses (Pastures and Rangelands [1])					
Individual mound treatment Ground/hand	0.73% G [241-322] 0.73% G [241-357] 0.88% G [241-260] 0.88% G [241-261] 0.88% G [241-358]	5 tablespoons of product per mound or maximum of 0.0132 lb ai/A	Not Specified	Not Specified	Distribute bait uniformly around the base of the mound without disturbing the ants. Apply when ants are active (normally when temperature is warmer than 60 F). Re-entry is prohibited for 12 hours. Unspecified preharvest, pregrazing, and retreatment intervals.
Broadcast Ground/aerial	0.73% G [241-322] 0.73% G [241-357] 0.88% G [241-260] 0.88% G [241-261] 0.88% G [241-358]	0.019 lb ai/A	Not Specified	Not Specified	Broadcast bait uniformly. Re-entry is prohibited for 12 hours. Unspecified preharvest, pregrazing, and retreatment intervals.

[1] Only grasses grown in pastures are being supported for reregistration. The registrant is not supporting pyrimidinone use on grasses grown in rangelands.

GLN 860.1300: Nature of the Residue - Plants

The reregistration requirements for plant metabolism are fulfilled. An acceptable study depicting the qualitative nature of the residue in grasses has been submitted and evaluated. The HED Metabolism Committee has determined that pyrimidinone is the terminal residue to be regulated in/on plants. The current tolerance expression for grasses is adequate and no changes are needed.

GLN 860.1300: Nature of the Residue - Animals

The reregistration requirements for animal metabolism are fulfilled. An acceptable ruminant metabolism study has been submitted and evaluated. The terminal residue to be regulated in the milk, meat, and meat byproducts of ruminants is pyrimidinone *per se*. The HED Metabolism Committed has determined that there is no reasonable expectation of finite pyrimidinone residues of concern in the milk, meat, and meat byproducts of ruminants [40 CFR §180.6(a)(3)] as a result of pyrimidinone use on pasture grasses; therefore tolerances for these animal commodities need not be established. A poultry metabolism study is not required at this time because there are no poultry feed items associated with grasses.

GLN 860.1340: Residue Analytical Method

The reregistration requirements for residue analytical methods are fulfilled. Adequate methodology is available for the enforcement of tolerances for residues of pyrimidinone *per se* in/on plant commodities. Because no tolerances are needed for animal commodities at this time, no analytical methodology is required for the determination of pyrimidinone residues to be regulated in animal commodities.

The Pesticide Analytical Manual (PAM) Vol. II lists a gas liquid chromatography method with electron capture detection (GLC/ECD) for the analysis of pyrimidinone residues in/on grass commodities (Pesticide Reg. Sec 180.395). The PAM Vol. II method, designated as Method I, has a detection limit of 0.05 ppm. CBRS has forwarded to FDA a confirmatory HPLC method (American Cyanamid Method M2334) for inclusion in PAM Vol. II as a lettered method. Method M2334 determines residues of pyrimidinone *per se* in/on grass commodities and has a detection limit of 0.05 ppm. It has undergone successful independent laboratory validation in accordance with PR Notice 96-1 dated 2/7/96.

GLN 860.1360: Multiresidue Method

The FDA PESTDATA database dated 1/94 (PAM Volume I, Appendix I) indicates that recovery of pyrimidinone using multiresidue methods is unlikely. The entry for pyrimidinone in the PESTDATA database is marked with an asterisk (*) which indicates that the chemicals has multiple GLC peaks. No additional multiresidue method data are required for the purposes of reregistration.

GLN 860.1380: Storage Stability Data

The reregistration requirements for storage stability data are fulfilled. The available storage stability data indicate that fortified residues of pyrimidinone *per se* are stable in/on pasture grass forage and hay for up to 24 months of frozen storage. Field trial samples of grass forage and hay were stored frozen for up to 19 months.

GLN 860.1500: Crop Field Trials

The reregistration requirements for magnitude of the residue in/on pasture grass forage and hay will be considered fulfilled pending compliance by the registrant with the recommended label amendments (see "Directions for Use" section) and tolerance revisions/proposals (see "Tolerance Reassessment Summary" section). Adequate pasture grass field trial data have been submitted and evaluated. These data indicate that residues of pyrimidinone *per se* will exceed the established tolerance following applications of a representative granular formulation according to the parameters of use patterns which the registrant wishes to support.

Should the registrant wish to add rangeland as a site to pyrimidinone EP labels in the future, additional field trial data on rangeland grass forage and hay will be required. The required field trials for rangeland grass commodities should be conducted in CA, CO/KS, ID/OR/WA, IL, and NE, and should reflect a 0-day PHI following applications of a representative granular formulation according to the maximum use patterns recommended for pastures. The current Agency policy is to set tolerances for grass forage and hay grown in rangelands at the residue level obtained on the day of application (0-day PHI). However, the Agency allows reasonable pregrazing/preharvest intervals for grass forage and hay grown in pastures because pastures are fenced, and thus livestock can be prevented from grazing.

GLN 860.1520: Processed Food/Feed

According to Table 1 (Raw Agricultural and Processed Commodities and Feedstuffs Derived From Crops) of OPPTS GLN 860.1000, there are no processed commodities associated with grasses. Therefore, no pyrimidinone processing data are required for reregistration.

GLN 860.1480: Meat, Milk, Poultry, and Eggs

The reregistration requirements for data on magnitude of the residue in animals are fulfilled. An acceptable cattle feeding study is available. However, the HED Metabolism Committed has determined that there is no reasonable expectation of finite pyrimidinone residues of concern in milk, meat, and meat byproducts of ruminants [40 CFR §180.6(a)(3)]; therefore tolerances for these animal commodities need not be established.

A poultry feeding study is not required at this time because there are no poultry feed items associated with grasses.

GLN 860.1400: Water, Fish, and Irrigated Crops

Pyrimidinone is presently not registered for direct use on potable water and aquatic food and feed crops; therefore, no residue chemistry data are required under these guideline topics.

GLN 860.1460: Food-Handling

CBRS has determined that the registered crack and crevice treatment of pyrimidinone for the control of cockroaches on food-handling establishments is a non-food use. Therefore, data depicting magnitude of the residue in food-handling establishments are not required for reregistration purposes. Pyrimidinone is non-volatile and is used only in enclosed bait stations; the likelihood of residue transfer to food is low.

GLNs 860.1850 and 1900: Confined/Field Accumulation in Rotational Crops

Grasses grown in pastures are typically not rotated. Therefore, no residue chemistry data are required under these guideline topics.

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

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [1]
860.1200: Directions for Use	N/A = Not Applicable	Yes [2]	See Tables A-1 and A-2
860.1300: Nature of the residue - Plant	N/A	No	*00032042*, *00035284*, *00071015*, 42310101 [3], 43744501 [4]
860.1300: Nature of the residue - Animal	N/A	No	**00032042**, 42871102 [5], **92163031**, **92163039**
860.1340: Residue Analytical Methods			
- Plant commodities	N/A	No	**00034020**, **00034024**, **00034025**, 43345203 [6], 43485201 [7], 43632801 [8], **92163032, 92163033, 92163034, 92163045, 92163046, 92163047**
- Animal commodities	N/A	No	**00034024, 00034025,** *00061804*, *00061805*, **92163033, 92163034, 92163046, 92163047**
860.1360: Multiresidue Methods	N/A	No	
860.1380: Storage Stability data	N/A	No	42066301 [9], 42871102 [5], 43485201 [7], 43636702 [10], 43744501 [4]
860.1500: Crop Field Trials			
<u>Grass Forage, Fodder, and Hay Group</u>			
- Grasses (pastures and rangelands)	0.05, grass (pasture and rangeland) 0.05, grass hay (pasture and rangeland) [§180.395]	No [11]	**00061797**, **00061798**, 43485201 [7], **92163036**, **92163049**

(continued; footnotes follow)

Table B *(continued)*.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [1]
860.1520: Processed Food/Feed	None	No	
860.1480: Meat, Milk, Poultry, and Eggs			
- Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep	None	No	**00071010**, 42066301 [9], **92163035**, **92163048**
- Eggs and the Fat, Meat, and Meat Byproducts of Poultry	None	No	
860.1400: Water, Fish, Irrigated Crops	None	No	
860.1460: Food-Handling	None	No	
860.1850: Confined Accumulation in Rotational Crops	None	No	
860.1900: Field Accumulation in Rotational Crops	None	No	

1. **Bolded** references were reviewed in the Pyrimidinone Phase 4 Review, 1/8/91, C. Olinger. *Italicized* references were reviewed in the List B Inventory of Pyrimidinone Residue Chemistry Data, 6/29/90. All other references were reviewed as noted.

2. The following label revisions are required: (i) delete rangeland as a site; (ii) amend the use pattern to that for which adequate data are available for pasture grasses [i.e., maximum rate of 0.019 lb ai/A for broadcast treatment, maximum of three broadcast treatments per year from June to October with retreatment intervals of 48-58 days, preharvest/pregrazing intervals (PHI/PGI) of 3 days for treated grass forage, and a 7-day baling interval for treated grass hay]; (iii) restrict use of pyrimidinone as a fire ant bait on pasture grasses to the following states: AL, AR, LA, FL, MS, NC, OK, SC, TN, TX, and VA, and (iv) restrict against harvesting of food/feed within one year of application on non-bearing nursery stocks.

3. CBRS No. 9937, DP Barcode D178563, 6/25/92, J. Abbotts.

4. CBRS No. 15717, DP Barcode D218345, 1/11/96, D. Hrdy.

5. CBRS No. 12402, DP Barcode D194154, 1/26/94, S. Knizner.

6. CBRS No. 14260, DP Barcode D206858, 3/27/95, D. Hrdy; DP Barcode D224986, 4/16/96, D. Hrdy.

7. CBRS Nos. 15063 and 15440, DP Barcodes D211370 and D214465, 6/7/95, D. Hrdy.

(continued; footnotes follow)

Table B *(continued)*.

9. CBRS No. 8927, DP Barcode D171338, 12/9/91, R. Perfetti.

8. CBRS No. 15570, DP Barcode D215253, 10/10/95, D. Hrdy.

10. CBRS No. 15532, DP Barcode D213237, 10/18/95, D. Hrdy.

11. The reregistration requirements for magnitude of the residue in/on grass forage and hay will be considered fulfilled pending compliance by the registrant in adapting the recommended label amendments and tolerance revisions/proposals.

TOLERANCE REASSESSMENT SUMMARY

Tolerances Listed Under 40 CFR §180.395

The tolerances listed in 40 CFR §180.395 are expressed in terms of pyrimidinone *per se*. The HED Metabolism Committee has concluded that the residue to be regulated in/on grass commodities is pyrimidinone *per se*. The current tolerance expression is appropriate and no changes are needed. A summary of tolerance reassessments, with respect to the reregistration of pyrimidinone uses on pasture grasses, is presented in Table C.

The reassessed tolerances for pasture grass forage and hay are 0.1 ppm. These reassessed tolerance levels are contingent upon compliance by the registrant with the recommended label amendments described under "Directions for Use" section.

Table C. Tolerance Reassessment Summary for Pyrimidinone

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR §180.395:			
Grass (pasture and rangeland)	0.05	0.1	Revoke tolerance for rangeland grass forage since the registrant is not supporting pyrimidinone uses on grasses grown in rangelands. *[Grasses, pasture, forage]*
Grass hay (pasture and rangeland)	0.05	0.1	Revoke tolerance for rangeland grass hay since the registrant is not supporting pyrimidinone uses on grasses grown in rangelands. *[Grasses, pasture, hay]*

Pending Tolerance Petition

American Cyanamid has submitted a petition, PP#2F2609, for the establishment of a tolerance for residues of pyrimidinone *per se* in/on pineapples at 0.05 ppm. This petition has been pending since 1982 and is currently in reject status (CBTS No. 16466, DP Barcode D220797, 4/24/96, S. Willett).

CODEX HARMONIZATION

No Codex MRLs have been established for pyrimidinone; therefore, issues of compatibility between Codex MRLs and U.S. tolerances do not exist.

DIETARY EXPOSURE ASSESSMENT

Dietary risk evaluation was conducted (CBRS No.16843, DP Barcode D222964, 2/15/96, D. Miller) for meat and milk exposure using worse case scenarios assuming total radioactive residues were present entirely as parent and incorporating an uncertainty factor of 1000. The Theoretical Maximum Residue Contribution (TMRC) and %RfD for the U.S. population are 0.008 ug/kg/dy and 2.8%, respectively. The TMRC was also estimated for twenty-two populations subgroups. The results of this worse case scenario DRES analysis were sufficiently low that further DRES runs for residues of pyrimidinone were not performed.

AGENCY MEMORANDA RELEVANT TO REREGISTRATION

CBRS Nos.: 8927
DP Barcodes: D171338
Subject: American Cyanamid Company: Response to the Amdro Phase IV Review: Addendum to a Cow Feeding Study.
From: R. Perfetti
To: K. Davis/L. DeLuise
Dated: 12/9/91
MRID(s): 42066301

CBRS No.: 9937
DP Barcodes: D178563
Subject: Pyrimidinone (Hydramethylnon, Amdro). Reregistration, Response to Phase 4 Review. Nature of the Residue in Range Grass.
From: J. Abbotts
To: K. Davis
Dated: 6/25/92
MRID(s): 42310101

CBRS No.: 11504
DP Barcodes: D188652
Subject: Pyrimidinone (hydramethylnon). List B Reregistration Case No. 2585/Chemical ID No. 118401.
From: C. Swartz
To: K. Davis
Dated: 4/7/93
MRID(s): None

CBRS No.: 12402
DP Barcodes: D194154
Subject: Pyrimidinone (Hydramethylnon). Nature of the Residue in Ruminants. Reregistration Case No. 2585. Chemical No. 118401.
From: S. Knizner
To: K. Depukat
Dated: 1/26/94
MRID(s): 42871102

CBRS No.: 13479
DP Barcodes: D201380
Subject: Pyrimidinone (Hydramethylnon). Addendum to Nature of the Residue in Ruminants - Need for Meat/Milk Tolerances.
From: S. Knizner
To: K. Depukat
Dated: 4/6/94
MRID(s): None

CBRS No.: 14260
DP Barcodes: D206858
Subject: Hydramethylnon (Pyrimidinone). American Cyanamid. Submission of Proposed Analytical Enforcement (HPLC) Method M2334 for Residues in Pasture Grass (Hay and Forage). Case No. 2585, Chemical ID No. 118401.
From: D. Hrdy
To: K. Davis
Dated: 3/27/95
MRID(s): 43345203

CBRS No.: 15063 and 15440
DP Barcodes: D211370 and D214465
Subject: Hydramethylnon (Pyrimidinone). American Cyanamid. Residues in Pasture Grass (Hay and Forage) After Ground Applications of AMDRO* Granular Insecticide.
From: D. Hrdy
To: K. Davis
Dated: 6/7/95
MRID(s): 43485201

CBRS No.: 15570
DP Barcodes: D215252
Subject: Hydramethylnon (Case Name Pyrimidinone). List B Reregistration Case No. 2585. Independent Laboratory Validation of (HPLC) Method M2334 for Residues in Pasture Grass (Hay and Forage). Chemical ID No. 118401.
From: D. Hrdy
To: K. Davis
Dated: 10/10/95
MRID(s): 43632801

CBRS Nos.: 15552
DP Barcodes: D215237
Subject: Hydramethylnon (Pyrimidinone). List B Reregistration Case No. 2585. Freezer Storage Stability Study for Hydramethylnon in Pasture Grass. Chemical ID No. 118401.
From: D. Hrdy
To: K. Davis
Dated: 10/18/95
MRID(s): 43636702

CBRS Nos.: 16309
DP Barcodes: D219933
Subject: Hydramethylnon (Pyrimidinone). List B Reregistration Case No. 2585. American Cyanamid's Response To The Agency's Letter of 6/30/95, Chemical ID No. 118401.
From: D. Hrdy
To: K. Davis
Dated: 11/27/95
MRID(s): None

CBRS Nos.: 15717
DP Barcodes: D218345
Subject: Hydramethylnon (Case Name: Pyrimidinone). American Cyanamid. GDLN 171-4(a) Nature of Hydramethylnon Residue in/on Pasture Grass.
From: D. Hrdy
To: K. Davis/D. Monos
Dated: 1/11/96
MRID(s): 43744501

CBRS Nos.: 16671
DP Barcodes: D221984
Subject: Issue to be Presented to the HED Metabolism Committee.
From: D. Hrdy
To: HED Metabolism Committee
Dated: 1/19/96
MRID(s): None

CBRS Nos.: 16745
DP Barcodes: D222283
Subject: Request for a Dietary Risk Assessment on Livestock to Resolve Issues from the 1/25/95 Metabolism Committee Meeting.
From: D. Hrdy
To: E. Zager and D. Miller
Dated: 1/31/96
MRID(s): None

CBRS Nos.: 16843
DP Barcodes: D222964
Subject: Hydramethylnon (118401). Dietary Exposure Analysis for Ruminant Commodities.
From: D. Miller
To: D. Hrdy
Dated: 2/15/96
MRID(s): None

CBRS No.: 16672
DP Barcodes: D221981
Subject: Hydramethylnon (Case Name: Pyrimidinone). Metabolism Committee Meeting on 01/25/96 Decision Document.
From: D. Hrdy
To: Files and HED Committee
Dated: 2/22/96
MRID(s): None

CB No.: 16466
DP Barcodes: D220797
Subject: PP No. 2F2609. AMDRO® (a.i. Hydramethylnon; Pyrimidinone) in/on Pineapple. Review of Petitioner's 10/27/95 Correspondence Concerning Status of Residue Chemistry Studies.
From: S. Willett
To: G. LaRocca/S. Moats
Dated: 4/24/96
MRID(s): None

CBTS No.: 17492
DP Barcodes: D226807
Subject: ID# 64248-5. Hydramethylnon (MAXFORCE Roach Killer Bait Gel) in Food Handling Establishments.
From: R. Loranger
To: D. Davis
Dated: 8/28/96
MRID(s): None

MASTER RECORD IDENTIFICATION NUMBERS

References Used To Support Reregistration

00032042 Lee, A.; Ammon, P.J.; Blagdan, B.B.; et al. (1979) A Study of the Excretion and Disposition of Carbon-14 Labelled CL 217,300 in Goat Tissues: Project No. 0-420. (Unpublished study received Jun 11, 1980 under 241-260; submitted by American Cyanamid Co., Princeton, N.J.; CDL:099455-B)

00034020 Tondreau, R.E. (1979) CL 217,300: Validation of GC Method M-1000 for the Determination of CL 217,300 Residues in Pasture Grass: Report No. C-1597. Includes method M-1000 dated Aug 24, 1979. (Unpublished study received Jun 11, 1980 under 241-260; submitted by American Cyanamid Co., Princeton, N.J.; CDL:099454-A)

00034024 Manuel, A.J. (1979) CL 217,300: Validation of GC Method M-1033 for the Determination of CL 217,300 Residues in Cattle Liver, Kidney, Fat and Muscle: Report No. C-1649. Includes method M-1033 dated Dec 18, 1979. (Unpublished study received Jun 11, 1980 under 241-260; submitted by American Cyanamid Co., Princeton, N.J.; CDL:099454-E)

00034025 Tondreau, R.E.; Manuel, A.J. (1980) CL 217,300: Validation of GC or HPLC Method M-1046 for the Determination of CL 217,300 Residues in Milk: Report No. C-1647. Includes method M-1046 dated Feb 4, 1980. (Unpublished study received Jun 11, 1980 under 241-260; submitted by American Cyanamid Co., Princeton, N.J.; CDL: 099454-F)

00035284 Gatterdam, P.E.; Knoll, B.; Pasarela, J. (1979) CL 217,300: Residues of CL 217,300 in Range Grass Grown in Soil Treated with Carbon-14 Labeled Compound at Gainesville, Florida: Project No. 0420. Final rept. (Unpublished study received Jul 1, 1980 under 241-260; submitted by American Cyanamid Co., Princeton, N.J.; CDL:099488-G)

00061797 Tondreau, R.E.; Wang, T.; Muzyk, K.R.; et al. (1979) CL 217,300: Residues of CL 217,300 in Grass (GND; FL, 1979) (C-1597): Report No. C-1598. (Unpublished study received Jul 1, 1980 under 241-260; submitted by American Cyanamid Co., Princeton, N.J.; CDL:099775-B)

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92163048 Garces, T.; Tondreau, R. Wang, T. (1990) American Cyanamid Company Phase 3 Reformat of MRID 00071010. AMDRO Fire Ant Insecticide (CL 217,300): Residues in Bovine Milk and Tissues: Report No. C-1809. Prepared by American Cyanamid Co. 30 p.

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