

them individually to inform them that no Technical Briefing will be held. EPA is willing to meet with stakeholders to discuss the naled and temephos revised risk assessments. Minutes of all meetings will be docketed.

In addition, this notice starts a 60-day public participation period during which the public is encouraged to submit risk management proposals or otherwise comment on risk management for naled and temephos. The Agency is providing an opportunity, through this notice, for interested parties to provide written risk management proposals or ideas to the Agency on the pesticides specified in this notice. Such comments and proposals could address ideas about how to manage dietary, occupational, or ecological risks on specific naled and temephos use sites or crops across the United States or in a particular geographic region of the country. To address dietary risk, for example, commenters may choose to discuss the feasibility of lower application rates, increasing the time interval between application and harvest ("pre-harvest intervals"), modifications in use, or suggest alternative measures to reduce residues contributing to dietary exposure. For occupational risks, for example, commenters may suggest personal protective equipment or technologies to reduce exposure to workers and pesticide handlers. For ecological risks, commentors may suggest ways to reduce environmental exposure, e.g., exposure to birds, fish, mammals, and other non-target organisms. EPA will provide other opportunities for public participation and comment on issues associated with the organophosphate tolerance reassessment program. Failure to participate or comment as part of this opportunity will in no way prejudice or limit a commenter's opportunity to participate fully in later notice and comment processes. All comments and proposals must be received by EPA on or before December 6, 1999, at the addresses given under the "ADDRESSES" section. Comments and proposals will become part of the Agency record for the organophosphate specified in this notice.

List of Subjects

Environmental protection, Chemicals, Pesticides and pests.

Dated: September 30, 1999.

Lois Rossi,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 99-26073 Filed 10-5-99; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[PF-835; FRL-6029-9]

American Cyanamid Company; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by the docket control number PF-835, must be received on or before November 5, 1999.

ADDRESSES: By mail submit written comments to: Information and Records Integrity Branch, Public Information and Services Division (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under "SUPPLEMENTARY INFORMATION." No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Marion M. Johnson, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 208, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305-6701; e-mail:johnson.marion@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition as follows

proposing the establishment and/or amendment of regulations for residues of certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF-835] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in "ADDRESSES" at the beginning of this document.

Electronic comments can be sent directly to EPA at:
opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number (PF-835) and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 28, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the views of the petitioner.

EPA is publishing the petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

American Cyanamid Company

PP 2F2609

EPA has received a pesticide petition (PP 2F2609) from American Cyanamid Company, P. O. Box 400, Princeton, NJ 08543-0400, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of tetrahydro-5,5-dimethyl-2(1H)-pyrimidinone[3-{4-(trifluoromethyl)phenyl}-1-[2-{4-(trifluoromethyl)phenyl}ethenyl]-2-propenylidene]hydrazon, hydramethylnon] in or on the raw agricultural commodity [pineapples] at 0.05 parts per million (ppm). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* Metabolism studies were conducted on grass and pineapples utilizing two distinct ^{14}C -radiolabeled forms of hydramethylnon. Based on these studies, the qualitative nature of the residues of hydramethylnon in plants is understood and the parent molecule is considered to be the only residue of concern.

2. *Analytical method.* Adequate enforcement methodology is available in PAM II (Method I) to enforce the tolerance expression. A confirmatory method has recently been submitted to the FDA for inclusion in PAM II.

3. *Magnitude of residue.* Based on the results of seven pineapple field trials, including two studies conducted at 5x the maximum application rate, residues of hydramethylnon are not expected to exceed 0.05 ppm in/on pineapples. Processing studies have demonstrated that residues are not expected to concentrate in pineapple processed commodities. The Agency has previously established a time-limited tolerance at this level to cover residues that may occur as a result of use under section 18 emergency authorizations

issued to the State of Hawaii. Secondary residues of hydramethylnon are not expected in animal commodities and no tolerances for secondary residues of hydramethylnon in livestock commodities are currently established.

B. Toxicological Profile

1. *Acute toxicity.* Based on the results of the acute toxicity data, hydramethylnon does not exhibit significant acute toxicity. For the acute oral study in rats, the LD_{50} in males was 817 milligram/kilogram (mg/kg) and the LD_{50} in females was 1,502 mg/kg. The LD_{50} for the acute dermal study in rabbits was greater than 2,000 mg/kg and the 4-hour LC_{50} for acute inhalation in rats was 2.9 mg/l (males and females combined). Hydramethylnon is not a dermal irritant or a skin sensitizer and is a mild eye irritant.

2. *Genotoxicity.* The following genotoxicity tests were all negative: *Salmonella typhimurium*/*Escherichia coli* reverse gene mutation assay, *Schizosaccharomyces pombe* P1 forward gene mutation assay, *in vitro* Chinese Hamster Ovary (CHO) chromosome aberration, *Saccharomyces cerevisiae* D4 mitotic gene conversion assay. The data suggest that hydramethylnon is not genotoxic in microbial test systems or clastogenic in cultured mammalian cells and does not induce dominant lethality in male rat germinal cells. The evidence of male infertility and testicular atrophy at 90 milligram/kilogram/day (mg/kg/day) in the dominant lethal assay is consistent with similar findings observed in the chronic rat study, the 18-month mouse feeding study, the 2-generation reproduction study, and the 91 day oral gavage study in dogs.

3. *Reproductive and developmental toxicity.* There is no evidence in the prenatal developmental toxicity studies in either rats or rabbits of alterations to CNS development, nor is there any indication of neurotoxicity in the other short or long-term oral studies in rats, mice or dogs. No evidence of the increased sensitivity of the developing offspring was noted as the No Observed Effect Levels (NOELs) for developmental toxicity in the rat (10 milligram/kilogram/body weight/day (mg/kg/bwt/day) and the rabbit (5 mg/kg/bwt/day) were greater than the NOELs for maternal toxicity (3 mg/kg/bwt/day for the rat and < 5 (mg/kg/bwt/day for the rabbit). Hydramethylnon is not teratogenic in either the rat or rabbit. Hydramethylnon is a male reproductive toxicant which appears to specifically target the germinal cells and/or tissues in the testes. In a 2-generation rat reproduction study, there was no

evidence of systemic toxicity, nor was there any evidence of direct toxicity in the offspring. The reproductive NOEL was 25 ppm (1.66 mg/kg/day for males) and the Lowest Observed Adverse Effect Level (LOAEL) was 50 ppm (3.32 mg/kg/day for males), based upon histopathological findings in the testes and the epididymides. Also at 75 ppm (5.05 mg/kg/day in males), reproductive performance of the males was decreased with longer precoital intervals, lower pregnancy rates, reduced gestation weight gain for females and smaller litters.

4. *Subchronic toxicity.* The following are the results of the subchronic toxicity tests that have been conducted with hydramethylnon: 91 day feeding study in rats (NOEL 2.5 mg/kg/bwt/day); 91 day gavage study in dogs (NOEL < 3 mg/kg/bwt/day); 21 day dermal study in rabbits (NOEL 250 mg/kg/bwt/day). For both the short- and intermediate-term Margin of Exposure (MOE) calculations, the Agency's Hazard Identification Committee recommended use of the Systemic NOEL (freestanding) of 250 mg/kg/day from the 21 day dermal toxicity study in New Zealand white rabbits. Non-adverse signs at the NOEL included decreased food consumption in males and females, and thrombocytopenia in females.

5. *Chronic toxicity.* The EPA has established the Reference Dose (RfD) for hydramethylnon at 0.01 mg/kg/day. This RfD is based on a 6-month feeding study in dogs with a NOEL of 1.0 mg/kg/day based on an increased incidence of soft stools, mucoid stools, and diarrhea at the LOAEL of 3.0 mg/kg/day. An uncertainty factor of 100 was used during calculation of the RfD. Based on a statistically significant increase in lung adenomas and combined lung adenomas/carcinomas in female mice, hydramethylnon has been classified as a Group C chemical (possible human carcinogen) by the Agency's Cancer Peer Review Committee. The Committee recommended using the RfD approach for risk assessment.

6. *Animal metabolism.* Adequate rat and goat metabolism studies are available for hydramethylnon. Results of ruminant metabolism and feeding studies clearly demonstrate that there is no reasonable expectation that residues of hydramethylnon in pineapple processed commodities will be transferred to milk or edible tissues. Hence, no tolerances on any food items derived from ruminants are required for hydramethylnon.

7. *Metabolite toxicology.* The parent molecule is the only moiety of toxicological significance which needs regulation in plant commodities.

8. *Endocrine disruption.* EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inert) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect." The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At the present time, no reliable information is available to indicate that hydramethylnon has a potential to have an effect in humans that is similar to effects produced by naturally occurring estrogen or other endocrine substances.

C. Aggregate Exposure

1. *Dietary exposure.* A 0.05 ppm tolerance for the residues of hydramethylnon has only been established for grasses and as there is no reasonable expectation that residues in grass will be transferred to the milk and edible tissues of ruminants, no tolerances for hydramethylnon have been established on any food items. Thus, there is no contribution to the aggregate exposure of hydramethylnon residues from dietary sources. Therefore, the following risk assessment to assess dietary exposures and risks from hydramethylnon will be based on dietary exposures resulting from only the pending tolerance in/on pineapples.

2. *Acute exposure and risk—i. Food.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. The acute dietary (food only) risk assessment is not required as the Agency's Hazard Identification

Committee did not identify any acute dietary risk endpoints.

ii. *Chronic exposure and risk.* In response to EPA's granting of an emergency exemption under FIFRA section 18 authorizing the use of hydramethylnon in pineapples in Hawaii, a time-limited tolerance of 0.05 ppm was established in/on pineapple fruits. The Agency has conducted a chronic dietary risk assessment based on very conservative assumptions -- 100% of pineapple commodities will contain hydramethylnon residues and those residues will be at the level of the required tolerance -- which results in an overestimate of human dietary exposure. Thus, in making a safety determination for this time-limited tolerance, HED has taken into account this conservative exposure assessment. Based on similar considerations, the pending hydramethylnon tolerance in/on pineapples results in a TMRC that is equivalent to the following percentages of the RfD of 0.01 mg/kg/day:

| Population Subgroup | % RfD |
|---|-------|
| U.S. Population | <0.1% |
| Nursing Infants | <0.1% |
| Non-Nursing Infants (<1-year old) | 0.2% |
| Children (1-6 years old) | 0.1% |
| Children (7-12 years old) | <0.1% |

The subgroups listed above are: (1) the U.S. population (48 States); (2) those for infants and children; and, (3) the other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 States).

3. *Drinking water.* Based on its physical and chemical properties, (extremely low water solubility of 7-9 ppb at 25 °C and rapid aqueous photolysis with a 1/2 of less than 1 hour), there is no concern for exposure to residues of hydramethylnon in potable water. Hydramethylnon is also immobile in soil and does not leach because it is strongly adsorbed to all common soil types; thus hydramethylnon and its degradates are not expected to leach to groundwater. There are no established Maximum Contaminant Levels (MCLs) for residues of hydramethylnon in drinking water and no health advisory levels for this active ingredient in drinking water have been issued. Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding

figure for the potential contribution of water-related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for exposure from contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause hydramethylnon to exceed the RfD if the tolerance being considered in this document were granted. The potential exposures associated with hydramethylnon in water, even at the higher levels the Agency is considering as a conservative upper bound, would be negligible and there is a reasonable certainty of no harm if the pending tolerance is granted.

4. *Non-dietary exposure.* Hydramethylnon is currently registered

for use on the following residential non-food sites: recreational areas, ornamental plants, lawns, turf, and household or domestic dwellings. However as the vapor pressure of hydramethylnon is less than 2×10^{-8} mm of Hg at 35 and 45 °C, the potential for non-occupational exposure by inhalation is insignificant. Moreover, based on the current and proposed use patterns, chronic exposure is not likely. Although there may be short- and intermediate-term non-occupational dermal exposure scenarios, dermal absorption studies conducted with the 2% gel formulation indicate that less than 1% of the dose is dermally absorbed after 10-hours. In addition, the Agency has reviewed risk assessments and accepted the existence of more than adequate margins of exposure ((MOE) of 658 for both commercial and homeowner applicators and MOEs of >540 for post-application homeowner exposures) for other hydramethylnon-based products, containing up to 2% active ingredient. Thus, this new use pattern does not present any incremental risk of exposure to hydramethylnon residues.

D. Cumulative Effects

To the best of our knowledge, hydramethylnon is the only registered pesticide which belongs to a unique chemical class, the pyrimidinones (amidinohydrazones). Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, hydramethylnon does not appear to produce a toxic metabolite produced by other substances. Therefore, the potential for cumulative effects of hydramethylnon and other chemicals having a common mechanism of toxicity should not be of concern and for the purposes of this tolerance action, it is assumed that hydramethylnon does not have a common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population—i. Acute risk.* An acute endpoint has not been identified. The Agency's Hazard Identification Committee determined that this risk assessment is not required.

ii. *Chronic risk.* Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to hydramethylnon from food will utilize <1% of the RfD of 0.01 mg/kg/day for the U.S. population. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. In view of the negligible potential for exposure to hydramethylnon in drinking water and from non-dietary, non-occupational exposure, the aggregate exposure is not expected to exceed 100% of the RfD. EPA has concluded that there is a reasonable certainty that no harm will result from aggregate exposure to hydramethylnon residues. According to Agency policy, the residential uses of hydramethylnon do not fall under a chronic exposure scenario. Thus, it can be concluded that there is a reasonable certainty that no harm will result from chronic aggregate exposure to hydramethylnon residues.

iii. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. Although hydramethylnon has residential uses, this new use pattern does not present any incremental risk of exposure to hydramethylnon residues. As discussed previously in section C. 4., the vapor pressure of hydramethylnon is less than

2×10^{-8} mm of Hg at 35 and 45 °C; thus, the potential for non-occupational exposure by inhalation is insignificant. Moreover, based on the physical and chemical properties of hydramethylnon, exposure from drinking water is not likely. Although there may be short- and intermediate-term occupational and non-occupational dermal exposures, the Agency has reviewed risk assessments and accepted the existence of more than adequate margins of exposure (MOE of 658 for both commercial and homeowner applicators and MOEs of >540 for post-application homeowner exposures) for other hydramethylnon-based products, containing up to 2% active ingredient. Thus, as in the case for chronic exposure scenarios, it can be concluded that there is a reasonable certainty that no harm will result from short and intermediate-term exposures to hydramethylnon residues.

2. *Infants and children—i. Chronic risk.* Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to hydramethylnon from food will utilize only 0.2% of the RfD of 0.01 mg/kg/day for non-nursing infants <1-year old.

ii. *Safety factor for infants and children—In general.* In assessing the potential for additional sensitivity of infants and children to residues of hydramethylnon, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. EPA has concluded that the toxicological database for hydramethylnon is adequate and does not indicate an increased sensitivity of perinatal animals to pre- and/or post natal exposures. Therefore, no additional uncertainty factor for protection of infants and children are warranted for hydramethylnon.

iii. *Developmental toxicity studies.* In the rat developmental toxicity study, the developmental NOEL was 10 mg/kg b.w./day with a NOEL for maternal toxicity of 3.0 mg/kg/bwt/day. In the rabbit developmental toxicity study the developmental NOEL was 5 mg/kg/bwt/day with a NOEL for maternal toxicity of less than 5 mg/kg/bwt/day.

iv. *Reproductive toxicity study.* A 2-generation reproduction study with hydramethylnon was conducted in rats. The data support a NOEL for reproductive toxicity of 50 ppm (4.2 mg/kg/bwt/day), while the NOEL for paternal toxicity was 25 ppm (2.1 mg/kg/bwt/day). No adverse effects were observed in the pups.

These values are significantly higher than the NOEL used to calculate the RfD for the general U.S. population which is 0.01 mg/kg/bwt/day. These results

demonstrate that there is a reasonable certainty that no harm will result to infants or children from aggregate exposure to hydramethylnon.

F. International Tolerances

There are no Codex, Canadian or Mexican residue limits established for hydramethylnon in/on pineapple. Thus, harmonization is not an issue for this petition.

[FR Doc. 99-26079 Filed 10-5-98; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[OPP-30477A; FRL-6380-2]

Pesticide Product; Registration Approval

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces Agency approval of an application to register the pesticide product MNDA M-9011 containing an active ingredient not included in any previously registered product pursuant to the provisions of section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

FOR FURTHER INFORMATION CONTACT: By mail: Richard J. Gebken, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: 2nd fl. Rm. 201, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703)-305-6701; and e-mail address: gebken.richard@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

| Categories | NAICS | Examples of Potentially Affected Entities |
|------------|----------------------------|---|
| Industry | 111 112 311 32532 | Crop production Animal production Food manufacturing Pesticide manufacturing |

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be