*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 $2 \times 10^{-8}$ 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 | Crop production |
| | 112 | Animal production |
| | 311 | Food manufacturing |
| | 32532 | Pesticide manufacturing |

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

affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the ''FOR FURTHER INFORMATION CONTACT.''

*B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?*

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the '' **Federal Register—** Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

To access a fact sheet which provides more detail on this registration, go to the Office of Pesticide Programs home page at http://www.epa.gov/pesticides/, and select ''factsheet.''

2. *In person*. The Agency has established an official record for this action under docket control number OPP–30477A. The official record consist of the document specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

In accordance with section 3(c)(2) of FIFRA, a copy of the approved label, the list of data references, the data and other scientific information used to support registration, except for material specifically protected by section 10 of FIFRA, are also available for public inspection. Requests for data must be made in accordance with the provisions of the Freedom of Information Act and must be addressed to the Freedom of Information Office (A-101), 401 M St., SW., Washington, DC 20460. The request should: Identify the product name and registration number and specify the data or information desired.

A paper copy of the fact sheet which provides more detail on this registration may be obtained from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

## II. Did EPA Approve the Application?

The Agency approved the application after considering all required data on risks associated with the proposed use of *N*-methylneodecanamide (MNDA), and information on social, economic, and environmental benefits to be derived from use. Specifically, the Agency has considered the nature of the chemical and its pattern of use, application methods and rates, and level and extent of potential exposure. Based on these reviews, the Agency was able to make basic health and safety determinations which show that use of *N*-methylneodecanamide (MNDA) when used in accordance with widespread and commonly recognized practice, will not generally cause unreasonable adverse effects to human health or to the environment.

## III. Approved Application

EPA issued a notice, published in the **Federal Register** of May 3, 1999, (64 FR 23617)(FRL–6076–7), which announced that Colgate-Palmolive Company, P.O. Box 1343, 909 River Road, Piscataway, NJ 08855-1343, had submitted an application to register a manufacturing use product MNDA M-9011 Technical, an insecticide (EPA File Symbol 4822–TR containing *N*-Methylneodecanamide (MNDA) at 96.3%, an active ingredient not included in any previously registered product.

The application was approved on July 8, 1999, as MNDA M-9011, as a manufacturing use product to formulate multipurpose cleaner/insect repellent products (EPA registration number 4582–71).

## List of Subjects

Environmental protection, Pesticides and pests.

Dated: September 22, 1999.

**James Jones,**

*Director, Registration Division, Office of Pesticide Programs.*

[FR Doc. 99–25575 Filed 10–5–99; 8:45 am]

BILLING CODE 6560–50–F

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## ENVIRONMENTAL PROTECTION AGENCY

**[PF–667A; FRL–6383–5]**

## Gentamicin Sulfate; Withdrawal of Tolerance Petition

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Agency is withdrawing pesticide petition (PP 5F4449) because the petitioner, Quimica, c/o Technology Sciences, Inc., 1101 17th St., NW., Suite 500, Washington, DC 20036, has withdrawn its pesticide registration applications and tolerance petition without prejudice to future filing for registration of the products containing gentamicin sulfate.

**FOR FURTHER INFORMATION CONTACT:** Mary L. Waller, Product Manager 21, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, telephone number (703) 308-9354, e-mail address: waller.mary@epa.gov.

**SUPPLEMENTARY INFORMATION:**

## I. Does This Action Apply to Me?

Although this action only applies to the registrant in question, it is directed to the public in general. Since various individuals or entities may be interested, the Agency has not attempted to describe all the specific entities that may be interested in this action. If you have any questions regarding this action, please consult the person listed in the ''FOR FURTHER INFORMATION CONTACT'' section.

## II. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically*. You may obtain copies of this document and certain other available support documents from the EPA Internet Home Page at http://www.epa.gov/. On the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**- Environmental Documents.''

2. *In person*. The Agency has established an official record for this