

ADI of 0.5 mg/kg. Based on this material's low-risk profile, there is reasonable certainty that no harm to the U. S. population will result from aggregate exposure to ethyl methylphenylglycidate.

2. *Infants and children.* FFDCA section 408 provides that EPA shall apply a ten-fold MOE for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA's risk assessment either directly through the MOE analysis or through using uncertainty (safety) factors in calculating a dose level that pose no appreciable risk to humans.

Due to the extensive available toxicological data base including chronic toxicity studies and the expected low toxicity of this compound, Firmenich Incorporated does not believe a safety factor analysis is necessary in assessing the risk of these compounds. For the same reasons, Firmenich believes the additional safety factor is unnecessary.

#### F. International Tolerances

There are no known international tolerances for ethyl methylphenylglycidate

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BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

[PF-987; FRL-6760-6]

### Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

**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 docket control number PF-987, must be received on or before January 19, 2001.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the

**SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative

that you identify docket control number PF-987 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Indira Gairola, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-6379; e-mail address: gairola.indira@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 codes	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 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 under **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," "Regulations and Proposed Rules," 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/>.

2. *In person.* The Agency has established an official record for this action under docket control number PF-987. The official record consists of the documents 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 Highway, 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.

###### C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-987 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: [opp-docket@epa.gov](mailto:opp-docket@epa.gov), or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file

format. All comments in electronic form must be identified by docket control number PF-987. Electronic comments may also be filed online at many Federal Depository Libraries.

#### *D. How Should I Handle CBI That I Want to Submit to the Agency?*

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI.

Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

#### *E. What Should I Consider as I Prepare My Comments for EPA?*

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

## **II. What Action is the Agency Taking?**

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a 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 support granting of the petition. Additional data may be needed before EPA rules on the petition.

### **List of Subjects**

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

Dated: December 8, 2000.

**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 view of the petitioner. EPA is publishing the petition summary verbatim without editing it 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.

### **Miller Chemical and Fertilizer Corporation**

*PP 1E6239*

EPA has received a pesticide petition (1E6239) from Miller Chemical and Fertilizer Corporation, P.O. Box 333, Radio Road, Hanover, PA 17331 proposing, pursuant to section 408(d) of the (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR 180.1001(c) and (e), to establish an exemption from the requirement of a tolerance for polybutylene as an inert ingredient in or on growing crops or when applied to the raw agricultural commodity (RAC) after harvest or when applied to animals. 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 support granting of the petition. Additional data may be needed before EPA rules on the petition.

### *A. Toxicological Profile*

As part of the EPA policy statement on inert ingredients published in the **Federal Register** (52 FR 13305, April 22, 1987), the Agency set forth a list of studies which would generally be used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. However, where it can be determined without the data that the inert ingredient will present minimal or no risk, the Agency generally does not require some or all of the listed studies to rule on the proposed tolerance or exemption from the requirement of a tolerance for an inert ingredient. Miller Chemical and Fertilizer Corporation believes that the data and the information described below are adequate to ascertain the toxicology and characterize the risk associated with the use of polybutylene (CAS Reg. No.9003-29-6) as an inert ingredient in pesticide formulations applied to growing crops, RACs after harvest, and to animals.

In the case of certain chemical substances that are defined as "polymers" EPA has established a set of criteria which identify categories of polymers that present low risk. These criteria (codified in 40 CFR 723.250) identify polymers that are relatively unreactive and stable compared to other chemical substances as well as polymers that are not readily absorbed. These properties generally limit a polymer's ability to cause adverse effects. In addition, these criteria exclude polymers about which little is known. EPA believes that polymers meeting the criteria noted below will present minimal or no risk.

Polybutylene conforms to the definition of a polymer given in 40 CFR 723.250(b) and meets the following criteria that are used to identify low risk polymers.

1. Polybutylene is not a cationic polymer, nor is it reasonably anticipated to become a cationic polymer in a natural aquatic environment.

2. Polybutylene contains as an integral part of its composition the atomic elements carbon and hydrogen.

3. Polybutylene does not contain as an integral part of its composition any elements other those listed in 40 CFR 723.250(d)(2)(ii).

4. Polybutylene is not designed, nor is it reasonably anticipated to substantially degrade, decompose, or depolymerize.

5. Polybutylene is not manufactured or imported from monomers and/or other reactants that are not already included on the Toxic Substances Control Act (TSCA) Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

6. Polybutylene is not a water absorbing polymer.

7. Polybutylene does not contain any group as reactive functional groups.

8. The minimum number-average molecular weight of polybutylene is listed as 1,330 daltons. Substances with molecular weights greater than 400 generally are not absorbed through the intact skin, and substances with molecular weights greater than 1,000 generally are not absorbed through the intact gastrointestinal (GI) tract. Chemicals not absorbed through the skin or GI tract generally are incapable of eliciting a toxic response.

9. Polybutylene has a number-average molecular weight of 1,330 and contains less than 10% oligomeric material below molecular weight of 500 and less than 25% oligomeric material below 1,000 molecular weight.

In addition, polybutylene is approved by the Food and Drug Administration (FDA) under 21 CFR for following food contact applications:

a. Polybutylene is cleared for use in contact with food under 21 CFR 177.1430. The specifications set forth in this regulation for isobutylene-butene copolymers include molecular weight range (150–5,000), viscosity range and maximum bromine values.

b. Polybutylene is approved under 21 CFR 175.125 for use as a component of release coatings on backings or linings for pressure sensitive adhesive labels for food contact applications.

c. Polybutylene is approved under 21 CFR 175.300 for use as a component of resinous and polymeric coatings for food contact surfaces.

d. Polybutylene is approved under 21 CFR 176.170 for use as a component of paper and paperboard in contact with aqueous and fatty foods.

e. Polybutylene is approved under 21 CFR 176.180 for use as a component of paper and paperboard in contact with dry foods.

f. Polybutylene is approved under 21 CFR 176.210 for use as a defoaming agent in the manufacture of paper and paperboard that come in contact with food.

g. Polybutylene is approved under 21 CFR 177.1520 for use as a plasticizer in polyethylene used in the manufacture of articles for food contact applications.

h. Polybutylene is approved under 21 CFR 177.1640 for use as a plasticizer in polystyrene used in the manufacture of articles for food contact applications.

i. Polybutylene is approved under 21 CFR 177.2800 for use as a component of textiles and textile fibers used in the manufacture of articles for food contact applications.

j. Polybutylene is approved for use in lubricants with incidental food contact under 21 CFR 178.3570.

k. Polybutylene is approved under 21 CFR 178.3710 for use as a component of articles that come in contact with food.

l. Polybutylene is approved under 21 CFR 178.3740 for use as a component of articles that come in contact with food.

The above regulations are applicable to polybutylenes manufactured from *stisobutylene* and *n-butene* as monomers (complying with 21 CFR 177.1430). The Food and Drug Administration (FDA) has also approved polybutylene for other food contact applications under 21 CFR 175.105, 21 CFR 177.1420, 177.1520, 177.2260, and 178.3910. In other words, the FDA has determined that polybutylenes are safe to use in articles that come in contact with food.

Polybutylene is widely used as a cosmetic ingredient in personal care products. The Cosmetic Toiletry and Fragrance Association (CTFA) evaluated the safety of polybutene for use in personal care products and found that it is safe to use in cosmetic products.

Polybutylene (CAS Reg. No.9003–29–6) and all components of polybutylene are listed on the TSCA Chemical Substances Inventory.

Polybutenes are exempt from the requirement of a tolerance under 40 CFR 180.1037 for residues in or on the RAC:

a. Cottonseed when used as a sticker agent for formulations of the attractant gossypure [1:1 mixture of (Z,Z)— and (Z,E)—7,11-hexadecadien-1-ol acetate] to disrupt the mating of the pink bollworm.

b. Artichokes when used as a sticker agent in multi-layered laminated controlled-release dispensers of (Z)—11-hexadecenal to disrupt the mating of the artichoke plume moth.

#### *B. Aggregate Exposure:*

Polybutylene and its formulations have been in commerce for more than 30 years. The copolymer is ubiquitous in our every day environment and it is commonly used in cosmetic formulations (concentrations ranging from 1 to >50%), adhesives, caulks, sealants, glazing compounds, coatings, lubricants, stretch wrap film, and electrical cable insulation.

Although exposure to polybutylene may occur through dietary (e.g., adhesives, lubricants, and food wrappings), and non-occupational (e.g., electrical cable insulation) sources, the chemical characteristics of polybutylene lead to the conclusion that there is a reasonable certainty of no harm from aggregate exposure to this polymer.

The Agency has maintained that polymers meeting the polymer exemption criteria (as described previously for polybutylene) will present minimal risk to human health when used as inert ingredients in pesticide products applied to food crops. EPA has also established exemptions from tolerance for polymeric materials used as pesticide inert ingredients that it considers to be intrinsically safe based on the fact that they are listed on the TSCA Inventory or meet the requirements of the amended TSCA polymer exemption and are thereby not subject to the requirements of the pre-manufacturing notification.

Given the existing widespread and historic use of polybutylene, any additional exposure resulting from the approval of polybutylene as an inert ingredient in pesticide formulations for use on growing crops or to RACs after harvest is not warranted.

#### *C. Cumulative Effects*

At this time there is no information to indicate that any toxic effects produced by polybutylene having a number average molecular weight of 1,330 would be cumulative with those of any other chemical substance(s). Given the categorization of polybutylene as a “low risk polymer” (40 CFR 723.250) and its proposed use as an inert ingredient in pesticide formulations, there is no reasonable expectation of increased risk due to cumulative exposure.

#### *D. Safety Determination*

1. *U.S. population.* As a matter of policy, EPA has in the past established exemptions from tolerance for polymeric substances used as pesticide inert ingredients that it considers to be intrinsically safe based on the fact that they are listed on the TSCA Inventory or meet the requirements of the amended TSCA polymer exemption and are thereby not subject to the requirements of premanufacture notice (PMN). The Agency has maintained that polymers meeting the polymer exemption criteria will present minimal risk to human health when used as inert ingredients in pesticide formulations applied to RACs.

2. *Infants and children.* FFDCA section 408 provides that EPA shall supply an additional 10-fold margin of safety for infants and children in the case of threshold effects where prenatal and/or postnatal toxicity are found or there is incompleteness of the data base, unless EPA concludes that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments

either directly through the use of margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. Due to the low expected toxicity of polybutylene, a safety factor analysis is not required for assessing the risk. For the same reasons the additional safety factor is unnecessary.

#### F. International Tolerances

Miller Chemical and Fertilizer Corporation is not aware of any country requiring a tolerance for polybutylene having a number average molecular weight of 1,330. Nor have there been any CODEX maximum residue levels (MRLs) established for any food crops at this time.

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### ENVIRONMENTAL PROTECTION AGENCY

[OPP-181078; FRL-6757-7]

#### Pesticide Emergency Exemptions; Agency Decisions and State and Federal Agency Crisis Declarations

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

**ACTION:** Notice.

**SUMMARY:** EPA has granted or denied emergency exemptions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for use of pesticides as listed in this notice. The exemptions or denials were granted during the period December 1999 to November 2000 to control unforeseen pest outbreaks.

**FOR FURTHER INFORMATION CONTACT:** See each emergency exemption or denial for the name of a contact person. The following information applies to all contact persons: Team Leader, Emergency Response Team, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-9366.

**SUPPLEMENTARY INFORMATION:** EPA has granted or denied emergency exemptions to the following State and Federal agencies. The emergency exemptions may take the following form: Crisis, public health, quarantine, or specific. EPA has also listed denied emergency exemption requests in this notice.

### I. General Information

#### A. Does this Action Apply to Me?

You may be potentially affected by this action if you petition EPA for authorization under section 18 of FIFRA to use pesticide products which are otherwise unavailable for a given use. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Federal Government	9241	Federal agencies that petition EPA for section 18 pesticide use authorization
State and Territorial government agencies charged with pesticide authority		State agencies that petition EPA for section 18 pesticide use authorization

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. Other types of entities not listed in the table in this unit could also be regulated. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action applies to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### B. How Can I Get Additional Information or Copies of this Document or Other 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/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-181078. The official record

consists of the documents specifically referenced in this action, 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.

### II. Background

Under FIFRA section 18, EPA can authorize the use of a pesticide when emergency conditions exist. Authorizations (commonly called emergency exemptions) are granted to State and Federal agencies and are of four types:

1. A "specific exemption" authorizes use of a pesticide against specific pests on a limited acreage in a particular State. Most emergency exemptions are specific exemptions.

2. "Quarantine" and "public health" exemptions are a particular form of specific exemption issued for quarantine or public health purposes. These are rarely requested.

3. A "crisis exemption" is initiated by a State or Federal agency (and is confirmed by EPA) when there is insufficient time to request and obtain EPA permission for use of a pesticide in an emergency.

EPA may deny an emergency exemption: If the State or Federal agency cannot demonstrate that an emergency exists, if the use poses unacceptable risks to the environment, or if EPA cannot reach a conclusion that the proposed pesticide use is likely to result in "a reasonable certainty of no harm" to human health, including exposure of residues of the pesticide to infants and children.

If the emergency use of the pesticide on a food or feed commodity would result in pesticide chemical residues, EPA establishes a time-limited tolerance meeting the "reasonable certainty of no harm standard" of the Federal Food, Drug, and Cosmetic Act (FFDCA).

In this document: EPA identifies the State or Federal agency granted the exemption or denial, the type of