

are used to identify low risk polymers, EPA can conclude that there is a reasonable certainty that no harm to the U.S. population will result from non-dietary exposures to it.

#### *G. International Tolerances*

There are no Codex Alimentarius Commission (Codex), Canadian or Mexican residue limits for polyvinyl acetate, sulfoxyl group modified, sodium salt.

[FR Doc. 99-1250 Filed 1-19-99; 8:45 am]

BILLING CODE 6560-50-F

## ENVIRONMENTAL PROTECTION AGENCY

[PF-839; FRL-6038-2]

### Kuraray America, Inc.; 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-839, must be received on or before February 19, 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:**

Bipin Gandhi, Registration Support Branch, 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. 707A, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 308-8380; e-mail: gandhi.bipin@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 Cosmetic 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-839] (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-839) 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: January 12, 1999.

**Peter Caulkins,**

*Acting 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.

**Kuraray America, Inc.**

*PP 8E4944*

EPA has received a pesticide petition (PP 8E4944) from Kuraray America, Inc., 200 Park Avenue, New York, N.Y. 10166-3098, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR 180.1001(c) and to establish an exemption from the requirement of a tolerance as a pesticide inert ingredient in or on raw agricultural commodities for polyvinyl acetate, carboxyl-modified, sodium salt (Vinylon VF-HH-4) in or on the raw agricultural commodities. 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. Toxicological Profile*

Polyvinyl acetate, carboxyl-modified, sodium salt conforms to the definition of polymer given in 40 CFR 723.250(b).

1. Polyvinyl acetate, carboxyl-modified, sodium salt is not cationic or potentially cationic.

2. Polyvinyl acetate, carboxyl-modified, sodium salt contains as an integral part of its composition at least two of the required atomic elements, and does not contain elements above permitted levels or any elements not permitted by the atomic element limitation.

3. Polyvinyl acetate, carboxyl-modified, sodium salt is not manufactured or imported from monomers and/or other reactants that are not already included on the TSCA Chemical Substance Inventory.

4. Polyvinyl acetate, carboxyl-modified, sodium salt has a number average molecular weight  $\geq 10,000$  Dalton (typical number average molecular weight of 62,800 Dalton) and maximum oligomer contents of 0.00% < 500 and 0.0% < 1,000.

Polyvinyl acetate, carboxyl-modified, sodium salt is not a water-absorbing polymer, and therefore is not excluded from eligibility for the amended TSCA exemption. The exclusion in the amended polymer exemption rule is intended to address concerns for "super absorbent" polymers or "super slurpers", which have the capacity to absorb 60 to 100 times their own mass of water, yet not dissolve. Polyvinyl acetate, carboxyl-modified, sodium salt does not fall within this exclusion because it dissolves in water rather than absorbing it.

#### B. Aggregate Exposure

The Agency has maintained that polymers meeting the polymer exemption criteria (as described previously for polyvinyl acetate, carboxyl-modified, sodium salt), 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 pre-manufacturing notification.

*Non-dietary exposure.* Based on the conformance of polyvinyl acetate, carboxyl-modified, sodium salt to the definition of a polymer given in 40 CFR 723.250(b), as well as the criteria that are used to identify low risk polymers, EPA can conclude that there is a reasonable certainty that no harm to the U.S. population will result from non-dietary exposures to it.

Based on conformance to the criteria for TSCA polymer exemption, a chemical can be anticipated to have no mammalian toxicity from dietary, inhalation or dermal exposure. The polymer, polyvinyl acetate, hydrolyzed, carboxyl-modified, sodium salt, conforms with all the criteria.

#### C. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or tolerance exemption, the Agency consider "available information" concerning the cumulative effects of a particular chemical's residues and "other substances that have a common mechanism of toxicity". In the case of the polyvinyl acetate, carboxyl-modified, sodium salt, the lack of expected toxicity of this substances based on its conformance to the definition of polymers as given in 40 CFR 723.250(b), as well as the criteria that identify low risk polymers, results in no expected cumulative effects. A cumulative risk assessment is therefore not necessary.

#### D. Safety Determination

1. *U.S. population.* As a matter of policy, EPA has in the past 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 premanufacturing notification. 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 products applied to food crops.

2. *Infants and children.* FFDCA section 408 provides that EPA shall supply an additional tenfold margin of safety for infants and children in the case of threshold effects where pre- 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 polyvinyl acetate, carboxyl-modified, sodium salt, a safety factor analysis is not required in assessing the risk. For the same reasons the additional safety factor is unnecessary.

#### E. Analysis of TSCA Polymer Exemption Applicability

1. *Polymer definition.* In order to apply the criteria of the polymer exemption, it is essential that the chemical identity of polymer be

established precisely, if possible. In the case of polyvinyl acetate, hydrolyzed, carboxylate-modified sodium salt (polyvinyl acetate, carboxyl-modified, sodium salt, the precursors are simple chemicals that can be fully characterized and their reaction products are clearly defined.

Under the amended TSCA polymer exemption, a substance must meet the definition of a polymer, which is: A chemical substance that consists of not less than 50.0% (a simple majority) of polymer molecules and less than 50.0% of molecules with the same molecular weight, wherein the polymer molecules are distributed over a range of molecular weights and the differences among polymer molecules are primarily due to differences in the number of internal monomer units. Polyvinyl acetate, carboxyl-modified, sodium salt satisfies the polymer definition.

2. *Exclusions: 40 CFR 723.250(d)—i. Unreviewed reactants.* Under the amended TSCA polymer exemption, a manufacturer or importer is not allowed to commercialize a polymer if any one or more of the reactants used or incorporated at 2% or more are not listed on the TSCA Inventory or manufactured under an applicable exemption to section 5 of TSCA. All monomers and other reactants involved in manufacturing polyvinyl acetate, carboxyl-modified, sodium salt are listed on the TSCA Inventory.

ii. *Positively charged polymers.* Cationic or potentially cationic polymers are excluded under paragraph (d)(1) from the TSCA polymer exemption unless the charge density is sufficiently low or the polymer is a non-dispersible, non-soluble solid. Polyvinyl acetate, carboxyl-modified, sodium salt is not cationic or potentially cationic.

iii. *Atomic element limitations.* The exclusion at 40 CFR 723.250 (d)(2) limits the identities of atomic elements in the composition of polymers eligible for the TSCA exemption. All such polymers must contain as an integral part of their composition two or more zirconium are permitted at less than 0.20 weight percent alone or in any combination. No other atomic elements are permitted and other exclusions may apply.

Polyvinyl acetate, carboxyl-modified, sodium salt contains at least two of the required atomic elements, and it does not contain elements above permitted levels or any elements not permitted by this limitation.

iv. *Instability.* Polymers cannot be manufactured under the amended TSCA exemption if they substantially degrade, decompose, or depolymerize, or are designed (or can be reasonably

anticipated) to substantially degrade, decompose or depolymerize prior to, during or after use. This exclusion includes polymers with such properties after disposal, for example, in a waste water treatment plant. A similar exclusion was made a part of the original TSCA exemption rule<sup>1</sup>. This provision is present in the amended rule, because it is not feasible for EPA to anticipate all possible breakdown products that could result from polymers otherwise eligible, and it is therefore not possible for EPA to define precisely in advance which polymers with this property are intrinsically safe. Polymers that otherwise satisfy all the criteria of the TSCA exemption, may still be intrinsically safe even if they are designed or reasonably anticipated to break down prior to, during, or after use, depending upon the extent to which they break down and the nature of any persistent breakdown products.

Kuraray America, Inc. conducted tests on the stability of the VF-HH-4 polymer and it was found not to be biodegradable under the test conditions.

v. *High molecular weight, water-absorbing polymers.* Water-absorbing polymers are excluded from eligibility for the amended TSCA exemption. A water-absorbing polymer is defined as one "that is capable of absorbing its own weight of water" and has a number-average molecular weight (NAMW) equal to or greater than 10,000. As discussed in the preamble of the amended polymer exemption rule<sup>2</sup>, the exclusion is intended primarily to address concerns for "super absorbent" polymers or "super slurpers". The exclusion responds to information received under section 8(e) of TSCA for a water-absorbing polyacrylate. The polymer in question had a NAMW of about 1,000,000 and could absorb about 100 times its own mass of water. EPA set the exclusion two orders of magnitude below these levels. "Super slurpers" have the capacity to absorb 60 to 100 times their own mass of water, yet not dissolve. Clearly, polyvinyl acetate, carboxyl-modified, sodium salt does not fall within this exclusion because it dissolves in water rather than absorbing it<sup>3</sup>.

3. *Conditions: 40 CFR 723.250(e)—i. Polymers of 1,000 > molecular weight >10,000.* To qualify for the exemption, polymers in the molecular weight range, 1,000 > MW >10,000 must also always have a molecular weight distribution such that there is less than 25% with molecular weights below 1,000 and less than 10% with molecular weights below 500. Both criteria must be simultaneously met. In addition, polymers that meet the molecular weight conditions of (e)(1) are subject to important reactive functional group limitations.

Polyvinyl acetate, carboxyl-modified, sodium salt has a number average molecular weights above 10,000 and does not fall within condition (e)(1).

ii. *Polymers with molecular weight ≤ 10,000.* Under conditions (e)(2), polymers with molecular weights of 10,000 or greater must have oligomer contents of less than 5% with molecular weights less than 1,000 and less than 2% with molecular weights less than 500. The properties of polyvinyl acetate, carboxyl-modified, sodium salt, supported by GPC molecular weight data, satisfies this condition, as summarized below:

Typical number-average molecular weight = 52,260

Maximum oligomer contents = 0.0% > 500, 0.0% > 1,000

#### F. Conclusions on the TSCA Polymer Exemption Criteria

Based on conformance to the criteria described above for TSCA polymer exemption, a chemical can be anticipated to have no mammalian toxicity from dietary, inhalation or dermal exposure. In the case of polyvinyl acetate, carboxyl-modified, sodium salt, polyvinyl acetate, hydrolyzed, carboxylate-modified sodium salt, conformance with all the criteria can be demonstrated. Additionally, this substance has been through the PMN review process and is listed on the TSCA Inventory. It is noted that an exemption from tolerance has already been established for a closely related WSP polymer, polyvinyl acetate, hydrolyzed, CASRN 25213-24-5.

Based on the conformance of polyvinyl acetate, carboxyl-modified, sodium salt to the definition of a polymer given in 40 CFR 723.250(b), as well as the criteria that are used to identify low risk polymers, EPA can conclude that there is a reasonable certainty that no harm to the U.S. population will result from non-dietary exposures to it.

the exclusion. Water-absorbing polymers are not water-soluble.

#### G. International Tolerances

There are no Codex Alimentarius Commission (Codex), Canadian or Mexican residue limits for polyvinyl acetate, carboxyl-modified, sodium salt. [FR Doc. 99-1251 Filed 1-19-99; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

[PF-828A; FRL-6054-9]

### Rohm & Haas Co.; Correction of Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of a correction.

SUMMARY: EPA is correcting a pesticide petition (PP 7F4894) from Rohm and Haas Company which was published in the **Federal Register** of September 30, 1998.

FOR FURTHER INFORMATION CONTACT: By mail: Mark Dow, Registration Division (7505C), Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location and telephone number: Rm. 214, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, Virginia 22202, (703) 305-5533; e-mail: Dow.mark@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 30, 1998 (63 FR 52260)(FRL 6023-7), EPA issued a notice of filing of a pesticide petition (PP 7F4894) from Rohm and Haas Company. The notice of filing inadvertently proposed a tolerance for residues of triazamate; ethyl (3-tert-butyl-1-dimethylcarbamoyl-1H-1,2,4-triazol-5-ylthio) acetate in or on the raw agricultural commodity apples at 0.1 parts per million (ppm). The petition that Rohm and Haas Company submitted requested a tolerance for pome fruits at 0.1 ppm. Therefore all references to apples in "PF-828", should be changed to read "pome fruits".

#### List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and record keeping requirements.

Dated: January 8, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 99-1248 Filed 1-19-99; 8:45 am]

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<sup>1</sup> 49 FR 46066 (November 21, 1984)

<sup>2</sup> 60 FR 16319-16320 (March 29, 1995).

<sup>3</sup> In the **Federal Register** notice that established a broad generic exemption from tolerance for acrylate polymers, described earlier in this volume. EPA's Office of Pesticide Programs stated: "Water soluble (sic) polymers in this molecular weight range [≥10,000 daltons] are excluded from the exemption under Sec. 723.250(d)...." 61 FR 6550-6551. The second time in the same notice that EPA/OPP mentions these polymers, they are called "highly water-absorbing," a correct interpretation of