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[FR Doc. 00–25048 Filed 9–28–00; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301067; FRL–6748–3]

RIN 2070–AB78

Yucca Extract; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the yucca extract on raw agricultural commodities when applied/used in accordance with good agricultural practices as an inert ingredient in pesticide formulations applied to growing crops. EDM Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of yucca extract.

DATES: This regulation is effective September 29, 2000. Objections and requests for hearings, identified by docket control number OPP–301067, must be received by EPA on or before November 28, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301067 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Vera Soltero, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9359; e-mail address: soltero.vera@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 OPP–301067. 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 and Statutory Findings

In the **Federal Register** of November 20, 1998 (63 FR 64494) (FRL–6027–7), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act (FQPA) (Public Law 104–170) announcing the filing of a pesticide tolerance petition by, EDM Corporation, 2278 S. Indiana St., Porterville, CA 93257. This notice included a summary of the petition prepared by the petitioner EDM Corporation. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1001(d) be amended by establishing an exemption from the requirement of a tolerance for residues of yucca extract.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this

action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by are discussed in this unit.

An acute oral gavage toxicity study performed on Sprague–Dawley derived rats was performed on a 70% yucca extract syrup. The LD_{50} for males was found to be greater than 5,000 milligram/kilogram (mg/kg), and for females it was calculated to be greater than 500 mg/kg. Even though the use of a 70% extract is a minor deviation from accepted guidelines, the Agency concluded that yucca extract belonged in Toxicity Category III. Thus, there are no concerns for acute oral exposure.

Yucca extract has been historically used among the Native American population in Mexico and the United States for medicinal purposes. It was approved by the U.S. Food and Drug Administration (FDA) as a natural food additive under 21 CFR 172.510. Furthermore, it has been used as a dietary supplement without evidence of toxicity. For these reasons, the Agency has concluded there are no concerns for chronic oral exposure, and that chronic toxicity data were not necessary.

IV. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non–occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

Yucca extract is derived from the species Yucca schidigera which is part of the lily family of plants and is native to the deserts of Southwestern United States and Northern Baja California, Mexico. The plant and its extracts have a long history of safe use as food material for both humans and livestock. It is used for human consumption in the soft drink industry, natural food supplement, cosmetics, etc. Other uses include: natural feed additive for livestock, poultry, swine, pets, and shrimp to reduce ammonia, hydrogen sulfide and offensive odors. The extract is approved by the FDA as a natural food additive under 21 CFR 172.510.

1. *Food*. Information supplied to the Agency indicates that approximately 350 tons of raw yucca material are used annually in the United States. It is expected that 150 tons of these materials would be used in making yucca extract for agricultural uses. A 70% yucca extract solution would be used in pesticide products in a concentration no greater than 6%. If yucca extract is approved as an inert ingredient in pesticide products to be applied to food crops, it can be assumed that exposure to yucca extract will increase. However, the amount of increase is necessarily limited by the availability of raw yucca. In addition, the main ingredient in yucca extract is sarsaponin which is naturally found in several types of food, such as legumes and asparagus at significant levels. The Agency concludes that the use of yucca extract as an inert ingredient would result in a negligible increase in exposure over those levels which would occur as the result of the use of yucca extract as an unrestricted food additive or naturally as the result of ingestion of various food items.

2. *Drinking water exposure*. Yucca extract has general history of safe use as a natural food additive approved by the FDA under 21 CFR 172.510 present in dietary supplements, herbal teas, soft drinks, among others. The main ingredient in yucca extract, sarsaponin, has been shown to degrade in 60°C water within 8 days. Because of this rapid degradation, the lack of toxicity and its history of safe use, the Agency is confident that the use of yucca extract as a food–use inert ingredient in pesticide products will not affect the water supply.

B. Other Non–Occupational Exposure

On October 6, 1998, the Agency approved the use of yucca extract as a non–food use inert ingredient in pesticide formulations applied to grasses grown for seeds and for sod. No data was required for this approval. The Agency has determined that due to the long history of safe use as a dietary supplement and food additive, there is no need for the petitioners to submit dermal and inhalation exposure data.

V. 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. The Agency has not made any conclusions as to whether or not yucca extract shares a common mechanism of toxicity with other chemicals. However, yucca extract is expected to be practically non-toxic to mammals. Due to the expected lack of toxicity, a cumulative risk assessment is not necessary.

VI. Determination of Safety for U.S. Population, Infants and Children

Yucca extract has been approved for use in food and beverages by the FDA under 21 CFR 172.510 with no limits. As previously stated in sections A1 and A2, approval of yucca extract as an inert ingredient for use on food crops will not significantly increase dietary exposure to this chemical. Accordingly, there is reasonable certainty that no harm will result from aggregate exposure of the U.S. population, including infants and children, to yucca extract.

The Agency did not use the safety factor analysis in evaluating the risk posed by the compound. The lack of toxicity of yucca extract supported not applying an additional tenfold safety factor to protect infants and children. In conclusion, the Agency is reasonably certain that no harm will result to infants and children, or to the general population from aggregate exposure to residues of yucca extract. Accordingly, EPA finds that exempting yucca extract from the requirement of a tolerance will be safe.

VII. Other Considerations

A. Endocrine Disruptors

FQPA requires EPA to develop a screening program to determine whether certain substances, including pesticides and inert ingredients, 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 has been working with interested stakeholders to develop a screening and testing program as well as a priority–setting scheme. As the Agency proceeds with implementation of this program, further testing of products containing the inert ingredient yucca extract for endocrine effects may be required. At this moment, there is no evidence that yucca extract is an endocrine disruptor.

B. Analytical Method(s)

Since an exemption from the requirement of a tolerance is being established without restriction on residue level, the Agency has concluded that an analytical method is not required for enforcement purposes for yucca extract from Yucca schidigera.

C. Existing Tolerance Exemptions

There are no existing tolerance exemptions for yucca extract from Yucca schidigera.

D. International Tolerances

There are no international tolerances or tolerance exemptions for yucca extract from Yucca schidigera.

E. Conclusion

Therefore, based on the information and the data considered, EPA is establishing an exemption from the requirement of a tolerance for residues of yucca extract from Yucca schidigera.

VIII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301067 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 28, 2000.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential 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. A copy of the information 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.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301067, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp–docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IX. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* October 4, 1993 (58 FR 51735). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* May 19, 1998 (63 FR 27655); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low–Income Populations* February 16, 1994 (59 FR 7629); or require OMB review or any Agency action under Executive Order

13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* April 23, 1997 (62 FR 19885). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* August 10, 1999 (64 FR 43255). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

X. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: September 21, 2000.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), (346a) and 371.

2. In § 180.1001, the table in paragraph (d) is amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(d)* * *

Inert ingredients	Limits	Uses
* * * * *		
Yucca extract from Yucca schidigera.	.....	Wetting agent
* * * * *		

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[FR Doc. 00–24946 Filed 9–28–00; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301061; FRL–6746–5]

RIN 2070–AB78

Hexythiazox; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of the ovicide/miticide hexythiazox (trans-5-(4-chlorophenyl)-*N*-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide) and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety (expressed as parent) in or on wet apple pomace, almonds, strawberries, stone fruit (excluding plums), milk, fat and meat byproducts in cattle, goats, horses, swine, and sheep. It also increases the tolerance in apples and establishes a tolerance with regional registration in cotton. Gowan Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective September 29, 2000. Objections and requests for hearings, identified by docket control number OPP–301061, must be received by EPA on or before November 28, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301061 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT By mail: William G. Sproat, Jr., Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 308–8587; and e-mail address: sproat.william@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
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	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