§ 165.T13–290 Safety Zone; 520 Bridge, Lake Washington; Seattle, WA.

(a) *Location:* The following area is designated as a safety zone: All waters within 100 yards of the east span of the 520 Bridge located on Lake Washington in Seattle, Washington.

(b) *Regulations:* In accordance with the general regulations in 33 CFR 165, Subpart C, no person may enter the safety zone or bring or cause to be brought any vessel into the safety zone without permission of the Captain of the Port. Persons wishing to enter the safety zone must request permission from the Captain of the Port by contacting the Joint Harbor Operation Center at 206–217–6001 or VHF Channel 16. If permission for entry is granted, vessels must proceed at a minimum speed for safe navigation.

(c) *Dates:* This rule is effective from October 2, 2015, through November 30, 2015, when a construction barge is present inside the safety zone.

Dated: September 30, 2015.

M.W. Raymond,

Captain, U.S. Coast Guard, Captain of the Port Puget Sound.

[FR Doc. 2015–26754 Filed 10–20–15; 8:45 am]

BILLING CODE 9110–04P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0374; FRL–9933–73]

Potassium Salts of Hops Beta Acids; 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 biochemical pesticide potassium salts of hops beta acids in or on honey and honeycomb for the control of Varroa mites in accordance with label directions and good agricultural practices. Interregional Research Project Number 4, on behalf of Beta Tec Hop Products, Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of potassium salts of hops beta acids in or on honey and honeycomb.

DATES: This regulation is effective October 21, 2015. Objections and requests for hearings must be received on or before December 21, 2015, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2014–0374, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *BPPDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2014–0374 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before December 21, 2015. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2014–0374, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Background and Statutory Findings

In the **Federal Register** of September 5, 2014 (79 FR 53009) (FRL–9914–98), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 3E8217) by Interregional Research Project Number 4, 500 College Road East, Suite 201W, Princeton, NJ 08540, on behalf of BetaTec Hop Products, Inc. (the

petitioner). The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of potassium salts of hop beta acids (K–HBAs) in or on honey and honeycomb resulting from the control of Varroa mites. That document referenced a summary of the petition prepared by the petitioner, which is available in the docket, *http://www.regulations.gov.* There were 63 comments received in response to the batched notice of filing but none were relevant to the establishment of a tolerance for potassium salts of hops beta acids.

Section 408(c)(2)(A)(i) of 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 exemption is ''safe.'' Section 408(c)(2)(A)(ii) of FFDCA 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. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require 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. . . .'' Additionally, EPA is required to take into account the factors set forth in FFDCA section 408(b)(2)(D).

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 FFDCA section 408(b)(2)(D), 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.

A. Overview of Potassium Salts of Hops Beta Acids

K–HBAs are derived from the resin components of the cones of female hop plants *Humulus lupulus.* The three major components of K–HBAs are Lupulone (30–55% with an isopropyl side chain), Colupulone (20–55% with an isobutyl side chain), and Adlupulone (5–10% with a secbutyl side chain); the components differ only in the R-side chain attached. K–HBA is classified as a biochemical pesticide because it is naturally occurring (found in *Humulus lupulus* plant), has a non-toxic mode of action against the target pest, and has a history of exposure to humans and the environment demonstrating minimal toxicity. There is a long history of safe use of HBAs via the oral and dietary exposure to humans from its use as a preservative on meats (estimated range 4.4 milligrams/kilograms (mg/kg) of cooked meat—5.5 mg/kg of frankfurter) and its presence in the beer brewing process. Due to its long history of exposure, K–HBAs are considered to be generally recognized as safe (GRAS) by FDA.

B. Biochemical Pesticide Toxicology Data Requirements

All applicable mammalian toxicology data requirements supporting the petition to establish an exemption from the requirement of a tolerance for the use of potassium salts of hops beta acids as an active ingredient for use to control Varroa mites in or on honey and honeycomb have been fulfilled. No significant toxicological effects were observed in the acute toxicity study or other information from the literature that was used to address the toxicity data requirements. For the Tier I subchronic toxicity studies, data and information from scientific literature were used in support of acceptable rationales to address the data requirements, focusing on the long history of exposure to K–HBAs in food preservation and in the production of beer, which is commonly consumed in the United States. K–HBAs are not structurally-related to known mutagens, nor are they in a chemical class known to contain a known mutagen. Further, from the available toxicity information, there were no systemic effects of potassium salts of hops beta acids via the oral, dermal, or inhalation routes of exposure. For a summary of the data upon which EPA relied, and its human health risk assessment based on that data, please refer to the document entitled, ''Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Potassium Salts of Hops Beta acids'' (July 15, 2015), available in the docket for this action.

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

Human dietary exposure through food to residues of K–HBAs already occurs via its use as a preservative in meats and its natural presence in beer brewing production. EPA does not expect much residue of potassium salts of hops beta acids in honey from its use as a pesticide in hives based on residue studies. In three different studies conducted over 3 years, only one honey sample from one honey super was shown to have residues of hops beta acids (0.44 part per million (ppm)), and the residue level was only slightly above the analytical limits of detection (0.41 ppm) and well below the Limit of Quantitation (1.2 ppm).

No significant exposure via drinking water is expected from its use as an active ingredient as a pesticide. K–HBAs are non-volatile and are expected to degrade rapidly, with 100% degradation in 36 hours in the light and 4 days in the dark. Furthermore, as an insecticide, K–HBAs are formulated into a viscous liquid and coated on fiber strips which are placed inside the beehive such that the product is not sprayed or applied in any way that it would be expected to contact any source of drinking water.

Should exposure occur, however, minimal to no risk is expected for the general population, including infants and children, due to the long history of dietary exposure to K–HBAs.

B. Other Non-Occupational Exposure

Non-occupational exposure to potasium salts of hops beta acids is not expected because potassium salts of hops beta acids is formulated into a viscous liquid and coated on fiber strips which are placed inside the beehive. There are no residential proposed uses. However, minimal to no risk is expected for the general population, including infants and children, due to the minimal toxicity of this chemical as

demonstrated in the data submitted and evaluated by the Agency, as fully explained in the document entitled, ''Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Potassium Salts of Hops Beta acids'' (July 15, 2015), available in the docket for this action.

V. Cumulative Effects From Substances With a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found potassium salts of hops beta acids to share a common mechanism of toxicity with any other substances, and potassium salts of hops beta acids does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that potassium salts of hops beta acids does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

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

FFDCA section 408(b)(2)(C) provides that, in considering the establishment of a tolerance or tolerance exemption for a pesticide chemical residue, EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure, unless EPA determines that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor. In applying this provision, EPA either retains the default value of 10X, or uses a different additional or no safety factor when reliable data are available to support a different additional or no safety factor.

As part of its qualitative assessment, EPA evaluated the available toxicity and exposure data on potassium salts of hops beta acids and considered its validity, completeness, and reliability, as well as the relationship of this information to human risk. EPA considers the toxicity database to be complete and has identified no residual uncertainty with regard to prenatal and postnatal toxicity or exposure. No hazard was identified based on the available studies; therefore, EPA concludes that there are no threshold effects of concern to infants, children, or adults from potassium salts of hops beta acids. As a result, EPA concludes that no additional margin of exposure (safety) is necessary.

VII. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

VIII. Conclusion

Based on its assessment of potassium salts of hops beta acids, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to potassium salts of hops beta acids. EPA is therefore establishing an exemption from the requirement of a tolerance for residues of potassium salts of hops beta acids for the control of Varroa mites in or on honey and honeycomb, in accordance with label directions and good agricultural practices.

IX. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement of a tolerance 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'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). 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.,* nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

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) (15 U.S.C. 272 note).

X. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 the rule in the **Federal Register**. This action 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 29, 2015.

Jack E. Housenger,

Director, 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. Add section 180.1333 to subpart D to read as follows:

§ 180.1333 Potassium Salts of Hops Beta acids; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biochemical potassium salts of hops beta acids in or on honey and honeycomb, when used for the control of Varroa mites in accordance with label directions and good agricultural practices.

[FR Doc. 2015–26600 Filed 10–20–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0442; FRL–9935–34]

Poly[oxy(methyl-1,2-ethanediyl)], α-[(9Z)-1-oxo-9-octadecen-1-yl]-ω-[[(9Z)-1-oxo-9-octadecen-1yl]oxy]-; 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 poly[oxy(methyl-1,2-ethanediyl)], α-[(9Z)-1-oxo-9-octadecen-1-yl]-ω-[[(9Z)-1-oxo-9-octadecen-1yl]oxy]- (CAS Reg. No. 26571–49–3) when used as an inert ingredient in a pesticide chemical formulation. BYK USA Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of poly[oxy(methyl-1,2-ethanediyl)], α-[(9Z)-1-oxo-9-octadecen-1-yl]-ω-[[(9Z)-1-oxo-9-octadecen-1yl]oxy]- on food or feed commodities.

DATES: This regulation is effective October 21, 2015. Objections and requests for hearings must be received on or before December 21, 2015, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2015–0442, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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B. How can I get electronic access to other related information?

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C. Can I file an objection or hearing request?

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Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Background and Statutory Findings

In the **Federal Register** of August 26, 2015 (80 FR 51759) (FRL–9931–74), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the receipt of a pesticide petition (PP) IN–10826 filed by BYK USA Inc., 524 South Cherry Street, Wallingford, CT 06492–4453. The