



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0123; FRL-9960-61]

***Bacillus simplex* strain BU288; 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 *Bacillus simplex* strain BU288 when used as an inert ingredient (emulsifier) in pesticide formulations applied to growing crops and raw agricultural commodities. BASF Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus simplex* strain BU288 when used in accordance with approved conditions.

DATES: This regulation is effective [*insert date of publication in the Federal Register*]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], 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-2016-0123, 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), EPA West 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: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: RDNRNotices@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 FFDCFA 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-2016-0123 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 *[insert date 60 days after date of publication in the **Federal Register**]*. 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-2016-0123, 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.htm>.

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

II. Petition for Exemption

In the **Federal Register** of May 19, 2016 (81 FR 31581) (FRL-9946-02), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10891) by BASF Corporation, 26 Davis Drive,

Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of *Bacillus simplex* strain BU288 when used as an inert ingredient (emulsifier) in pesticide formulations applied to growing crops or raw agricultural commodities after harvest. That document referenced a summary of the petition prepared by BASF Corporation, the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

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. Section 408(c)(2)(B) of the FFDCA requires EPA to take into account the factors found in subparagraphs (b)(2)(C) and (b)(2)(D) in establishing an exemption. Section 408(b)(2)(C) of FFDCA 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 establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors referenced in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other

relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for *Bacillus simplex* strain BU288, including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with *Bacillus simplex* strain BU288 follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies 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. Specific information on the studies received and the nature of the adverse effects caused by *Bacillus simplex* strain BU288 as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

In an acute oral toxicity study of *Bacillus simplex* strain BU288 in rats the acute oral Lethal Dose (LD)₅₀ was estimated to be greater than 5,000 milligrams/kilogram (mg/kg).

In an acute dermal toxicity study of *Bacillus simplex* strain BU288 in rats, the LD₅₀ was determined to be greater than 5,050 mg/kg.

In an acute inhalation toxicity study of *Bacillus simplex* strain BU288 in rats, the acute inhalation Lethal Concentration (LC)₅₀ is greater than 2.14 mg/Liter (L).

In an acute ocular irritation study of *Bacillus simplex* strain BU288 in rats, minimal ocular irritation was observed during the 24-hr treatment period, with clearance by 48 hours.

A primary dermal irritation study was conducted for *Bacillus simplex* strain BU288 on rabbits. Very slight erythema was observed, with clearance by 24 hours.

In an acute intravenous toxicity and infectivity study with *Bacillus simplex* strain BU288 in rats the test substance *Bacillus simplex* strain BU288 was determined to be non-toxic at a dose of 1.0×10^9 CFU (colony forming units). There are no chronic toxicity studies available for *Bacillus simplex* strain BU288. *Bacillus simplex* and other closely related endospore-forming *Bacillus* species are ubiquitous in the environment. There are no reports of any potential human health or ecological hazards caused by *Bacillus simplex* strain BU288.

Based on the results of the Tier I testing, the Agency does not require any additional testing on potential subchronic or chronic toxicity. The absence of acute toxicity or pathogenicity in laboratory animals indicates that it is unlikely that the strain produces recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The results of *in vivo* toxicity testing identified no potential human health hazard following oral exposure to *Bacillus simplex* strain BU288. There are no reports of ecological or human health hazards caused by *Bacillus simplex* strain BU288. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the overall benign nature of this strain. The acute studies also cover chronic endpoints because the pathogenicity/infectivity studies are of longer duration, typically at least 21-days. This longer duration allows for the expression of possible toxicities associated with the

microbe as well as ensuring that the microbe is recognized and cleared by the immune system of the exposed rodent. The information provided by the identification of the microbe and its potential hazards, both toxin production and possible clinical history, along with results of the infectivity/pathogenicity studies provide a basis for stating that *Bacillus simplex* strain BU288 is not expected to result in any subchronic or chronic, including cancer, toxicity.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. [For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.]

Due to the lack of hazard associated with *Bacillus simplex* strain BU288 based on the available data, no points of departure were identified for assessing risk.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to *Bacillus simplex* strain BU288, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from *Bacillus simplex* strain BU288 in food as follows:

Acute and chronic dietary assessments take into account exposure estimates from dietary consumption of food and drinking water. Because no adverse effects attributable to a single or repeat exposures to *Bacillus simplex* strain BU288 were seen in the toxicity databases, quantitative dietary risk assessments are not appropriate. Due to expected use of *Bacillus simplex* strain BU288 in pesticide formulations applied to growing crops and raw agricultural commodities after harvest, it is reasonable to expect that there will be some exposure to these substances from their use in pesticide products.

2. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and dapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). It is possible that *Bacillus simplex* strain BU288 may be used as an inert ingredient in pesticide products that may result in residential exposures, although no residential uses are currently proposed. A residential exposure assessment was not conducted because no endpoint of concern following a single or repeat dose exposure was identified in the available studies.

3. *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.”

Because *Bacillus simplex* strain BU288 does not have a toxic mode of action or a mechanism of toxicity, this provision does not apply.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA 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 based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

Because there are no threshold effects associated with *Bacillus simplex* strain BU288, EPA conducted a qualitative assessment. As part of that assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children. Based on an assessment of *Bacillus simplex* strain BU288, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children.

E. Aggregate Risks and Determination of Safety

Based on the available data indicating a lack of toxicity associated with *Bacillus simplex* strain BU288, 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 *Bacillus simplex* strain BU288 residues.

V. Analytical Enforcement Methodology

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

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for residues of *Bacillus simplex* strain BU288 when used as an inert ingredient (emulsifier) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest.

VII. 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).

VIII. 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: March 28, 2017.

Michael Goodis,

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 §180.910, alphabetically add the following inert ingredient to the table to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

Inert ingredients	Limits	Uses
* * *	*	* * *
<i>Bacillus simplex</i> strain BU288		Emulsifier
* * *	*	* * *