This document is scheduled to be published in the Federal Register on 2026-08-28 and available online at https://www.federalregister.gov/d/2026-17579, and on https://govinfo.gov

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2025-0286; FRL-13571-01-OCSPP]

Alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates in Pesticide Formulations; 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 alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates (CAS Reg. No. 84066-95-5) when used as an inert ingredient (surfactant) on growing crops pre-harvest at no more than 12% of the final pesticide formulation. Elicit Plant S.A.S 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 alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates, when used in accordance with the terms of this exemption.

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 this document).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2025-0286, is available online at *https://www.regulations.gov*. Additional information about dockets generally, along with instructions for visiting the docket in-person, is available at *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Charles Smith, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; main telephone number: (202) 566-1030; email address: *RDFRNotices@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.

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

If you have any questions regarding the applicability of this proposed action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. *What is EPA's authority for taking this action?*

EPA is issuing this rulemaking under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. FFDCA section 408(c)(2)(A)(i) 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." FFDCA section 408(c)(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. 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, FFDCA section 408(b)(2)(D) requires that the Agency consider, among other things, "available information concerning the cumulative effects of a particular pesticide's residues" and "other substances that have a common mechanism of toxicity."

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

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. If you fail to file an objection to the final rule within the time period specified in the final rule, you will have waived the right to raise any issues resolved in the final rule. 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 the docket ID number EPA-HQ-OPP-2025-0286 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*]**.

EPA's Administrative Law Judges Division (ALJD), in which the Hearing Clerk is housed, urges parties to file and serve documents by electronic means only, notwithstanding any other particular requirements set forth in other procedural rules governing those proceedings. *See* "Order Urging Electronic Filing and Service," dated December 3, 2025, which can be found at *https://www.epa.gov/system/files/documents/2025-12/2025-12-03-order-urging-electronic-filing-and-service.pdf*. Although EPA's regulations require submission via U.S. Mail or hand delivery,

EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. When submitting documents to the ALJD electronically, a person should utilize the e-filing system at *https://yosemite.epa.gov/oa/eab/eab-alj_upload.nsf*.

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 at *https://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. If you wish to include CBI in your request, please follow the applicable instructions at *https://www.epa.gov/dockets/commenting-epa-dockets#rules* and clearly mark the information that you claim to be CBI. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice.

II. Petition for Exemption

In the **Federal Register** of July 3, 2025 (90 FR 29515) (FRL–12474–05– OCSPP), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-11962) by TSG Consulting on behalf of Elicit Plant S.A.S, 1 Passage de la Croix, Lieu-dit le chataignier, 16220 Moulins-sur-tardoire, France. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates (CAS Reg. No. 84066-95-5) when used as an inert ingredient (surfactant) in pesticide formulations applied to growing crops pre-harvest. That document referenced a summary of the petition prepared by Elicit Plant S.A.S, which is available in the docket. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is establishing an exemption limiting the

concentration of alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates to no more than 12% of the final pesticide formulation to decrease any potential for surfactant effects on the respiratory system.

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. Final Tolerance Actions

A. *Aggregate Risk Assessment and Determination of Safety*

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 harm 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 specified 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 alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates, including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates follows.

B. *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 alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates 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.

The toxicological database of alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates is supported by data regarding several other mixtures of sucrose esters of fatty acids which have similar compositions and are manufactured by inter-esterification of sucrose with fatty acids derived from edible vegetable oils and fats (stearic acid and palmitic acid). These include fatty acids, C16-18 (even numbered), mono diesters with sucrose; Ryoto Sugar Ester S-570; and Ryoto Sugar Ester S-1170. EPA has determined that it is appropriate to bridge data from these three compounds to assess alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates due to similarities in the manufacturing processes and composition.

Based on the available toxicity studies, alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates is anticipated to have low overall toxicity. Physico-chemical

properties suggest low potential for dermal toxicity. Studies with surrogate chemicals showed low acute toxicity via the oral route, and low potential for skin irritation or sensitization. Alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates may be irritating to the eye.

There is a general concern regarding the disruption of natural surfactants in the lungs from inhalation of chemicals with surfactant properties. EPA lacks acute inhalation toxicity data for alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates to determine whether it may cause such effects. However, the chemical's physico-chemical properties suggest low potential for inhalation toxicity. Moreover, EPA is establishing a tolerance exemption with a 12% concentration limitation to reduce exposure, which EPA believes will also reduce any potential for such effects.

Read-across information did not identify adverse effects in a subchronic study, a combined developmental/reproductive toxicity study, or a chronic/carcinogenicity study. There was also no evidence of mutagenicity. Therefore, concern for mutagenicity and carcinogenicity is low. Neurotoxicity and immunotoxicity studies are not available for review. However, no evidence of neurotoxicity or immunotoxicity was observed in the available studies.

C. *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 or a reference dose, and a safe margin of exposure. 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 *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program.*

The hazard profile of alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates is adequately defined. Overall, alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates is of low acute, subchronic, and developmental toxicity. No systemic toxicity is observed up to 1,000 mg/kg/day. Since signs of toxicity were not observed, no toxicological endpoints of concern or PODs were identified. Therefore, a qualitative risk assessment for alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates can be performed.

D. *Exposure Assessment*

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates, EPA considered exposure under the proposed exemption from the requirement of a tolerance and existing uses. EPA assessed dietary exposures from alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates in food as follows:

Dietary exposure (food and drinking water) to alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates may occur following ingestion of foods with residues from their use in accordance with this exemption. Dietary exposure also may occur following ingestion of alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates when used as a food additive. Although alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates itself is not a food additive authorized by the U.S. Food and Drug Administration, similar sucrose esters of fatty acids, meeting the criteria

outlined in 21 CFR § 172.859 and 21 CFR § 172.869, are authorized for use as emulsifiers, stabilizers, and texturizers in various food products (e.g., chewing gum, coffee, beverages, sauces, meat, and seafood). However, a quantitative dietary exposure assessment was not conducted since a toxicological endpoint for risk assessment was not identified.

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 diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates may be present in pesticide and non-pesticide products (e.g., cosmetics) that may be used in and around the home. However, a quantitative residential exposure assessment was not conducted since a toxicological endpoint for risk assessment was not identified.

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."

Based on the lack of toxicity in the available database, EPA has not found alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates to share a common mechanism of toxicity with any other substances, and alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance exemption, therefore, EPA has assumed that alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates 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 website at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides*.

E. *Additional Safety Factor for the Protection of Infants and Children*

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 Food Quality Protection Act safety factor. 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.

Based on an assessment of alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children. Because there are no threshold effects associated with alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates, 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.

F. *Determination of Safety*

Because no toxicological endpoints of concern were identified, 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 residues of alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates.

G. *Analytical Enforcement Methodology*

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates in or on any food commodities. EPA is establishing a limitation on the amount of alpha-d-glucopyranoside, beta-d-fructofuranosyl,

mixed palmitates and stearates that may be used in pesticide formulations applied pre-harvest. This limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. 136 *et seq*. EPA will not register any pesticide formulation for food use that exceeds 12% alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates in the final pesticide formulation.

H. *Conclusion*

Therefore, an exemption from the requirement of a tolerance is established for residues of alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates (CAS Reg. No. 84066-95-5) when used as an inert ingredient (surfactant) in pesticide formulations applied to growing crops pre-harvest under 40 CFR 180.920 at no more than 12% of the final pesticide formulation.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders*.

A. *Executive Order 12866: Regulatory Planning and Review*

This action is exempt from review under Executive Order 12866 (58 FR 51735, October 4, 1993), because it establishes or modifies a pesticide tolerance or a tolerance exemption under FFDCA section 408 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.

B. *Executive Order 14192: Unleashing Prosperity Through Deregulation*

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because actions that establish a tolerance or a tolerance exemption under FFDCA section 408 are exempted from review under Executive Order 12866.

C. *Paperwork Reduction Act (PRA)*

This action does not impose an information collection burden under the PRA, 44 U.S.C.

3501 *et seq*., because it does not contain any information collection activities.

D. *Regulatory Flexibility Act (RFA)*

This action is not subject to the RFA, 5 U.S.C. 601 *et seq*. The RFA applies only to rules subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA), 5 U.S.C. 553, or any other statute. This rule is not subject to the APA but is subject to FFDCA section 408(d), which does not require notice and comment rulemaking to take this action in response to a petition.

E. *Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate of $100 million or more (in 1995 dollars and adjusted annually for inflation) as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

F. *Executive Order 13132: Federalism*

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not 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.

G. *Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on Tribal governments, on the relationship between the Federal government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal government and Indian Tribes.

H. *Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks*

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866

(see Unit IV.A.), and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

However, EPA's 2026 *Policy on Children's Health* applies to this action. This rule finalizes tolerance actions under the FFDCA, which 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 ..." (FFDCA 408(b)(2)(C)). The Agency's consideration is documented in the pesticide-specific registration review documents, located in the applicable docket at *https://www.regulations.gov*

I. *Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use*

This action is not subject to Executive Order 13211 (66 FR 28355) (May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

J. *National Technology Transfer Advancement Act (NTTAA)*

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

K. *Congressional Review Act (CRA)*

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action 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: August 25, 2026.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

For the reasons stated in the preamble, 40 CFR chapter I is amended as follows:

PART 180--TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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

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

2. Amend §180.920, by adding an entry for "Alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates (CAS Reg. No. 84066-95-5)" in alphabetical order to Table 1 to read as follows:

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

* * * * *

Table 1 to §180.920

Inert ingredients	Limits	Uses
* * * * * * *		
Alpha-d-glucopyranoside, beta-d-fructofuranosyl, mixed palmitates and stearates (CAS Reg. No. 84066-95-5)	No more than 12% of the final pesticide formulation	Surfactant
* * * * * * *		

[FR Doc. 2026-17579 Filed: 8/27/2026 8:45 am; Publication Date: 8/28/2026]