

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 73

[Docket No. FDA-2017-C-6238]

#### Colorcon, Inc.; Filing of Color Additive Petition

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification of petition.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Colorcon, Inc., proposing that the color additive regulations be amended to expand the safe use of calcium carbonate to include use in dietary supplement tablets and capsules.

**DATES:** The color additive petition was filed on October 15, 2020.

**ADDRESSES:** For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this document into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Christopher Kampmeyer, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1255.

**SUPPLEMENTARY INFORMATION:** Under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(d)(1)), we are giving notice that we have filed a color additive petition (CAP 0C0318), submitted by Colorcon, Inc., 275 Ruth Rd., Harleysville, PA 19438. The petition proposes to amend the color additive regulations in 21 CFR 73.70, "Calcium carbonate," to expand the use of calcium carbonate to include use in dietary supplement tablets and capsules, including coatings and printing inks, in amounts consistent with good manufacturing practice.

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(k) because the substance is intended to remain in food through ingestion by consumers and is not intended to replace macronutrients in food. In addition, the petitioner has stated that, to their knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental

assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: November 16, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2020-25600 Filed 11-19-20; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 73

[Docket No. FDA-2020-C-2131]

#### Ecoflora SAS; Filing of Color Additive Petition

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification of petition.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Ecoflora SAS, proposing that the color additive regulations be amended to provide for the safe use of jagua (genipin-glycine) blue in various food categories at levels consistent with good manufacturing practice.

**DATES:** The color additive petition was filed on July 31, 2020.

**ADDRESSES:** For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this document into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Richard E. Bonnette, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1235.

**SUPPLEMENTARY INFORMATION:** Under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(d)(1)), we are giving notice that we have filed a color additive petition (CAP 0C0317), submitted by Ecoflora, SAS, c/o Exponent, Inc., 1150 Connecticut Ave. NW, Suite 1100, Washington, DC 20036. The petition proposes to amend the color additive regulations in part 73 (21 CFR part 73, "Listing of Color Additives Exempt From Certification") to provide

for the safe use of jagua (genipin-glycine) blue derived from jagua fruit pulp (*Genipa americana*) as a color additive in: (1) Flavored milk; (2) dairy drinks and substitutes (milk shakes, milk substitutes, and other dairy drinks); (3) yogurt (dairy and non-dairy); (4) desserts (ice cream and frozen dairy and non-dairy desserts; pudding; gelatins, ices, and sorbets); (5) ready-to-eat cereals; (6) savory snacks (flavored potato chips; tortilla, corn, other chips); (7) candy and chewing gum; (8) non-alcoholic beverages (fruit drinks; nutritional beverages; smoothies); (9) flavored cream cheese-based spread; and (10) jams, syrups, icings, frostings, and fruit toppings and fillings, at levels consistent with good manufacturing practice.

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(k) because the substance is intended to remain in food through ingestion by consumers and is not intended to replace macronutrients in food. In addition, the petitioner has stated that, to their knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: November 16, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2020-25604 Filed 11-19-20; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG-2020-0459]

**RIN 1625-AA00**

#### Safety Zone; Tanapag Harbor, Saipan, CNMI

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard is proposing to establish a recurring safety zone for navigable waters within Tanapag Harbor, Saipan. This safety zone will encompass the designated swim course for the Escape from Managaha swim event in the waters of Tanapag Harbor, Saipan, Commonwealth of the Northern

Mariana Islands. This action is necessary to protect all persons and vessels participating in this marine event from potential safety hazards associated with vessel traffic in the area. Race participants, chase boats, and organizers of the event will be exempt from the safety zone. Entry of persons or vessels into the safety zone is prohibited unless authorized by the Captain of the Port (COTP) Guam. We invite your comments on this proposed rulemaking.

**DATES:** Comments and related material must be received by the Coast Guard on or before December 21, 2020.

**ADDRESSES:** You may submit comments identified by docket number USCG–2020–0459 using the Federal eRulemaking Portal at <https://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this proposed rulemaking, call or email Chief Petty Officer Robert Davis, Sector Guam, U.S. Coast Guard, by telephone at (671) 355–4866, or email at [WWMGuam@uscg.mil](mailto:WWMGuam@uscg.mil).

#### **SUPPLEMENTARY INFORMATION:**

#### **I. Table of Abbreviations**

CFR Code of Federal Regulations  
DHS Department of Homeland Security  
FR Federal Register  
NPRM Notice of proposed rulemaking  
§ Section  
U.S.C. United States Code

#### **II. Background, Purpose, and Legal Basis**

The Escape from Managaha swim event is a recurring annual event. We have established safety zones for this swim event in past years.

The purpose of this rule is to ensure the safety of the participants and the navigable waters in the safety zone before, during, and after the scheduled swim event. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034 (previously codified in 33 U.S.C. 1231).

#### **III. Discussion of Proposed Rule**

The COTP is proposing to establish a safety zone from 5:00 a.m. to 8:30 a.m. for one day on a Saturday or Sunday occurring annually between February and April. This safety zone is necessary to protect all persons and vessels participating in this marine event from potential safety hazards associated with vessel traffic in the area. Race participants, chase boats, and organizers of the event will be exempt from the

safety zone. Entry of persons or vessels into this safety zone is prohibited unless authorized by the COTP. The regulatory text we are proposing appears at the end of this document.

#### **IV. Regulatory Analyses**

We developed this proposed rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive Orders, and we discuss First Amendment rights of protestors.

##### *A. Regulatory Planning and Review*

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This NPRM has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. Vessel traffic will be able to safely transit around this safety zone, which will impact a small designated area of Tanapag Harbor for 2 hours. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule allows vessels to seek permission to enter the zone.

##### *B. Impact on Small Entities*

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

##### *C. Collection of Information*

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

##### *D. Federalism and Indian Tribal Governments*

A rule has implications for federalism under Executive Order 13132 (Federalism), if it has a substantial direct effect 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. We have analyzed this proposed rule under that Executive Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments) because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

##### *E. Unfunded Mandates Reform Act*

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires

Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

#### F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a safety zone lasting for 2 hours that will prohibit entry within 100-yards of swim participants. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A preliminary Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

#### G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

#### V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment

applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at <https://www.regulations.gov>. If your material cannot be submitted using <https://www.regulations.gov>, call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to <https://www.regulations.gov> and will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's Correspondence System of Records notice (84 FR 48645, September 26, 2018).

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at <https://www.regulations.gov> and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

#### List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 165 as follows:

#### PART 165—SAFETY ZONE; TANAPAG HARBOR, SAIPAN, CNMI

- 1. The authority citation for part 165 continues to read as follows:

**Authority:** 46 U.S.C. 70034; 46 U.S.C. 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

- 2. Add § 165.1417 before the center heading “Seventeenth Coast Guard District” to read as follows:

#### § 165.1417 Safety Zone; Tanapag Harbor, Saipan, CNMI.

(a) *Location.* The following area, within the Guam Captain of the Port (COTP) Zone (See 33 CFR 3.70–15), all navigable waters within a 100-yard radius of race participants for Escape for Managaha Swim in Tanapag Harbor, Saipan. Race participants, chase boats, and organizers of the event will be exempt from the safety zone.

(b) *Definitions.* As used in this section, designated representative means a Coast Guard Patrol Commander, including a Coast Guard

coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port (COTP) Sector Guam in the enforcement of the safety zone.

(c) *Regulations.* (1) In accordance with the general regulations in section § 165.23, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the COTP or a designated on-scene representative.

(2) This safety zone is closed to all persons and vessel traffic, except as may be permitted by the COTP or a designated on-scene representative.

(3) The “on-scene representative” of the COTP is any Coast Guard commissioned, warrant, or petty officer who has been designated by the COTP to act on his or her behalf.

(4) Persons and Vessel operators desiring to enter or operate within the safety zone must contact the COTP or an on-scene representative to obtain permission to do so. The COTP or an on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP or an on-scene representative.

(d) *Enforcement period.* This safety zone will be enforced at a specified date between February and April. The Coast Guard will provide advance notice of enforcement and a broadcast notice to mariners to inform public of specific date.

Dated: November 17, 2020.

**Christopher M. Chase,**  
Captain, U.S. Coast Guard, Captain of the Port, Guam.

[FR Doc. 2020–25766 Filed 11–19–20; 8:45 am]

**BILLING CODE 9110–04–P**

#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 300

[EPA–HQ–SFUND–1983–0002; EPA–HQ–SFUND–1986–0005; EPA–HQ–SFUND–1990–0010; FRL–10016–73–OLEM]

#### Proposed Deletions From the National Priorities List

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule; notice of intent.

**SUMMARY:** The Environmental Protection Agency (EPA) is issuing a Notice of Intent to partially delete four sites from the National Priorities List (NPL) and requests public comments on this