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Issued in Des Moines, Washington, on May 1, 2019.

**Michael Kaszycki,**

*Acting Director, System Oversight Division, Aircraft Certification Service.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 73

[Docket No. FDA-2019-C-1782]

#### CooperVision, 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 CooperVision, Inc., proposing that the color additive regulations be amended to provide for the safe use of disperse orange 3 methacrylamide to color contact lenses. The color additive is intended to be copolymerized with various monomers to produce colored contact lens materials.

**DATES:** The color additive petition was filed on March 28, 2019.

**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.

**FOR FURTHER INFORMATION CONTACT:** Molly A. Harry, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1075.

**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 9C0315), submitted by CooperVision, Inc., 5870 Stoneridge Dr., Suite 1, Pleasanton, CA 94588. The petition proposes to amend the color additive regulations in 21 CFR part 73, *Listing of*

*Color Additives Exempt from Certification*, to provide for the safe use of disperse orange 3 methacrylamide (CAS Reg. No. 58142-15-7; CAS name 2-propenamamide, 2-methyl-N-[4-[2-(4-nitrophenyl)diazenyl]phenyl]-) to color contact lenses. The color additive is intended to be copolymerized with various monomers to produce colored contact lens materials.

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(l) because disperse orange 3 methacrylamide is intended for use in contact lenses. 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: May 2, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019-09411 Filed 5-7-19; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 100

[Docket Number USCG-2019-0300]

**RIN 1625-AA08**

#### Special Local Regulations; Festival of Sail Duluth 2019 Parade of Sail, Lake Superior, Duluth, MN

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard is proposing to establish a temporary special local regulation for a designated area of the Duluth Harbor entrance to Superior Bay on Lake Superior during the Festival of Sail 2019 event in Duluth, MN. This action is necessary to provide for the safety of life on these navigable waters around the port of Duluth, MN during a parade of sail event on August 11, 2019. This proposed rulemaking would prohibit persons and vessels from being in the designated region unless authorized by the Captain of the Port Duluth or a designated representative. We invite your comments on this proposed rulemaking.

**DATES:** Comments and related material must be received by the Coast Guard on or before June 7, 2019.

**ADDRESSES:** You may submit comments identified by docket number USCG-2019-0300 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 Lieutenant Abbie Lyons, Waterways Management, MSU Duluth, U.S. Coast Guard; telephone 218-725-3818, email [Abbie.E.Lyons@uscg.mil](mailto:Abbie.E.Lyons@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**

On December 11, 2018, Draw Events LLC notified the Coast Guard that it will be conducting a Parade of Sail from 7 a.m. through 1 p.m. on August 11, 2019, as part of the 2019 Festival of Sail event in Duluth, MN from August 11 through August 13, 2019. Hazards from spectator vessels and the limited maneuverability of the sailing vessels exist. The Captain of the Port Duluth (COTP) has determined that potential hazards associated with the parade of sail would be a safety concern for anyone within the route of the parade.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within the parade route before, during, and immediately after the scheduled event. The legal basis for this proposed rule is the Coast Guard's authority under 46 U.S.C. 70041; 33 CFR 1.05-1.

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

The COTP is proposing to establish a special local regulation from 7 a.m. through 1 p.m. on August 11, 2019. The special local regulation would cover all navigable waters encompassed within the following boundaries: Beginning at position 46°46'48.36" N, 092°05'16.44" W, across Duluth Harbor to 46°47'02.76" N, 092°05'17.88" W, turning north toward the Duluth Lift Bridge at to 46°47'19.32" N, 092°04'04.80" W, to 46°46'50.88" N, 092°05'17.88" W, out

the Duluth Harbor Entrance at 46°46'45.12" N, 092°05'35.16" W, then northwest to 46°46'45.12" N, 092°05'39.84" W back to the north Duluth Entrance Light at 46°47'01.32" N, 092°05'51.00" W, through the canal at 46°47'00.60" N, 092°05'52.08" W, then along Minnesota Point at 46°46'51.60" N, 092°05'46.32" W, entering Minnesota Slip at 46°46'39.00" N, 092°06'03.96" W, encompassing the slip from 46°46'32.16" N, 092°05'38.76" W to 46°46'41.52" N, 092°05'36.24" W and back out the slip at 46°46'42.60" N, 092°05'34.44" W and back to the starting position of 46°46'48.36" N, 092°05'16.44" W.

The duration of the zone is intended to protect the safety of vessels and these navigable waters before, during, and immediately after the scheduled 7 a.m. through 1 p.m. Parade of Sail. Only the designated sailing vessels associated with the event are permitted within the zone. No other vessels or persons will be permitted to enter the zone without obtaining permission from the COTP or a designated representative. The COTP or a designated representative may be contacted via VHF Channel 16 or by telephone at (218) 428-9357. The regulatory text proposed 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 availability of the Superior Harbor entrance as an alternate entry into Superior Bay, the short time frame of the special local regulation, and the estimated number of spectator vessels around the Duluth Harbor entrance for the event. We anticipate

that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues. The Coast Guard will issue a Broadcast Notice to Mariners via VHF-FM marine Channel 16 about the zone, and the rule would allow 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 restricted area 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 contact 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 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 contact 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 and Commandant Instruction M16475.1D, 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 special local regulation lasting 6 hours that would prohibit entry within a designated area around the Duluth Harbor entrance. Normally such actions are categorically excluded

from further review under paragraph L[61] of Appendix A, Table 1 of DHS Instruction Manual 023-01-001-01, Rev. 01. 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 contact 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 <http://www.regulations.gov>. If your material cannot be submitted using <http://www.regulations.gov>, contact 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 the docket, visit <https://www.regulations.gov/privacyNotice>.

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 100

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

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 100 as follows:

#### PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS.

■ 1. The authority citation for part 100 continues to read as follows:

**Authority:** 46 U.S.C. 70041; 33 CFR 1.05-1.

■ 2. Add § 100.T09-0300 to read as follows:

#### § 100.T09-0300 Special Local Regulations; Festival of Sail Duluth 2019 Parade of Sail, Lake Superior, Duluth, MN.

(a) *Regulated areas.* (1) This Area includes all waters of Lake Superior and Duluth Harbor bounded by Rice's Point to the west and Duluth to the north, within the following boundaries: Beginning at position 46°46'48.36" N, 092°05'16.44" W, across Duluth Harbor to 46°47'02.76" N, 092°05'17.88" W, turning north toward the Duluth Lift Bridge to 46°47'19.32" N, 092°04'04.80" W, to 46°46'50.88" N, 092°05'17.88" W, out the Duluth Harbor Entrance at 46°46'45.12" N, 092°05'35.16" W, then northwest to 46°46'45.12" N, 092°05'39.84" W back to the north Duluth Entrance Light at 46°47'01.32" N, 092°05'51.00" W, through the canal at 46°47'00.60" N, 092°05'52.08" W, then along Minnesota Point at 46°46'51.60" N, 092°05'46.32" W, entering Minnesota Slip at 46°46'39.00" N, 092°06'03.96" W, encompassing the slip from 46°46'32.16" N, 092°05'38.76" W to 46°46'41.52" N, 092°05'36.24" W and back out the slip at 46°46'42.60" N, 092°05'34.44" W and back to the starting position of 46°46'48.36" N, 092°05'16.44" W.

(b) *Special local regulations.* (1) In accordance with the general regulations in § 100.35 of this part, entry into, transiting, or anchoring within the regulated areas is prohibited unless authorized by the Captain of the Port (COTP) Duluth or on-scene representatives.

(2) Vessels and persons receiving COTP Duluth or on-scene representative authorization to enter the area of this special local regulation must do so in accordance with the following restrictions:

(i) Vessels and persons must transit at a speed not exceed six (6) knots or at no wake speed, whichever is less. Vessels proceeding under sail will not be allowed in this Area unless also propelled by machinery, due to limited maneuvering ability around numerous other spectator craft viewing the Festival of Sail.

(ii) Vessels and persons will not be permitted to impede the parade of sail once it has commenced, as the tall ships are extremely limited in their ability to maneuver.

(3) The Coast Guard will provide notice of the regulated area prior to the event through Local Notice to Mariners and Broadcast Notice to Mariners. Notice will also be provided by on-scene representatives.

(4) The "on-scene representative" of the COTP Duluth is any Coast Guard commissioned, warrant, or petty officer and any Federal, State, or local officer designated by the COTP to act on his or her behalf.

(5) Vessel operators desiring to enter or operate within the regulated area shall contact the COTP Duluth by telephone at (218) 428-9357, or on-scene representative via VHF radio on Channel 16, to obtain permission to do so. Vessel operators given permission to enter, operate, transit through, anchor in, or remain within the regulated areas must comply with all instructions given by COTP Duluth or on-scene representatives.

(c) *Effective date.* These regulations are effective Sunday, August 11, 2019; from 7 a.m. through 1 p.m.

Dated: May 2, 2019.

**E. E. Williams,**

*Commander, U.S. Coast Guard, Captain of the Port Duluth.*

[FR Doc. 2019-09421 Filed 5-7-19; 8:45 am]

**BILLING CODE 9110-04-P**

#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Chapter I

[EPA-HQ-OPPT-2019-0038; FRL-9992-67]

#### TSCA Section 21 Petition To Initiate a Reporting Rule Under TSCA Section 8(a) for Asbestos; Reasons for Agency Response

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

**ACTION:** Petition for rulemaking; denial.

**SUMMARY:** This document provides the reasons for EPA's response to a January 31, 2019, petition it received under section 21 of the Toxic Substances Control Act (TSCA) from the Attorneys General of Massachusetts, California, Connecticut, Hawaii, Maine, Maryland, Minnesota, New Jersey, New York, Oregon, Pennsylvania, Rhode Island, Vermont, Washington, and the District of Columbia ("petitioners"). Generally, the petitioners requested that EPA initiate a rulemaking proceeding under TSCA section 8(a) for the reporting of the manufacture (including import) and processing of asbestos. After careful consideration, EPA denied the petition for the reasons discussed in this document.