

"Guidance for Industry Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products."

3. Section 886.5928 is revised to read as follows:

§ 886.5928 Soft (hydrophilic) contact lens care products.

(a) *Identification.* A soft (hydrophilic) contact lens care product is a device intended for use in the cleaning, rinsing, disinfecting, lubricating/rewetting, or storing of a soft (hydrophilic) contact lens. This includes all solutions and tablets used together with soft (hydrophilic) contact lenses and heat disinfecting units intended to disinfect a soft (hydrophilic) contact lens by means of heat.

(b) *Classification.* Class II (Special Controls) Guidance Document: "Guidance for Industry Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products."

§ 886.5933 [Removed and Reserved]

4. Section 886.5933 *Contact lens heat disinfection unit* is removed and reserved.

Dated: May 28, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97-14751 Filed 6-5-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD01-97-009]

RIN 2115-AE46

Special Local Regulation: Fireworks Displays Within the First Coast Guard District

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is revising the special local regulation for annual fireworks displays in the First Coast Guard District. The final rule includes additional fireworks displays and arranges the events listed in Table 1 by event date. This regulation is necessary to control vessel traffic within the immediate vicinity of the fireworks launch sites and to ensure the safety of life and property during each event.

DATE: Effective June 23, 1997.

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander James B.

Donovan, Office of Search and Rescue, First Coast Guard District, (617) 223-8268.

SUPPLEMENTARY INFORMATION:

Regulatory History

A notice of proposed rulemaking (NPRM) was published on April 21, 1997, (62 FR 19240) in the **Federal Register** proposing to update the permanent special local regulation for the annually recurring fireworks displays in the First Coast Guard District. The Coast Guard received no comments on the proposed rulemaking. A public hearing was not requested and one was not held.

Background and Purpose

Each year, organizations in the First District sponsor fireworks displays in the same general location during the same general time period. The Coast Guard is updating the special local regulation at 33 CFR 100.114 which provides a regulated area surrounding the launch platform used during each fireworks display. Table 1 of the regulation provides dates and locations for the annual fireworks events. This final rule updates Table 1 by adding and deleting several events. Table 1 has also been revised to list the events in chronological order to ease administration by the Coast Guard and provide better notice to the public.

Each event listed in Table 1 will use a barge or on-shore site as the fireworks launch platform. The special local regulation controls vessel movement within a 500 yard radius around the launch platform to ensure the safety of persons and property at these events. In the event the fireworks are launched from shore, the regulated area only includes navigable waters that fall within a 500 yard radius of the launch site. Coast Guard personnel on-scene may allow persons within the 500 yard radius should conditions permit. The Coast Guard publishes notices in the **Federal Register** each year which provide the exact dates and times for these events.

Good cause exists for this rule to become effective in less than 30 days. Due to the need to publish notice in the **Federal Register** of the exact dates and times of each event and the necessity to have the regulation in effect for events celebrating the Fourth of July, this final rule is being made effective in less than 30 days after publication. Any delay encountered in making this rule effective would be contrary to the public interest as the rule is needed to ensure the safety of the boating public during these events.

Discussion of Changes

No comments were received. The Coast Guard has deleted the Museum of Science Memorial Day Fireworks and the Yampol Family Fireworks from Table 1. Both events are no longer held. Also, the Macys' July 4th Fireworks Display has been deleted from Table 1 since it is not an appropriate event for inclusion in section 100.114.

Regulatory Evaluation

This proposal is not a significant regulatory action under Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been reviewed by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). Due to the short duration of each fireworks display, the advance notice provided to the marine community, and the small size of each regulated area, the Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation, under paragraph 10e of the regulatory policies and procedures of DOT, is unnecessary.

Small Entities

The Coast Guard has considered the economic impact of this rule on small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) For the reasons discussed in the Regulatory Evaluation, the Coast Guard has determined that this rule will have no significant economic impact on small entities. If, however, you think that your business or organization qualifies as a small entity and that this rule will have a significant economic impact on your business or organization, please submit a comment explaining why you think it qualifies and in what way and to what degree this rule will economically affect it.

Collection of Information

This proposal contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this proposal under the principles and criteria contained in Executive Order 12612 and has determined that this proposal does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard has considered the environmental impacts of this proposal and concluded that, under paragraph 2.B.2.e.34(h) of COMDTINST 16475.1B, (as revised by 61 FR 13564, March 27, 1996) this proposal is a special local regulation issued in conjunction with annual regattas or marine parades and is categorically excluded from further environmental documentation.

List of Subjects in 33 CFR Part 100

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

Final Regulation

For reasons set out in the preamble, the Coast Guard amends 33 CFR Part 100 as follows:

PART 100—[AMENDED]

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

Authority: 33 USC 1233 through 1236; 49 CFR 1.46; 33 CFR 100.35.

2. In section 100.114 table 1 is revised to read as follows:

§ 100.114 First Coast Guard District Fireworks.

* * * * *

Table 1—Fireworks Displays

December

1. First Night Fireworks
Sponsor: First Night Inc.
Date: December 31
Location: Boston Inner Harbor, Boston, MA
2. Night Martha's Vineyard
Sponsor: Town of Martha's Vineyard Chamber of Commerce
Date: December 31
Location: Vineyard Haven Harbor, Martha's Vineyard, MA
3. First Night Mystic
Sponsor: Mystic Community Center
Date: December 31
Location: Mystic River, Mystic, CT
4. City of New Bedford First Night
Sponsor: City of New Bedford
Date: December 31
Location: New Bedford Harbor, New Bedford, MA

May

1. Hull Memorial Day Festival
Sponsor: Town of Hull
Date: Memorial Day week or weekend
Location: Nantasket Beach, Hull, MA
2. Ellis Island Medals of Honor Ceremony Fireworks Display
Sponsor: National Ethnic Coalition of Organizations
Date: Third Sunday of May
Location: Upper Bay New York Harbor, New York, NY

June

1. Brick Founders Day Fireworks
Sponsor: Brick Township Chamber of Commerce
Date: First weekend in June
Location: Metedeconk River, Windward Beach, Brick Township, NJ
2. Barnum Festival Fireworks
Sponsor: The Barnum Foundation
Date: A date during the last week of June or first week of July
Location: Location Seaside Park—Bridgeport Harbor, Bridgeport, CT

July

1. Boston Harborfest Fireworks
Sponsor: Harborfest Committee
Date: A date during late June/early July
Location: Boston Inner Harbor, Boston, MA
2. American Legion Post 83 Fireworks
Sponsor: Town of Branford American Legion Post 83
Date: A date during late June/early July
Location: Branford Point, Branford, CT
3. Devon Yacht Club Fireworks
Sponsor: Devon Yacht Club, Amagansett, NY
Date: A date within the first week of July
Location: Devon Yacht Club, Amagansett, NY
4. Hempstead Fireworks
Sponsor: Town of Hempstead, NY
Date: A date within the first week of July
Location: Point Lookout, Hempstead, NY
5. Schooner Days Fireworks
Sponsor: Town of Rockland Chamber of Commerce
Date: A date within the first two weeks of July
Location: Rockland Harbor, Rockland, ME
6. Summer Music Fireworks
Sponsor: Summer Music, Inc.
Date: On or about July 3
Location: Niantic River, Harkness Park, Waterford, CT
7. Bangor Fireworks
Sponsor: Bangor 4th of July Corporation
Date: On or about July 4
Location: Bangor/Brewer waterfront, ME
8. Bar Harbor Fireworks
Sponsor: Bar Harbor Chamber of Commerce
Date: On or about July 4
Location: Bar Harbor/Bar Island, ME
9. Stewarts 4th of July Fireworks Display
Sponsor: W. P. Stewart
Date: On or about July 4
Location: Soms Sound, Northeast Harbor, ME
10. Walsh's Fireworks
Sponsor: Mr. Patrick Walsh
Date: On or about July 4

Location: Union River Bay, ME

11. Colchester Bay, VT
Sponsor: Town of Colchester Parks and Recreation Dept.
Date: On or about July 4
Location: Malletts Bay, Lake Champlain, Colchester, VT
12. Town of Barnstable Fireworks
Sponsor: Town of Barnstable
Date: On or about July 4
Location: Dunbar Point/Kalmus Beach, Barnstable, MA
13. Fourth of July Celebration
Sponsor: Farms-Pride 4th of July Committee, Inc.
Date: On or about July 4
Location: West Beach, Manchester Bay, Beverly Farms, MA
14. Edgartown Fireworks
Sponsor: Edgartown Firefighters Association
Date: On or about July 4
Location: Edgartown Harbor, Edgartown, MA
15. Falmouth Fireworks
Sponsor: Falmouth Fireworks Committee
Date: On or about July 4
Location: Falmouth Harbor, .25 nm east of buoy #16, Falmouth, MA
16. Gloucester Fireworks
Sponsor: Gloucester Chamber of Commerce
Date: On or about July 4
Location: Gloucester Harbor, Gloucester, MA
17. Marion Fireworks
Sponsor: Town of Marion Fireworks Committee
Date: On or about July 4
Location: Silver Shell Beach, Marion, MA
18. City of New Bedford Fireworks
Sponsor: City of New Bedford
Date: On or about July 4
Location: New Bedford Harbor, New Bedford, MA
19. Onset Fireworks
Sponsor: Prudential Commerce Onset Fire District
Date: On or about July 4
Location: Onset Harbor, Onset, MA
20. Plymouth Fireworks Display
Sponsor: July Four Plymouth Inc.
Date: On or about July 4
Location: Plymouth Harbor, Plymouth, MA
21. Wellfleet Fireworks
Sponsor: Wellfleet Fireworks Committee
Date: On or about July 4
Location: Indian Neck Jetty, Wellfleet, MA
22. Weymouth 4th of July Fireworks
Sponsor: Town of Weymouth Harbormaster
Date: On or about July 4
Location: Weymouth Fore River, Weymouth, MA
23. Yarmouth-Dennis Fireworks

- Sponsor: Yarmouth-Dennis Chamber of Commerce
Date: On or about July 4
Location: Nantucket Sound, east of channel entrance to Bass River, Yarmouth, MA
24. Bristol 4th of July Fireworks
Sponsor: Bristol Fourth of July Committee
Date: On or about July 4
Location: Bristol Harbor, Bristol, RI
25. Oyster Harbor Club Fourth of July Festival
Sponsor: Oyster Harbor Club, Inc.
Date: On or about July 4
Location: Tim's Cove, North Bay, Osterville, RI
26. Shooters Independence Day
Sponsor: Shooters Waterfront Cafe USA
Date: On or about July 4
Location: Providence River off India Point Park, Providence, RI
27. Tiverton Waterfront Festival
Sponsor: Tiverton Waterfront Festival Committee
Date: On or about July 4
Location: Grinnel's Beach, Sakonnet River, Tiverton, RI
28. Fairfield Aerial Fireworks
Sponsor: Fairfield Park Commission
Date: On or about July 4
Location: Jennings Beach, Long Island Sound, Fairfield, CT
29. Subfest Fireworks
Sponsor: U.S. Naval Submarine Base
Date: On or about July 4
Location: Thames River, Groton, CT
30. Middletown Fireworks
Sponsor: City of Middletown
Date: On or about July 4
Location: Connecticut River, Middletown, CT
31. Hartford Riverfest
Sponsor: July 4th Riverfest, Inc.
Date: On or about July 4
Location: Connecticut River, Hartford, CT
32. City of Norwalk Fireworks
Sponsor: Norwalk Recreation and Parks Department
Date: On or about July 4
Location: Calf Pasture Beach, Long Island Sound, Norwalk, CT
33. Norwich American Wharf Fireworks
Sponsor: American Wharf Marina
Date: On or about July 4
Location: Norwich Harbor, Norwich, CT
34. Old Lyme Fireworks
Sponsor: Mr. James R. Rice
Date: On or about July 4
Location: South View Beach, Long Island Sound, Old Lyme, CT
35. Stratford Fireworks
Sponsor: Town of Stratford
Date: On or about July 4
Location: Short Beach, Stratford, CT
36. Westport P.A.L. Fireworks
Sponsor: Westport Police Athletic League
Date: On or about July 4
Location: Compo Beach, Westport, CT
37. Bayville Crescent Club Fireworks
Sponsor: Bayville Crescent Club, Bayville, NY
Date: On or about July 4
Location: Cooper Bluff, Cove Neck, NY
38. Montauk Independence Day
Sponsor: Montauk Chamber of Commerce
Date: On or about July 4
Location: Montauk Town Beach, Montauk, NY
39. Dolan Family Fireworks
Sponsor: Mr. Charles F. Dolan
Date: On or about July 4
Location: Cove Point, Oyster Bay, NY
40. Jones Beach State Park Fireworks
Sponsor: Long Island State Park Administration Headquarters
Date: On or about July 4
Location: Fishing Pier, Jones Beach State Park, Wantagh, NY
41. Staten Island's 4th of July
Sponsor: Borough of Staten Island
Date: On or about July 4
Location: Raritan Bay, vicinity of federal anchorages 44 and 45, Ward Point Bend, NY/NJ
42. Fireworks on the Navesink
Sponsor: Red Bank Fireworks Committee
Date: On or about July 4
Location: Navesink River, 4 nm WSW Oceanic Bridge, Red Bank, NJ
43. Brick Summerfest Fireworks
Sponsor: Brick Township Chamber of Commerce
Date: On or about July 4
Location: Metedeconk River, Windward Beach, Brick Township, NJ
44. Thames River Fireworks
Sponsor: Town of Groton
Date: Weekend following July 4
Location: Thames River, off Electric Boat, Groton, CT
45. Stamford Fireworks
Sponsor: City of Stamford
Date: A date within first two weeks of July
Location: Westcott Cove, Stamford, CT
46. Town of Babylon Fireworks
Sponsor: Town of Babylon, NY
Date: A date within the first two weeks of July
Location: Nezeras Island, Babylon, NY
47. Boys Harbor Fireworks Extravaganza
Sponsor: Boys Harbor Inc.
Date: Second or third weekend in July
Location: Three Mile Harbor, East Hampton, NY
48. Belfast Fireworks
Sponsor: Belfast Bay Festival Committee
Date: Third Saturday in July
Location: Belfast Bay, ME
- August
1. National Night Out Against Crime
Sponsor: 100th Precinct Community Council
Date: First Tuesday of August
Location: Rockaway Park, Rockaway Beach, NY
2. Summer Music Fireworks
Sponsor: Summer Music Inc.
Date: On or about August 3
Location: Niantic River, Harkness Park, Waterford, CT
3. Hartford Riverfront Regatta
Sponsor: Riverfront Recapture Inc.
Date: First or second weekend in August
Location: Connecticut River, Hartford, CT
4. Fall River Celebrates America Fireworks
Sponsor: Fall River Chamber of Commerce
Date: Second Saturday in August
Location: Taunton River, vicinity of bouy #17, Fall River, MA
5. Summer Music Fireworks
Sponsor: Summer Music Inc.
Date: On or about August 23
Location: Niantic River, Harkness Park, Waterford, CT
6. Oaks Bluff Fireworks
Sponsor: Oaks Bluff Fireman's Civic Association
Date: A date during the last two weeks in August
Location: Oaks Bluff Beach, Oaks Bluff, MA
7. Camden Fireworks Display
Sponsor: Town of Camden Chamber of Commerce
Date: Labor Day weekend
Location: Camden Harbor, Camden, ME
8. Gloucester Fireworks
Sponsor: Gloucester Chamber of Commerce
Date: Labor Day holiday weekend
Location: Gloucester Harbor, Gloucester, MA
9. Salute to Summer
Sponsor: Naval Education and Training Center
Date: Friday of weekend preceding Labor Day holiday weekend
Location: Narragansett Bay, East Passage, off Coasters Harbor Island, Newport, RI
10. Norwich Harbor Day Fireworks
Sponsor: Harbor Day Committee
Date: Last Sunday in August
Location: Norwich Harbor, off American Wharf Marina, Norwich, CT
- September
1. Grand Fiesta Italiana
Sponsor: Sons of Italy, Port Washington, NY
Date: First Saturday following Labor Day
Location: Hempstead Harbor, Hempstead, NY
2. Taste of Italy
Sponsor: Italian Heritage Committee
Date: Weekend following Labor Day holiday weekend

Location: Norwich Harbor, off Norwich Marina, Norwich, CT

3. Norwalk Oyster Festival Fireworks
Sponsor: Norwalk Seaport Association
Date: A date within the first two weekends of September

Location: Norwalk Harbor, Norwalk, CT
4. Anniversary Fireworks

Sponsor: Town of Chilmark

Date: On or about 14 September

Location: Menemsha Beach, Chilmark, MA

5. City of Yonkers Fireworks

Sponsor: City of Yonkers

Date: Third Saturday of September

Location: Hudson River, Yonkers, NY

6. City of Yonkers Fireworks

Sponsor: City of Yonkers

Date: A date during the second or third weekend of September

Location: Hudson River

7. Cow Harbor Day Fireworks

Sponsor: Village of Northport Harbor

Date: A date within last two weekends of September

Location: Sand Pit, Northport Harbor, Northport, NY

8. Rensselaer Festival

Sponsor: City of Rensselaer

Date: A date during the second or third weekend in September

Location: Hudson River, Rensselaer, NY

9. Deepavali Festival

Sponsor: Association of Indians in America, Inc.

Date: A day during last week of September or first week of October

Location: East River, Manhattan, NY

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Dated: May 22, 1997.

J.L. Linnon,

Rear Admiral, U.S. Coast Guard Commander,
First Coast Guard District.

[FR Doc. 97-14742 Filed 6-5-97; 8:45 am]

BILLING CODE 4910-14-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[AL-044-1 9710a; FRL5829-9]

Approval and Promulgation of Implementation Plans: Revisions to Several Chapters and Appendices of the Alabama Department of Environmental Management (ADEM) Administrative Code for the Air Pollution Control Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: On October 30, 1996, the State of Alabama through ADEM submitted a State Implementation Plan

(SIP) revision of the ADEM Administrative Code for the Air Pollution Control Program. Revisions were made to Chapters 335-3-1, -2, -3, -4, -5, -6, -8, -9, -10, -11, -12, -13, -14, -15, -16, -17, and -18, Appendices C, E, and F. The EPA will not be taking action in this document on the revisions made to chapters 335-3-10, -11, -16, -17, and -18 because they are not a part of the federally approved SIP for Alabama.

DATES: This action will be effective August 5, 1997 unless adverse or critical comments are received by July 7, 1997. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: Comments may be mailed to Kimberly Bingham at the EPA Region 4 address listed below. Copies of the material submitted by ADEM may be examined during normal business hours at the following locations:

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street, SW, Washington DC 20460.

Environmental Protection Agency, Atlanta Federal Center, Region 4 Air Planning Branch, Atlanta Federal Center, 61 Forsyth Street, SW, Atlanta, Georgia 30303-3104.
Alabama Department of Environmental Management, 1751 Congressman W. L. Dickinson Drive, Montgomery, Alabama 36109.

FOR FURTHER INFORMATION CONTACT: Kimberly Bingham, Regulatory Planning Section, Air Planning Branch, Air Pesticides and Toxics Management Division, Region 4, Environmental Protection Agency, Atlanta Federal Center, 61 Forsyth Street, SW, Atlanta, Georgia 30303. The telephone number is (404)562-9038.

SUPPLEMENTARY INFORMATION: On October 30, 1996, the State of Alabama through ADEM submitted numerous changes to their Air Division Administrative Code to be incorporated into their SIP. Many of the revisions were made to make the SIP consistent with the Alabama State law including a more uniform numbering system. The following is a brief summary of the major revisions made to Chapters 335-3-1, -2, -3, -4, -5, -6, -8, -9, -12, -13, and -14, Appendices C, E, and F. There are also numerous minor numbering and wording changes that are not specifically discussed in this notice.

Summary of Revisions

Chapter 335-3-1—General Provisions

ADEM is revising 335-3-1-.02(gggg) to add perchloroethylene (PERC or

tetrachloroethylene) to the list of compounds excluded from the definition of volatile organic compounds (VOC) on the basis that this compound has been determined to have negligible photochemical reactivity. The EPA published a notice in the **Federal Register** on February 7, 1996, (61 FR 4590), which documents the Agency's decision to add perchloroethylene to this list of excluded compounds.

ADEM revised 335-3-1-.04 to clarify reports the ADEM Director may require.

Chapter 335-3-3—Control of Open Burning and Incineration

Rule 335-3-.01(8) was revised to make clear that only wood vegetation, coal, propane, kerosene, and fuel oil or used oil may be used as fuel in salamanders for heating purposes.

Chapter 335-3-4—Control of Particulate Emissions

This chapter was revised to change all references to "equivalent opacity" to opacity. The adjective equivalent is not needed when describing visible emission restrictions from sources.

Rule 335-3-4-.01 was amended to delete paragraph (3) which addresses uncombined water. Paragraph (2) requires that sources' opacity standards comply with EPA Reference Method 9 which adequately addresses uncombined water.

Chapter 335-3-6—Control of Organic Emissions

Rules 335-3-6-.19 and 335-3-6-.40 were deleted because they address requirements for perc dry cleaning control technique guidelines which are no longer needed because perc was exempted from the list of VOCs.

Rule 335-2-6-.37(13) and Appendix F were amended to incorporate by reference EPA's revised capture efficiency guidance.

Chapter 335-3-15—Synthetic Minor Operating Permits

Rule 335-3-15-.04 was amended to better define the application process for stationary sources applying for synthetic minor operating permits. It also states that new stationary sources applying for a permit at a greenfield site will not be able to initiate construction until the permit is issued.

Final action

The EPA is approving the aforementioned revisions because they meet the Agency requirements. This action is being published without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments.