

dibasic sodium phosphate/monobasic sodium phosphate oral solution) as a single daily dose. "Do not take more than 45 mL (9 teaspoonfuls or 3 tablespoonfuls) in a 24-hour period." Children 10 and 11 years of age: Oral dosage is dibasic sodium phosphate 1.71 to 3.78 grams and monobasic sodium phosphate 4.5 to 10.1 grams (10 to 20 mL dibasic sodium phosphate/monobasic sodium phosphate oral solution) as a single daily dose. "Do not take more than 20 mL (4 teaspoonfuls) in a 24-hour period." Children 6 to 9 years of age: Oral dosage is dibasic sodium phosphate 0.86 to 1.89 gram and monobasic sodium phosphate 2.2 to 5.05 grams (5 to 10 mL dibasic sodium phosphate/monobasic sodium phosphate oral solution) as a single daily dose. "Do not take more than 10 mL (2 teaspoonfuls) in a 24-hour period." Children under 6 years of age: ask a doctor.

(ii) *Rectal enema dosage.* (A) Adults and children 12 years of age and over: Enema dosage is dibasic sodium phosphate 6.84 to 7.56 grams and monobasic sodium phosphate 18.24 to 20.16 grams in a single daily dose. Children 2 to 11 years of age: Enema dosage is dibasic sodium phosphate 3.42 to 3.78 grams and monobasic sodium phosphate 9.12 to 10.08 grams in a single daily dose. "Do not use in children under 2 years of age." (Manufacturers should convert these dosages to the amount of solution to be used.)

(B) "If no urge is felt after 5 minutes of using, try to empty bowel. Call a doctor promptly if no liquid comes out of the rectum after 30 minutes because dehydration could occur."

(C) "Stop using if tip is hard to insert. Forcing the tip into the rectum can cause injury (especially if you have hemorrhoids). If enema tip causes rectal bleeding or pain, get immediate medical care."

(6) *For products containing dibasic sodium phosphate identified in § 334.16(e).* Adults and children 12 years of age and over: Oral dosage is 3.42 to 7.56 grams in a single daily dose. Children 10 to 11 years of age: Oral dosage is 1.71 to 3.78 grams in a single daily dose. Children 6 to 9 years of age: Oral dosage is 0.86 to 1.89 gram in a single daily dose. Children under 6 years of age: ask a doctor.

(7) *For products containing monobasic sodium phosphate identified in § 334.16(f).* Adults and children 12 years of age and over: Oral dosage is 4.5 to 20.2 grams in a single daily dose. Children 10 to 11 years of ages: Oral dosage is 2.25 to 10.1 grams in a single daily dose. Children 6 to 9 years of age:

Oral dosage is 1.12 to 5.05 grams in a single daily dose. Children under 6 years of age: ask a doctor.

4. Section 334.80 is amended by redesignating paragraph (b)(2) as paragraph (b)(2)(i) and revising it, and by adding paragraph (b)(2)(ii), to read as follows.

§ 334.80 Professional labeling.

* * * * *

(b) * * *

(2) *For products containing dibasic sodium phosphate or monobasic sodium phosphate identified in § 334.16(d), (e), or (f)—(i) Oral and rectal dosage forms—(A) "Do not use"* (these three words in bold print) "in patients with congestive heart failure."

(B) "Use with caution" (these three words in bold print) "in patients with impaired renal function, heart disease, acute myocardial infarction, unstable angina, preexisting electrolyte disturbances (such as dehydration or those secondary to the use of diuretics), the elderly, or people taking drugs that may affect electrolyte levels."

(C) "Monitor electrolytes." (these two words in bold print) "Give sufficient fluid replacement with all oral and rectal sodium phosphates products to prevent dehydration."

(D) "What can occur:" (these three words in bold print) "Hypocalcemia, hyperphosphatemia, hypernatremia, hypokalemia, and acidosis. These conditions are more likely to occur when more than one dose of sodium phosphates is given in a 24-hour period."

(E) "What you should do:" (these four words in bold print) "Advise people to follow recommended dose. Treatment of electrolyte imbalance may require immediate medical intervention with appropriate electrolyte and fluid replacement. (Some examples of references for treatment of this condition are Fonkalsrud, E., and J. Keen, 'Hypernatremic Dehydration Hypertonic Enemas in Congenital Megacolon,' *The Journal of the American Medical Association*, 199:584-586, 1967, and Edmondson, S., and T. D. Almquist, 'Iatrogenic Hypocalcemic Tetany,' *Annals of Emergency Medicine*, 19:938-940, 1990.)"

(ii) *Rectal dosage forms.* (A) "Do not use" (these three words in bold print) "sodium phosphates enema in children under 2 years of age or in patients with congenital megacolon or imperforate anus because of the risk of hyperosmotic dehydration and hyperphosphatemia." (B) "Stop using" (these two words in bold print) "if there is resistance to the enema tip. Forcing the tip into the

rectum can result in a serious injury that requires immediate medical attention."

(C) "Use sodium phosphates enema with extreme caution" (these seven words in bold print) "in patients with a colostomy or atonic colon (because of the risk of hyperosmotic dehydration and hyperphosphatemia) or with a rectal abnormality, such as hemorrhoids (because sodium phosphates can cause serious damage to the rectal mucosa if an enema tip injury occurs). Using more than one sodium phosphates enema in a 24-hour period can cause serious electrolyte problems."

* * * * *

Dated: April 27, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-12054 Filed 5-20-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD01-98-002]

RIN 2121-AA97

Safety Zone; New York Super Boat Race, New York

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone in the lower Hudson River, for the New York Super Boat Race. The temporary safety zone would be in effect on Sunday, September 13, 1998, from 11:30 a.m. until 4:00 p.m. unless extended or terminated sooner by the Captain of the Port, New York. The proposed safety zone would restrict vessel traffic in the Lower Hudson River between Battery Park and Pier 76 in Manhattan. The proposed safety zone is needed to protect racing participants and spectator craft from the hazards associated with high speed powerboat racing.

DATES: Comments must be received on or before August 19, 1998.

ADDRESSES: Comments should be mailed to Lieutenant Junior Grade Alma Kenneally, Waterways Oversight Branch, Coast Guard Activities New York, 212 Coast Guard Drive, Staten Island, New York 10305.

FOR FURTHER INFORMATION CONTACT: Lieutenant Junior Grade Alma Kenneally, Waterways Oversight Branch, Coast Guard Activities New York (718) 354-4195.

SUPPLEMENTARY INFORMATION:**Request for Comments**

The Coast Guard encourages interested persons to participate in this rulemaking by submitting written data, views, or arguments.

Persons submitting comments should include their names and addresses, identify this notice (CGD01-98-002) and the specific section of the proposal to which their comments apply, and give reasons for each comment. Persons wanting acknowledgment of receipt of comments should enclose a stamped, self-addressed postcard or envelope.

The Coast Guard will consider all comments received during the comment period. It may change this proposal in view of the comments. The Coast Guard plans no public hearing; however, persons may request a public hearing by writing to the Waterways Oversight Branch at the address under **ADDRESSES**. If it is determined that the opportunity for oral presentations will aid this rulemaking, the Coast Guard will hold a public hearing at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

Super Boat International Productions, Inc. has submitted an Application for Approval of Marine Event for a Super Boat Race in the waters of the Lower Hudson River. This regulation would establish a temporary safety zone in the waters of the Lower Hudson River south of a line drawn from the northwest corner of Pier 76 in Manhattan and a point in Weehawken, New Jersey at approximate position 40°45'52"N 074°01'01"W, and north of a line connecting the following points:

<i>Latitude</i>	<i>Longitude</i>
40°42'16.0"N	074°01'09.0"W, then south to
40°41'55.0"N	074°01'16.0"W, then southwest to
40°41'47.0"N	074°01'36.0"W, then northwest to
40°41'55.0"N	074°01'59.0"W, then to shore at
40°42'20.5"N	074°02'06.0"W.

The safety zone would be effective on Sunday, September 13, 1998, from 11:30 a.m. until 4:00 p.m., unless extended or terminated sooner by the Captain of the Port of New York. This safety zone would restrict vessel traffic in the Lower Hudson River south of a line drawn from Pier 76 in Manhattan to a point located directly opposite on the New Jersey shoreline and north of a line drawn between Battery Park in Manhattan and the southern most point of Ellis Island in the Upper New York

Bay. This safety zone is needed to protect mariners from the hazards associated with a boat race in which the participants transit at excessive speeds.

This event will include up to 40 powerboats, 24 to 50 feet in length, racing on an 8 mile oval course at speeds in excess of 100 mph. No more than 100 spectator craft are expected for the event.

Regulatory Evaluation

This proposal is not a significant regulatory action under section 3(f) of 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 exempted from review 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). The Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of DOT is unnecessary. This safety zone would restrict vessel traffic in the Lower Hudson River south of a line drawn from Pier 76 in Manhattan to a point located directly opposite on the New Jersey shoreline and north of a line drawn between Battery Park in Manhattan and the southern most point of Ellis Island in the Upper New York Bay on Sunday, September 13, 1998, from 11:30 a.m. until 4:00 p.m., unless extended or terminated sooner by the Captain of the Port of New York. Although this regulation would prevent traffic from transiting this area, the effect of this regulation would not be significant for several reasons: the volume of commercial vessel traffic transiting the Lower Hudson River on a Sunday is less than half of the normal daily traffic volume; pleasure craft desiring to view the event will be directed to designated spectator viewing areas outside the safety zone; pleasure craft can take an alternate route through the East River and the Harlem River; the duration of the event is limited to four and one half hours; the extensive advisories which will be made to the affected maritime community by Local Notice to Mariners, Safety Voice Broadcast, and facsimile notification.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), the Coast Guard must consider whether this proposal will have a significant economic impact on a substantial number of small entities. "Small entities" include independently owned and operated

small businesses that are not dominant in their field and that otherwise qualify as "small business concerns" under Section 3 of the Small Business Act (21 U.S.C. 632).

For reasons set forth in the above Regulatory Evaluation, the Coast Guard expects the impact of this proposal to be minimal. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposal will not have a significant economic impact on a substantial number of small entities. If, however, you think that your business or organization qualifies as a small entity and that this rule, if adopted, will have 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).

Federalism

The Coast Guard has analyzed this action in accordance with the principles and criteria contained in Executive Order 12612 and has determined that this proposal does not raise sufficient federal implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard has considered the environmental impact of this proposal and concluded that under Figure 2-1, paragraph 34(g), of Commandant Instruction M16475.1C, it is categorically excluded from further environmental documentation.

List of Subjects in 33 CFR Part 165

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

Proposed Regulations

For reasons set out in the preamble, the Coast Guard proposes to amend 33 CFR Part 165 as follows:

PART 165—[AMENDED]

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05-1(g), 6.04-1, 6.04-6, and 160.5; 49 CFR 1.46.

2. A temporary section 165.T01-002, is added to read as follows:

§ 165.T01-002 Safety Zone; New York Super Boat Race, Hudson River, New York and New Jersey.

(a) *Location.* The following area is a safety zone: All waters of the Lower Hudson River between Pier 76 in Manhattan and a point on the New Jersey shore in Weehawken, New Jersey at 40°45'52"N 074°01'01"W, and north of a line connecting the following points:

Latitude	Longitude
40°42'16.0"N	074°01'09.0"W, then south to
40°41'55.0"N	074°01'16.0"W, then west to
40°41'47.0"N	074°01'36.0"W, then northwest to
40°41'55.0"N	074°01'59.0"W, then to shore at
40°42'20.5"N	074°02'06.0"W.

(b) *Effective period.* This safety zone is in effect on Sunday, September 13, 1998, from 11:30 a.m. until 4 p.m., unless terminated sooner by the Captain of the Port New York.

(c) *Regulations.* (1) The general regulations contained in 33 CFR 165.23 apply.

(2) All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the designated on scene patrol personnel. U.S. Coast Guard patrol personnel include commissioned, warrant, and petty officers of the Coast Guard. Upon being hailed by a U.S. Coast Guard vessel via siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed.

Dated: May 8, 1998.

L.M. Brooks,

Captain, U.S. Coast Guard, Acting Captain of the Port, New York.

[FR Doc. 98-13581 Filed 5-20-98; 8:45 am]

BILLING CODE 4910-15-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[OH115-1; FRL-6100-7]

Approval and Promulgation of Maintenance Plan Revisions; Ohio

AGENCY: Environmental Protection Agency, (USEPA).

ACTION: Proposed rule.

SUMMARY: The United States Environmental Protection Agency (USEPA) is proposing to approve an April 27, 1998, request from Ohio, for State Implementation Plan (SIP) maintenance plan revisions for the

following maintenance areas in Ohio: Canton (Stark County), Cleveland (Lorain, Cuyahoga, Lake, Ashtabula, Geauga, Medina, Summit and Portage Counties), Columbus (Franklin, Delaware and Licking Counties), Steubenville (Jefferson County), Toledo (Lucas and Wood Counties), Youngstown (Mahoning and Trumbull Counties) as well as Clinton County, Columbiana County and Preble County. The revisions would remove the air quality triggers from each area's contingency plan. The contingency plans were included in these areas' maintenance plans to correct violations of the one hour ozone National Ambient Air Quality Standard (NAAQS).

DATES: Written comments on this proposal must be received on or before June 22, 1998.

ADDRESSES: Copies of the documents relevant to this action are available for inspection during normal business hours at the following location: Regulation Development Section, Air Programs Branch, (AR-18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Please contact Scott Hamilton at (312) 353-4775 before visiting the Region 5 office.

Written comments should be sent to: J. Elmer Bortzer, Chief, Regulation Development Section, Air Programs Branch, (AR-18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Scott Hamilton, Environmental Scientist, Regulation Development Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353-4775.

SUPPLEMENTARY INFORMATION:

I. Attainment Areas in Ohio

Since the Clean Air Act (CAA) attainment status designations were made, all of the Ohio areas listed in the summary section of this **Federal Register** Notice have attained the one hour ozone standard and have been redesignated to attainment for ozone. As a requirement to being redesignated to attainment, these areas developed maintenance plans. The purpose of the maintenance plans is to assure maintenance of the one hour ozone NAAQS for at least ten years. Included in the maintenance plans were contingency provisions. The purpose of the contingency provisions are to identify and correct any violation of the one hour ozone NAAQS in a timely

fashion. Triggers are included in the contingency provisions to identify the need to implement measures and correct air quality problems until such time as a revised maintenance or attainment plan could be developed to address the level of the air quality problem. Triggering events in the contingency plans could be linked to ozone air quality and/or an emission level of ozone precursors.

The maintenance plan approvals were finalized by USEPA and published in the **Federal Register** for these Ohio areas as follows: Canton and Youngstown (61 FR 3319; January 31, 1996), Cleveland (61 FR 20458; May 7, 1996), Columbus (61 FR 3591; February 1, 1996), Steubenville, Columbiana County and Preble County (60 FR 7453; February 8, 1995), Toledo (60 FR 39115; August 1, 1995) and Clinton County (61 FR 11560; March 21, 1996).

II. One Hour Ozone Standard Revocation

On July 18, 1998, USEPA finalized a revision to the NAAQS for ozone which changed the standard from 0.12 parts per million (ppm) averaged over one hour, to 0.08 ppm, averaged over eight hours. USEPA is revoking the one hour standard in separate rulemakings based on an area's attainment of the one hour ozone standard. The first round of revocations will be for areas attaining the one hour standard based on quality assured air monitoring data for the years 1994-1996. The second round of one hour ozone standard revocations will be for areas attaining the one hour standard based on quality assured air monitoring data for the years 1995-1997. After these two rulemakings are finalized, the USEPA intends to publish rulemakings on an annual basis revoking the one hour ozone standard for additional areas that come into attainment of the one hour standard.

On January 16, 1998, USEPA published a proposed rule (63 FR 2726) in the **Federal Register** proposing to revoke the one hour ozone standard in areas attaining the standard based on quality assured air monitoring data for the years 1994-1996 (first round of revocations). In that proposal, USEPA proposed to revoke the one hour ozone standard in the Ohio areas subject to this proposed action [Canton (Stark County), Cleveland (Lorain, Cuyahoga, Lake, Ashtabula, Geauga, Medina, Summit and Portage Counties), Columbus (Franklin, Delaware and Licking Counties), Steubenville (Jefferson County), Toledo (Lucas and Wood Counties), Youngstown (Mahoning and Trumbull Counties)] as