

point type for a label above ten but below fifteen square inches in area, fourteen point type for a label above fifteen but below thirty square inches in area, or eighteen point type for a label over thirty square inches in area. The type size of the remainder of the warning statement shall be no smaller than six point type. All required label text shall be of sufficient prominence, and shall be placed with such conspicuousness relative to other label text and graphic material, to insure that the warning statement is read and understood by the ordinary individual under customary conditions of purchase and use.

(e) *Liability and determining whether a chemical substance is subject to this section.* (1) If a manufacturer or importer of a chemical substance which is described by the generic chemical name in paragraph (a) of this section makes an inquiry under § 710.7(g) of this chapter or § 720.25(b) of this chapter as to whether the specific substance is on the Inventory and EPA informs the manufacturer or importer that the substance is on the Inventory, EPA will also inform the manufacturer or importer whether the substance is subject to this section.

(2) Except for manufacturers and importers of P-84-529, no processor, distributor, or user of P-84-529 will be in violation of this section unless that person has received a letter specified in paragraph (d)(1) of this section or a container with the label specified in paragraph (d)(2) of this section.

(f) *Exemptions.* A person identified in paragraphs (c) and (d) of this section is not subject to the requirements of those paragraphs if:

(1) The person manufactures, imports, processes, distributes in commerce, or uses the substance only in small quantities solely for research and development and in accordance with section 5(h)(3) of the Act.

(2) The person manufactures, imports, processes, distributes in commerce, or uses the substance only as an impurity.

(3) The person imports, processes, distributes in commerce, or uses the substance only as part of an article.

(4) The person processes or distributes the substance in commerce solely

for export and, when distributing in commerce, labels the substance in accordance with section 12(a)(1)(B) of the Act.

(g) *Enforcement.* (1) Failure to comply with any provision of this section is a violation of section 15 of the Act [15 U.S.C. 2614].

(2) Failure or refusal to permit access to or copying of records, as required under section 11 of the Act, is a violation of section 15 of the Act [15 U.S.C. 2614].

(3) Failure or refusal to permit entry or inspection, as required under section 11 of the Act, is a violation of section 15 of the Act [15 U.S.C. 2614].

(4) Violators may be subject to the civil and criminal penalties in section 16 of the Act [15 U.S.C. 2615] for each violation.

(5) EPA may seek to enjoin the processing, distribution in commerce, or use of a chemical substance in violation of this section; act to seize any chemical substance processed, distributed in commerce, or used in violation of this section; or take other actions under the authority of sections 7 and 17 of the Act [15 U.S.C. 2605 and 2616].

[49 FR 36855, Sept. 20, 1984]

#### § 747.195 Triethanolamine salt of a substituted organic acid.

This section identifies activities with respect to a chemical substance which are prohibited and requires that warnings and instructions accompany the substance when distributed in commerce.

(a) *Chemical substance subject to this section.* The following chemical substance, referred to by its premanufacture notice number and generic chemical name, is subject to this section: P-84-310, triethanolamine salt of a substituted organic acid.

(b) *Definitions.* Definitions in section 3 of the Act, 15 U.S.C. 2602, apply to this section unless otherwise specified in this paragraph. In addition, the following definitions apply:

(1) The terms *Act*, *article*, *chemical substance*, *commerce*, *importer*, *impurity*, *Inventory*, *manufacturer*, *person*, *process*, *processor*, and *small quantities solely for research and development*, have the same meaning as in § 720.3 of this chapter.

(2) *Metalworking fluid* means a liquid of any viscosity or color containing intentionally added water used in metal machining operations for the purpose of cooling, lubricating, or rust inhibition.

(3) *Nitrosating agent* means any substance that has the potential to transfer a nitrosyl group ( $-\text{NO}$ ) to a primary, secondary, or tertiary amine to form the corresponding nitrosamine.

(4) *Process or distribute in commerce solely for export* means to process or distribute in commerce solely for export from the United States under the following restrictions on domestic activity:

(i) Processing must be performed at sites under the control of the processor.

(ii) Distribution in commerce is limited to purposes of export.

(iii) The processor or distributor may not use the substance except in small quantities solely for research and development.

(c) *Use limitations.* (1) Any person producing a metalworking fluid, or a product which could be used in or as a metalworking fluid, which includes as one of its components P-84-310, is prohibited from adding any nitrosating agent to the metalworking fluid or product.

(2) A person using as a metalworking fluid a product containing P-84-310 is prohibited from adding any nitrosating agent to the product.

(d) *Warnings and instructions.* (1) Any person who distributes in commerce P-84-310 in a metalworking fluid, or in any form in which it could be used as a component of a metalworking fluid, must send to each recipient of P-84-310 and confirm receipt in writing prior to the first shipment to that person:

(i) A letter that includes the following statements: A substance, identified generically as a triethanolamine salt of a substituted organic acid, contained in the product (*insert distributor's trade name or other identifier for product containing P-84-310*) has been regulated by the Environmental Protection Agency, at 40 CFR 747.195, as published in the FEDERAL REGISTER of June 14, 1984. A copy of the regulation is enclosed. The regulation prohibits the addition of any nitrosating agent, including nitrites, to the triethanol-

amine salt of a substituted organic acid, when the substance is or could be used in metalworking fluids. The addition of nitrites or other nitrosating agents to this substance leads to formation of a substance known to cause cancer in laboratory animals. The triethanolamine salt of a substituted organic acid has been specifically designed to be used without nitrites. Consult the enclosed regulation for further information.

(ii) A copy of this § 747.195.

(2)(i) Any person who distributes in commerce a metalworking fluid containing P-84-310 must affix a label to each container containing the fluid.

(ii) The label shall contain a warning statement which shall consist only of the following language:

WARNING! Do Not Add Nitrites to This Metalworking Fluid under Penalty of Federal Law. Addition of nitrites leads to formation of a substance known to cause cancer. This product is designed to be used without nitrites.

(iii) The first word of the warning statement shall be capitalized, and the type size for the first word shall be no smaller than six point type for a label five square inches or less in area, ten point type for a label above five but below ten square inches in area, twelve point type for a label above ten but below fifteen square inches in area, fourteen point type for a label above fifteen but below thirty square inches in area, or eighteen point type for a label over thirty square inches in area. The type size of the remainder of the warning statement shall be no smaller than six point type. All required label text shall be of sufficient prominence, and shall be placed with such conspicuousness relative to other label text and graphic material, to insure that the warning statement is read and understood by the ordinary individual under customary conditions of purchase and use.

(e) *Liability and determining whether a chemical substance is subject to this section.* (1) If a manufacturer or importer of a chemical substance which is described by the generic chemical name in paragraph (a) of this section makes an inquiry under § 710.7(g) of this chapter or § 720.25(b) of this chapter as to whether the specific substance is on

the Inventory and EPA informs the manufacturer or importer that the substance is on the Inventory, EPA will also inform the manufacturer or importer whether the substance is subject to this section.

(2) Except for manufacturers and importers of P-84-310, no processor, distributor, or user of P-84-310 will be in violation of this section unless that person has received a letter specified in paragraph (d)(1) of this section or a container with the label specified in paragraph (d)(2) of this section.

(f) *Exemptions.* A person identified in paragraphs (c) and (d) of this section is not subject to the requirements of those paragraphs if:

(1) The person manufactures, imports, processes, distributes in commerce, or uses the substance only in small quantities solely for research and development and in accordance with section 5(h)(3) of the Act.

(2) The person manufactures, imports, processes, distributes in commerce, or uses the substance only as an impurity.

(3) The person imports, processes, distributes in commerce, or uses the substance only as part of an article.

(4) The person processes or distributes the substance in commerce solely for export, and when distributing in commerce, labels the substance in accordance with section 12(a)(1)(B) of the Act.

(g) *Enforcement.* (1) Failure to comply with any provision of this section is a violation of section 15 of the Act (15 U.S.C. 2614).

(2) Failure or refusal to permit access to or copying of records, as required under section 11 of the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Failure or refusal to permit entry or inspection, as required under section 11 of the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

[49 FR 24668, June 14, 1984]

**§ 747.200 Triethanolamine salt of tricarboxylic acid.**

This section identifies activities with respect to two chemical substances which are prohibited and requires that warnings and instructions accompany

the substances when distributed in commerce.

(a) *Chemical substances subject to this section.* The following chemical substances, referred to by their premanufacture notice numbers and generic chemical names, are subject to this section:

P-83-1005, triethanolamine salt of tricarboxylic acid; and

P-83-1062, tricarboxylic acid.

(b) *Definitions.* Definitions in section 3 of the Act, 15 U.S.C. 2602, apply to this section unless otherwise specified in this paragraph. In addition, the following definitions apply:

(1) The terms *Act*, *article*, *byproducts*, *chemical substance*, *commerce*, *imported*, *impurity*, *Inventory*, *manufacture or import for commercial purposes*, *manufacture solely for export*, *manufacturer*, *new chemical substance*, *person*, *process*, *processor*, and *small quantities solely for research and development* have the same meaning as in § 720.3 of this chapter.

(2) *Metalworking fluid* means a liquid of any viscosity or color containing intentionally added water used in metal machining operations for the purpose of cooling or lubricating.

(3) *Nitrosating agent* means any substance that has the potential to transfer a nitrosyl group (—NO) to a secondary or tertiary amine to form the corresponding nitrosamine.

(c) *Use limitations.* (1) Any person producing a metalworking fluid, or a product which could be used in or as a metalworking fluid, which includes as one of its components P-83-1005 is prohibited from adding any nitrosating agent to the metalworking fluid or product.

(2) Any person using as metalworking fluid a product containing P-83-1005 is prohibited from adding any nitrosating agent to the product.

(d) *Warnings and instructions.* (1) Any person who distributes in commerce P-83-1005 in a metalworking fluid, or in any form in which it could be used as a component of a metalworking fluid, must send to each recipient of P-83-1005 and confirm receipt prior to the first shipment to that person:

(i) A letter that includes the following statements: