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TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 178--INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS--Table of Contents

Subpart D--Certain Adjuvants and Production Aids

Sec. 178.3570 Lubricants with incidental food contact.

Lubricants with incidental food contact may be safely used on machinery used for producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section:

(a) The lubricants are prepared from one or more of the following substances:

(1) Substances generally recognized as safe for use in food.

(2) Substances used in accordance with the provisions of a prior sanction or approval.

(3) Substances identified in this paragraph (a)(3).

Substances	Limitations
Aluminum stearoyl benzoyl hydroxide....	For use only as a thickening agent in mineral oil lubricants at a level not to exceed 10 pct by weight of the mineral oil.
N,N-Bis(2-ethylhexyl)-ar-methyl-1H-benzotriazole-1-methanamine (CAS Reg. No. 94270-86-7)..	For use as a copper deactivator at a level not to exceed 0.1 percent by weight of the lubricant.
BHA.....	
BHT.....	
<greek-a>-Butyl-omega-hydroxypoly(oxyethylene) poly(oxypropylene) produced by random condensation of a 1:1 mixture by weight of ethylene oxide and propylene oxide with butanol; minimum molecular weight 1,500; Chemical Abstracts Service Registry No. 9038-95-3.	Addition to food not to exceed 10 parts per million.
<greek-a>-Butyl-omega-	Do.

hydroxypoly(oxypropylene); minimum molecular weight 1,500; Chemical Abstracts Service Registry No. 9003-13-8.	
Castor oil.....	Do.
Castor oil, dehydrated.....	Do.
Castor oil, partially dehydrated.....	Do.
Dialkyldimethylammonium aluminum silicate (CAS Reg. No. 68953-58-2), which may contain up to 7 percent by weight 1,6-hexanediol (CAS Reg. No. 629-11-8), where the alkyl groups are derived from hydrogenated tallow fatty acids (C<INF>14-C<INF>18) and where the aluminum silicate is derived from bentonite.	For use only as a gelling agent in mineral oil lubricants at a level not to exceed 15 percent by weight of the mineral oil.
Dimethylpolysiloxane (viscosity greater than 300 centistokes).	Addition to food not to exceed 1 part per million.

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Disodium decanedioate (CAS Reg. No. 17265-14-4).	For use only: 1. As a corrosion inhibitor or rust preventative in mineral oil-bentonite lubricants at a level not to exceed 2 percent by weight of the grease. 2. As a corrosion inhibitor or rust preventative only in greases at a level not to exceed 2 percent by weight of the grease.
Disodium EDTA (CAS Reg. No. 139-33-3)..	For use only as a chelating agent and sequestrant at a level not to exceed 0.06 percent by weight of lubricant at final use dilution.
Ethoxylated resin phosphate ester mixture consisting of the following compounds: 1. Poly(methylene-p-tert-butyl-phenoxy)poly-(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters (0 to 40 percent of the mixture). The resin is formed by condensation of 1 mole of p-tert-butylphenol with 2 to 4 moles of formaldehyde and subsequent ethoxylation with 4 to 12 moles of ethylene oxide;. 2. Poly(methylene-p-nonylphenoxy) poly(oxyethylene) mixture of	For use only as a surfactant to improve lubricity in lubricating fluids complying with this section at a level not to exceed 5 percent by weight of the lubricating fluid.

dihydrogen phosphate and monohydrogen phosphate esters (0 to 40 percent of the mixture). The resin is formed by condensation of 1 mole of p-nonylphenol with 2 to 4 moles of formaldehyde and subsequent ethoxylation with 4 to 12 moles of ethylene oxide; and.

3. n-Tridecyl alcohol mixture of dihydrogen phosphate and monohydrogen phosphate esters (40 to 80 percent of the mixture; CAS Reg. No. 56831-62-0).

Fatty acids derived from animal or vegetable sources, and the hydrogenated forms of such fatty acids.

2-(8-Heptadecenyl)-4,5-dihydro-1H-imidazole-1-ethanol (CAS Reg. No. 95-38-5). For use at levels not to exceed 0.5 percent by weight of the lubricant.

Hexamethylenebis(3,5-di-tert-butyl-4-hydroxyhydrocinnamate) (CAS Reg. No. 35074-77-2). For use as an antioxidant at levels not to exceed 0.5 percent by weight of the lubricant.

<greek-a>-Hydro-omega-hydroxypoly (oxyethylene) poly(oxypropylene) produced by random condensation of mixtures of ethylene oxide and propylene oxide containing 25 to 75 percent by weight of ethylene oxide; minimum molecular weight 1,500; Chemical Abstracts Service Registry No. 9003-11-6. Addition to food not to exceed 10 parts per million.

12-Hydroxystearic acid.....

Isopropyl oleate..... For use only as an adjuvant (to improve lubricity) in mineral oil lubricants.

Magnesium ricinoleate..... For use only as an adjuvant in mineral oil lubricants at a level not to exceed 10 percent by weight of the mineral oil.

Mineral oil..... Addition to food not to exceed 10 parts per million.

N-Methyl-N-(1-oxo-9-octadecenyl)glycine (CAS Reg. No. 110-25-8). For use as a corrosion inhibitor at levels not to exceed 0.5 percent by weight of the lubricant.

N-phenylbenzenamine, reaction products with 2,4,4-trimethylpentene (CAS Reg. No. 68411-46-1). For use only as an antioxidant at levels not to exceed 0.5 percent by weight of the lubricant.

Petrolatum..... Complying with Sec. 178.3700. Addition to food not to exceed 10 parts per million.

Phenyl-<greek-a>-and/or phenyl-<greek-b>-naphthylamine. For use only, singly or in combination, as antioxidant in mineral oil lubricants at a

	level not to exceed a total of 1 percent by weight of the mineral oil.
Phosphoric acid, mono- and dihexyl esters, compounds with tetramethylnonylamines and C<INF>11-14 alkylamines.	For use only as an adjuvant at levels not to exceed 0.5 percent by weight of the lubricant.
Phosphoric acid, mono- and diisooctyl esters, reacted with tert-alkyl and (C<INF>12-C<INF>14) primary amines (CAS Reg. No. 68187-67-7).	For use only as a corrosion inhibitor or rust preventative inlubricants at a level not to exceed 0.5 percent by weight of the lubricant.
Polyurea, having a nitrogen content of 9-14 percent based on the dry polyurea weight, produced by reacting tolylene diisocyanate with tall oil fatty acid (C<INF>16 and C<INF>18) amine and ethylene diamine in a 2:2:1 molar ratio.	For use only as an adjuvant in mineral oil lubricants at a level not to exceed 10 percent by weight of the mineral oil.
Polybutene (minimum average molecular weight 80,000).	Addition to food not to exceed 10 parts per million.
Polybutene, hydrogenated; complying with the identity prescribed under Sec. 178.3740.	Do.
Polyethylene.....	Do.
Polyisobutylene (average molecular weight 35,000-140,000 (Flory)).	For use only as a thickening agent in mineral oil lubricants.
Sodium nitrite.....	For use only as a rust preventive in mineral oil lubricants at a level not to exceed 3 percent by weight of the mineral oil.
Tetrakis[methylene(3,5-di-tert-butyl-4-hydroxyhydro-cinnamate)]methane (CAS Reg. No. 6683-19-8).	For use only as an antioxidant in lubricants at a level not to exceed 0.5 percent by weight of the lubricant.

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Thiodiethylenebis (3,5-di-tert-butyl-4-hydroxyhydrocinnamate) (CAS Reg. No. 41484-35-9).	For use as an antioxidant at levels not to exceed 0.5 percent by weight of the lubricant.
Tri[2(or 4)-C<INF>9-10-branched alkylphenyl]phosphorothioate (CAS Reg. No. 126019-82-7)..	For use only as an extreme pressure-antiwear adjuvant at levels not to exceed 0.5 percent by weight of the lubricant.
Triphenyl phosphorothionate (CAS Reg. No. 597-82-0).	For use as an adjuvant in lubricants herein listed at a level not to exceed 0.5 percent by weight of the lubricant.
Tris(2,4-di-tert-butylphenyl)phosphite (CAS Reg. NO. 31570-04-4).	For use only as a stabilizer at levels not to exceed 0.5

	percent by weight of the lubricant.
Thiodiethylenebis(3,5-di-tert-butyl-4-hydroxy-hydro- cinnamate) (CAS Reg. No. 41484-35-9).	For use as an antioxidant at levels not to exceed 0.5 percent by weight of the lubricant.
Zinc sulfide.....	For use at levels not to exceed 10 percent by weight of the lubricant.

(b) The lubricants are used on food-processing equipment as a protective antirust film, as a release agent on gaskets or seals of tank closures, and as a lubricant for machine parts and equipment in locations in which there is exposure of the lubricated part to food. The amount used is the minimum required to accomplish the desired technical effect on the equipment, and the addition to food of any constituent identified in this section does not exceed the limitations prescribed.

(c) Any substance employed in the production of the lubricants described in this section that is the subject of a regulation in parts 174, 175, 176, 177, 178 and Sec. 179.45 of this chapter conforms with any specification in such regulation.

[42 FR 14609, Mar. 15, 1977]

Editorial Note: For Federal Register citations affecting Sec. 178.3570, see the List of CFR Sections Affected in the Finding Aids section of this volume.