Food and Drug Administration, HHS

§ 172.250 Petroleum naphtha.

Petroleum naphtha may be safely used in food in accordance with the following conditions:

(a) The additive is a mixture of liquid hydrocarbons, essentially paraffinic and naphthenic in nature obtained from petroleum.

(b) The additive is refined to meet the following specifications when subjected to the procedures described in this paragraph.

(1) Boiling-point range: 175 °F–300 °F.

(2) Nonvolatile residue: 0.002 gram per 100 milliliters maximum.

(3) Ultraviolet absorbance limits, as follows:

<table>
<thead>
<tr>
<th>Wavelength (milli-microns)</th>
<th>Maximum absorbance per centimeter optical pathlength</th>
</tr>
</thead>
<tbody>
<tr>
<td>280–289</td>
<td>0.15</td>
</tr>
<tr>
<td>290–299</td>
<td>0.13</td>
</tr>
<tr>
<td>300–350</td>
<td>0.08</td>
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<tr>
<td>360–400</td>
<td>0.02</td>
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</tbody>
</table>

APPARATUS

Separatory funnels, 250-milliliter, and 2,000-milliliter capacity, equipped with tetrafluoroethylene polymer stopcocks.

Erlenmeyer flask. 125-milliliter with 24/40 standard taper neck.

Evaporation flask. 250-milliliter capacity all-glass flask equipped with 24/40 standard taper stopper having inlet and outlet tubes to permit passage of nitrogen across the surface of the container liquid to be evaporated.

Condenser. 24/40 joints, fitted with drying tube, length optional.

Spectrophotometric cells. Fused quartz cells, optical path length in the range of 5,000 centimeters ±0.005 centimeter; also for checking spectrophotometer performance only, optical path length in the range 1,000 centimeter ±0.005 centimeter. With distilled water in the cells, determine any absorbance difference.

Spectrophotometer. Spectral range 250–400 μm with spectral slit width of 2 μm or less; under instrument operating conditions for these absorbance measurements, the spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ±0.01 at 0.4 absorbance.

Absorbance accuracy, ±0.05 at 0.4 absorbance.

Wavelength repeatability, ±0.2 millimicron.

Wavelength accuracy, ±1.0 millimicron.

Ultraviolet lamp. Long wavelength (3400–3800Å).

REAGENTS

Isooctane (2,2,4-trimethylpentane). Use 180 milliliters in a 250-milliliter Erlenmeyer flask, add 1 milliliter of purified n-hexadecane, insert the head assembly, allow nitrogen gas to flow into the inlet tube and connect the outlet tube to a solvent trap and vacuum line in such a way as to prevent any back flow of condensate into the flask. The

As determined by procedure using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce, (1949). The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons. The procedure is incorporated by reference. Copies of the material incorporated by reference are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6039, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.
Dilute 1.0 milliliter of \( n \)-hexadecane to 25 milliliters with isooctane and determine the absorbance per centimeter of path length should be 0.00 between 280–400 μ. If necessary, isooctane may be purified by passage through a column of activated silica gel (Grade 12, Davison Chemical Co., Baltimore, Md., or equivalent) or by distillation.

**Sodium borohydride.**

Immediately fit a water-cooled condenser in a 5-centimeter cell compared to isooctane as reference. The absorbance should not exceed 0.01 per centimeter path length between 280–400 μ. If necessary, isooctane may be purified by passage through a column of activated silica gel (Grade 12, Davison Chemical Co., Baltimore, Md., or equivalent) or by distillation.

**Methyl alcohol, A.C.S. reagent grade.** Use 10 milliliters and proceed as with isooctane. The absorbance per centimeter of path length should be 0.00 between 280–400 μ. Methyl alcohol may be purified by simple distillation or by refluxing in the presence of potassium hydroxide (10 grams/2 liters) and zinc dust (25 grams/2 liters) for 3 hours followed by distillation.

**n-Hexadecane, 99 percent olefin-free.** Dilute 1.0 milliliter of \( n \)-hexadecane to 25 milliliters with isooctane and determine the absorbance in a 5-centimeter cell compared to isooctane as reference between 280–400 μ. The absorbance per centimeter path length shall not exceed 0.00 in this range. Purify, if necessary, by percolation through activated silica gel or by distillation.

**Water.** All distilled water must be extracted with isooctane before use. A series of three successive extracts of 1.5 liters of distilled water with 100-milliliter portions of isooctane in the second funnel to the volumetric flask.

**Determination of boiling-point range.** Use ASTM method D86-82, "Standard Method for Distillation of Petroleum Products," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/

(c) Petroleum naphtha containing antioxidants shall meet the specified ultraviolet absorbance limits after correction for any absorbance due to the antioxidants. Petroleum naphtha may contain antioxidants authorized for use in food in an amount not to exceed that reasonably required to accomplish the intended effect or to exceed any prescribed limitations.

(d) Petroleum naphtha is used or intended for use as a solvent in protective coatings on fresh citrus fruit in compliance with §172.210.

§ 172.255 Polyacrylamide.

Polyacrylamide containing not more than 0.2 percent of acrylamide monomer may be safely used as a film former in the imprinting of soft-shell gelatin capsules when the amount used is not in excess of the minimum required to produce the intended effect.

§ 172.260 Oxidized polyethylene.

Oxidized polyethylene may be safely used as a component of food, subject to the following restrictions:

(a) Oxidized polyethylene is the basic resin produced by the mild air oxidation of polyethylene. The polyethylene used in the oxidation process conforms to the density, maximum n-hexane extractable fraction, and maximum xylene soluble fraction specifications prescribed in item 2.3 of the table in §177.1520(c) of this chapter. The oxidized polyethylene has a minimum number average molecular weight of 1,200, as determined by high temperature vapor pressure osmometry; contains a maximum of 5 percent by weight of total oxygen; and has an acid value of 9 to 19.

(b) The additive is used or intended for use as a protective coating or component of protective coatings for fresh avocados, bananas, beets, coconuts, eggplant, garlic, grapefruit, lemons, limes, mango, muskmelons, onions, oranges, papaya, peas (in Pods), pineapple, plantain, pumpkin, rutabaga, squash (acorn), sweetpotatoes, tangerines, turnips, watermelon, Brazil nuts, chestnuts, filberts, hazelnuts, pecans, and walnuts (all nuts in shells).

(c) The additive is used in accordance with good manufacturing practice and in an amount not to exceed that required to produce the intended effect.

§ 172.270 Sulfated butyl oleate.

Sulfate butyl oleate may be safely used in food, subject to the following prescribed conditions:

(a) The additive is prepared by sulfation, using concentrated sulfuric acid, of a mixture of butyl esters produced by transesterification of an edible vegetable oil using 1-butanol. Following sulfation, the reaction mixture is washed with water and neutralized with aqueous sodium or potassium hydroxide. Prior to sulfation, the butyl oleate reaction mixture meets the following specifications:

(1) Not less than 90 percent butyl oleate.

(2) Not more than 1.5 percent unsaponifiable matter.

(b) The additive is used or intended for use at a level not to exceed 2 percent by weight in an aqueous emulsion in dehydrating grapes to produce raisins, whereby the residue of the additive on the raisins does not exceed 100 parts per million.

§ 172.275 Synthetic paraffin and succinic derivatives.

Synthetic paraffin and succinic derivatives identified in this section may