(a) It is used as the salt(s) of one or more of the fatty acids meeting the requirements of §172.860, as a component of protective coatings applied to fresh fruits and vegetables.

(b) It is used at a level not in excess of that reasonably required to produce its intended effect.

§ 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-micron)</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>300–359</td>
<td>0.08</td>
</tr>
<tr>
<td>360–400</td>
<td>0.02</td>
</tr>
</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 mμ 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 (3400–3800μ).

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 vacuum line in such a way as to prevent any back flow of condensate into the flask. The

1 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.
PROCEDURE

Determination of ultraviolet absorbance. Add a 25-milliliter aliquot of the hydrocarbon solvent together with 1 millilitre of hexadecane to the 125-milliliter Erlenmeyer flask. While flushing with nitrogen, evaporate to 1 millilitre on a steam bath. Nitrogen is admitted through a 5-cm-millimeter outer-diameter tube, drawn out into a 2.51-centimeter long and 15.5-millimeter inner-diameter capillary tip. This is positioned so that the capillary tip extends 4 centimeters into the flask. The nitrogen flow rate is such that the surface of the liquid is barely disturbed. After the volume is reduced to that of the 1 millilitre of hexadecane, the flask is left on the steam bath for 10 more minutes before removing. Add 10 millilitres of purified iso-octane to the flask and reevaporate the solution to a 1-millilitre volume in the same manner as described above, except do not heat for an added 10 minutes. Repeat this operation twice more. Let the flask cool.

Add 10 millilitres of methyl alcohol and about 0.5 gram of sodium borohydride. (Minimize exposure of the borohydride to the atmosphere; a measuring dipper may be used.) Immediately fit a water-cooled condenser equipped with a 24/40 joint and with a drying tube into the flask, mix until the sodium borohydride is dissolved, and allow to stand for 30 minutes at room temperature, with intermittent swirling. At the end of this time, disconnect the flask and evaporate the methyl alcohol on the steam bath under nitrogen until sodium borohydride begins to drop out of solution. Remove the flask and let it cool.

Add 6 millilitres of iso-octane to the flask and swirl to wash the crystalline slurry. Carefully transfer the iso-octane extract to a 250-millilitre separatory funnel. Dissolve the crystals in the flask with about 25 millilitres of distilled water, and pour this also into the separatory funnel. Adjust the water volume in the separatory funnel to about 100 millilitres and shake for 1 minute. After separation of the layers, draw off the aqueous layer into a second 250-millilitre separatory funnel. Transfer the hydrocarbon layer in the first funnel to a 25-millilitre volumetric flask. Carefully wash the Erlenmeyer flask with a further 6 millilitres of iso-octane, swirl, and transfer to the second separatory funnel. Shake the funnel for 1 minute. After separation of the layers, draw off the aqueous layer from a second 250-millilitre separatory funnel. Transfer the iso-octane in the second funnel to the volumetric flask. Again wash the Erlenmeyer flask with an additional 6 millilitres of iso-octane, swirl, and transfer to the first separatory funnel. Shake the funnel for 1 minute. After separation of the layers, draw off the aqueous layer and discard. Transfer the iso-octane layer to the volumetric flask and adjust the volume to 25 millilitres of iso-octane. Mix the contents well, then transfer to the first separatory funnel and wash twice with 50-millilitre portions of distilled water. Discard the aqueous layers after each wash.

Determine the ultraviolet absorbance of the iso-octane extract in 5-centimeter path length cells compared to iso-octane as reference between 280–400 μm. Determine a reagent blank concurrently with the sample, using 25 millilitres of purified iso-octane instead of a solvent sample and measuring the ultraviolet absorbance of the blank between 280–400 μm.

The reagent blank absorbance should not exceed 0.04 per centimeter path length between 280–289 μm; 0.020 between 290–359 μm; and 0.010 between 360–400 μm.

Determination of boiling-point range. Use ASTM method D98–42, “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 xylenesoluble 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.

[57 FR 12711, Apr. 13, 1992]

§ 172.275 Synthetic paraffin and succinic derivatives.

Synthetic paraffin and succinic derivatives identified in this section may