SEVENTH EDITION

FOOD CHEMICALS CODEX

FCC 7

By authority of the United States Pharmacopeial Convention.
Prepared by the Council of Experts and published by the Board of Trustees

THE UNITED STATES PHARMACOPEIAL CONVENTION
12601 Twinbrook Parkway, Rockville, MD 20852

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Acceptance criteria
Total non-fluorine containing organic compounds: NMT 5 mg/kg, including NMT 0.05 mg/kg benzene
Total fluorinated organic compounds: NMT 0.0025%

SPECIFIC TESTS

- **COLOR,** *Readily Carbonizable Substances,* Appendix IIB
  Acceptance criteria: A sample shows no more color than does *Matching Fluid A.*
- **DEGREES BAUMÉ**
  Sample: 200 mL, previously cooled to a temperature below 15°
  Analysis: Transfer the *Sample* into a 250-mL hydrometer cylinder. Insert a suitable Baumé hydrometer graduated at 0.1 °Bé intervals, adjust the temperature to 15.6°, and note the reading at the bottom of the meniscus.
  Acceptance criteria: Within the range shown on the label or claimed by the vendor.
- **NONVOLATILE RESIDUE**
  Sample: 1 g
  Analysis: Transfer the *Sample* into a tared glass dish, evaporate to dryness on a steam bath, then dry at 110° for 1 h. Cool in a desiccator and weigh.
  Acceptance criteria: The weight of the residue does not exceed 5 mg. (NMT 0.5%)
- **SPECIFIC GRAVITY**
  Analysis: Determine 15.6° with a hydrometer, or calculate from the degrees Baumé observed in *Degrees Baumé* (above).
  Acceptance criteria: Within the range specified or implied by the vendor.

OTHER REQUIREMENTS

- **LABELING:** Indicate the content, by weight, of Hydrochloric Acid (HCl). Alternatively, indicate the range of Hydrochloric Acid content, the range of degrees Baumé, and/or the specific gravity range.

Hydrogen Peroxide

First Published: Prior to FCC 6

H_2O_2 Formula wt 34.01
CAS: [7722-84-1]

DESCRIPTION

Hydrogen Peroxide occurs as a clear, colorless liquid. The grades of Hydrogen Peroxide suitable for food use usually have a concentration between 30% and 50%. It is miscible with water.

[NOTE—Although Hydrogen Peroxide undergoes exothermic decomposition in the presence of dirt and other foreign materials, it is safe and stable under recommended conditions of handling and storage. Information on safe handling and use may be obtained from the supplier.]

Function: Bleaching, oxidizing agent; starch modifier; antimicrobial agent

Packaging and Storage: Store in a cool place in containers with a vent in the stopper.

IDENTIFICATION

- **PROCEDURE**
  Sample: 1 mL
  Analysis: Shake the *Sample* with 10 mL of water containing 1 drop of 2 N sulfuric acid, and add 2 mL of ether. Add one drop of potassium dichromate TS.
  Acceptance criteria: An evanescent blue color is produced in the water layer that, upon agitation and standing, passes into the ether layer.

ASSAY

- **PROCEDURE**
  Sample solution: Dilute an amount of sample equivalent to 300 mg of H_2O_2 to 100 mL with water.
  Analysis: Add 25 mL of 2 N sulfuric acid to 20.0 mL of *Sample solution,* and titrate with 0.1 N potassium permanganate. Each mL of 0.1 N potassium permanganate is equivalent to 1.701 mg of H_2O_2.
  Acceptance criteria: NLT the labeled concentration or within the range stated on the label

IMPURITIES

Inorganic Impurities

- **IRON**
  Sample: 18 mL (20 g)
  Analysis: Evaporate the *Sample* to dryness with 10 mg of sodium chloride on a steam bath. Dissolve the residue in 2 mL of hydrochloric acid and dilute to 50 mL with water. Add 40 mg of ammonium persulfate crystals and 10 mL of ammonium thiocyanate TS, and mix.
  Acceptance criteria: Any red or pink color produced by the *Sample* does not exceed that produced by 1.0 mL of *Iron Standard Solution* (10 µg Fe) in an equal volume of solution containing the quantities of the reagents used in the test. (NMT 0.5 mg/kg)
- **LEAD,** *Lead Limit Test, Flame Atomic Absorption Spectrophotometric Method,* Appendix IIIB
  Analysis: Determine as directed with the following modifications: (1) Prepare only one *Diluted Standard Lead Solution* by transferring 40 mL of *Lead Nitrate Stock Solution* into a 1000-mL volumetric flask and diluting to volume with water to obtain a solution containing 4 µg/mL of lead (Pb) ion; (2) Replace the first paragraph under *Sample Preparation* with the following: Transfer 10 g of sample, into an evaporation dish; (3) Under *Procedure,* determine the absorbances of the *Sample Preparation* and *Diluted Standard Lead Solution* only.
  Acceptance criteria: The absorbance of the *Sample Preparation* is NMT that of the *Diluted Standard Lead Solution.* (NMT 4 mg/kg)
- **PHOSPHATE**
  Sample: 400 mg
  Analysis: Evaporate the *Sample* to dryness on a steam bath. Dissolve the residue in 25 mL of 0.5 N sulfuric acid, add 1 mL of a 50 mg/mL ammonium molybdate tetrahydrate solution and 1 mL of *p*-methylamino-phenol sulfate TS, and allow it to stand for 2 h. Prepare

a *Control* using 2.0 mL of *Phosphate Standard Solution* (20 µg PO_4) (see *Solutions and Indicators*) in an equal volume of solution containing the quantities of the reagents used for the *Sample*.

Acceptance criteria: Any blue color produced by the *Sample* does not exceed that produced by the *Control*. (NMT 0.005%)

- **TIN**

Aluminum chloride solution: 8.93 mg/mL of aluminum chloride ($AlCl_3 \cdot 6H_2O$)

Gelatin solution: 2 mg/mL of gelatin in boiled water that has been cooled to between 50° and 60°. [NOTE—Prepare on the day of use.]

Standard stock solution: Dissolve 250.0 mg of lead-free tin foil in 10 to 15 mL of hydrochloric acid, and dilute to 250.0 mL with 1:2 hydrochloric acid.

Standard solution: Transfer 5.0 mL of *Standard stock solution* into a 100-mL volumetric flask, dilute to volume with water, and mix. Transfer 2.0 mL of this solution (100 µg Sn) into a 250-mL Erlenmeyer flask, and add 15 mL of water, 5 mL of nitric acid, and 2 mL of sulfuric acid. Place a small, stemless funnel in the mouth of the flask, and heat until strong fumes of sulfuric acid evolve. Cool, add 5 mL of water, evaporate again to strong fumes, and cool. Repeat the addition of water and heating to strong fumes, then add 15 mL of water, heat to boiling, and cool. Dilute to about 35 mL with water, add 1 drop of methyl red TS and 2.0 mL of the *Aluminum chloride solution*, and mix. Make the solution just alkaline by adding, dropwise, ammonium hydroxide and stirring gently, then add 0.1 mL in excess. [**CAUTION**—To avoid dissolving the aluminum hydroxide precipitate, do not add more ammonium hydroxide than 0.1 mL in excess.]

Centrifuge for about 15 min at 4000 rpm, and then decant the supernatant liquid as completely as possible without disturbing the precipitate. Dissolve the precipitate in 5 mL of 1:2 hydrochloric acid, add 1.0 mL of the *Gelatin solution*, and dilute to 20.0 mL with a saturated solution of aluminum chloride. [NOTE—Prepare on the day of use.]

Sample solution: Transfer 9 mL (10 g) of sample into a 250-mL Erlenmeyer flask, and add 15 mL of water, 5 mL of nitric acid, and 2 mL of sulfuric acid. Mix, and heat gently on a hot plate to initiate and maintain a vigorous decomposition. When decomposition is complete, place a small, stemless funnel in the mouth of the flask, and continue as directed for the *Standard solution*, beginning with 'and heat until strong fumes of sulfuric acid evolve.'

Analysis: Rinse a polarographic cell or other vessel with a portion of the *Standard solution*, then add a suitable volume to the cell, immerse it in a constant-temperature bath maintained at 35° ± 0.2°, and deaerate by bubbling oxygen-free nitrogen or hydrogen through the solution for at least 10 min. Insert the dropping mercury electrode of a suitable polarograph, and record the polarogram from –0.2 to –0.7 V at a sensitivity of 0.0003 µA/mm, using a saturated calomel reference electrode. In the same manner, record a polarogram of a portion of the *Sample solution* at the same current sensitivity.

Acceptance criteria: The height of the wave produced by the *Sample solution* is not greater than that produced by the *Standard solution* at the same half-wave potential. (NMT 10 mg/kg)

SPECIFIC TESTS

- **ACIDITY (AS H_2SO_4)**

Sample: 9 mL (10 g)

Analysis: Dilute the *Sample* in 90 mL of carbon dioxide-free water, add methyl red TS and titrate with 0.02 N sodium hydroxide. Perform a blank determination by repeating the preceding, omitting the addition of the *Sample*.

Acceptance criteria: The volume of sodium hydroxide solution required for titration of the *Sample* should not be more than 3 mL greater than the volume required for the blank titration. (NMT 0.03%)

- **RESIDUE ON EVAPORATION**

Sample: 25 g

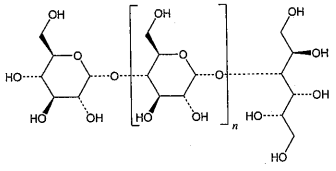
Analysis: Evaporate the *Sample* to dryness in a tared porcelain or silica dish on a steam bath, and continue drying to constant weight at 105°.

Acceptance criteria: The weight of the residue does not exceed 1.5 mg. (NMT 0.006%)

Hydrogenated Starch Hydrolysate

First Published: Prior to FCC 6

Polyglucitol



$C_6H_{14}O_6$ Formula wt, Sorbitol 182.17

$C_{12}H_{24}O_{11}$ Formula wt, Manitol 344.31

$C_{12}H_{24}O_{11}$ plus $C_6H_{10}O_5$ for each additional glucose moiety in the chain — Formula wt, Dextrose Monomer 162.14

CAS: [68425-17-2]

DESCRIPTION

Hydrogenated Starch Hydrolysate occurs as a concentrated, aqueous solution or spray-dried or dried powder. It is a mixture of sorbitol, maltitol, maltitriol, and hydrogenated polysaccharides containing greater than three D-glucopyranosyl units joined by α-1,4-linkages and terminated with a D-glucityl unit. It is soluble in water.

Function: Humectant; texturizing agent; stabilizer; thickener; crystal modification agent

Packaging and Storage: Store in well-closed containers.