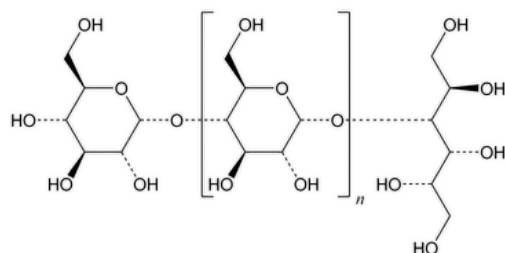


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Hydrogenated Starch Hydrolysate



Hydrogenated Polysaccharides $C_{12}H_{24}O_{11}(C_6H_{10}O_5)_n$

Polyglucitol;

Polyglycitol syrup

CAS RN[®]: 68425-17-2.

DEFINITION

Hydrogenated Starch Hydrolysate is a mixture that contains NLT 50% of hydrogenated polysaccharides containing more than 3 D-glucopyranosyl units terminated with a D-glucityl unit, calculated on the anhydrous basis. Other ingredients can include sorbitol, maltitol, and other sugar polyols.

IDENTIFICATION

- **A.** It meets the requirements of the test for *Content of Maltitol and Sorbitol*.
- **B.** It meets the requirements of the test for *Content of Hydrogenated Polysaccharides*.
- **C. LIMIT OF DIETHYLENE GLYCOL AND ETHYLENE GLYCOL**

[NOTE—Perform this test for liquid products of Hydrogenated Starch Hydrolysate.]

Diluent: Acetone and water (96:4)

Standard stock solution: 0.5 mg/mL of [USP Diethylene Glycol RS](#) and 0.5 mg/mL of [USP Ethylene Glycol RS](#) in *Diluent*

Internal standard stock solution: 0.5 mg/mL of 1,3-butanediol (internal standard) in *Diluent*

Standard solution: 0.04 mg/mL of [USP Diethylene Glycol RS](#), 0.04 mg/mL of [USP Ethylene Glycol RS](#), and 0.04 mg/mL of 1,3-butanediol (internal standard), in *Diluent*, prepared from the *Standard stock solution* and the *Internal standard stock solution*

Sample solution: Transfer 1.0 g of Hydrogenated Starch Hydrolysate to a 25-mL volumetric flask. Add 1.0 mL of water to the flask, and mix on a vortex mixer for 3 min. Add 2.0 mL of the *Internal standard stock solution*, and add the remaining *Diluent* to the flask in three equal portions to volume. Mix the contents for about 3 min after each addition of *Diluent*. Pass a portion of the supernatant layer through a nylon filter of 0.45-μm pore size. Discard the first 2 mL of the filtrate, and collect the rest of the filtrate for analysis. [NOTE—Acetone is used to precipitate sugar alcohols.]

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: GC

Detector: Flame ionization

Column: 0.32-mm × 15-m fused-silica capillary; 0.25-μm layer of phase G46

Temperature

Detector: 300°

Injection port: 240°

Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
70	—	70	2
70	50	300	5

Carrier gas: Helium

Flow rate: 3.0 mL/min

Injection size: 1.0 µL

Injection type: Split injection. The split ratio is about 10:1. [NOTE—A general-purpose split/splitless, tapered, glass wool, deactivated liner is used.]

System suitability

Sample: *Standard solution*

[NOTE—See [Table 2](#). Relative retention times are provided for information only, and the standards should be used to ensure appropriate peak identification.]

Table 2

Name	Relative Retention Time
Ethylene glycol	1.0
1,3-Butanediol (internal standard)	2.0
Diethylene glycol	2.5

Suitability requirements

Resolution: NLT 15 between ethylene glycol and 1,3-butanediol

Analysis

Samples: *Standard solution* and *Sample solution*

Based on the *Standard solution*, identify the peaks of ethylene glycol, 1,3-butanediol (internal standard), and diethylene glycol. Compare peak area ratios of ethylene glycol to the internal standard and of diethylene glycol to the internal standard in the *Standard solution* and *Sample solution*, respectively.

Acceptance criteria

Diethylene glycol: The peak area ratio of diethylene glycol to the internal standard in the *Sample solution* is NMT the peak area ratio of diethylene glycol to the internal standard in the *Standard solution*, corresponding to NMT 0.10% of diethylene glycol in Hydrogenated Starch Hydrolysate.

Ethylene glycol: The peak area ratio of ethylene glycol to the internal standard in the *Sample solution* is NMT the peak area ratio of ethylene glycol to the internal standard in the *Standard solution*, corresponding to NMT 0.10% of ethylene glycol in Hydrogenated Starch Hydrolysate.

ASSAY

• CONTENT OF MALTITOL AND SORBITOL

Mobile phase: Degassed water

Standard solution: Dissolve accurately weighed quantities of [USP Maltose Monohydrate RS](#), [USP Maltitol RS](#), [USP Dextrose RS](#), and [USP Sorbitol RS](#) in water to obtain a solution having known concentrations of about 1.0 mg/mL for each, calculated on the anhydrous basis.

Sample solution: Transfer a quantity of Hydrogenated Starch Hydrolysate, equivalent to 100 mg on the anhydrous basis, to a 100-mL volumetric flask. Dilute with water to volume, and mix. Transfer approximately 10 mL of the solution into a separate container, shake the solution for 30 s, pass through a filter of 0.45-µm or finer pore size into a suitable autosampler vial, and seal.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC