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Report Name: National Food Safety Standard for Food Additive Polydextrose Notified to WTO

Country: China - People's Republic of

Post: Beijing

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Report Highlights:

On October 25, 2023, China notified the National Food Safety Standard for Food Additive L-Polydextrose to the World Trade Organization (WTO) under G/SPS/N/CHN/1290. The proposed date of entry into force is to be determined. Comments may be submitted to China's SPS National Notification and Enquiry Center at sps@customs.gov.cn until December 24, 2023. The report provides an unofficial translation of the draft standard.

Report Summary:

On October 25, 2023, China notified the National Food Safety Standard for Food Additive L-Malic Acid to the World Trade Organization (WTO) under G/SPS/N/CHN/1290. The proposed date of entry into force is to be determined. Comments may be submitted to China's SPS National Notification and Enquiry Center at sps@customs.gov.cn until December 24, 2023.

This standard is applicable to polyglucose products, which are mixed glucose, sorbitol, citric acid, or phosphoric acid in certain proportions, polymerized, and refined under high temperature, and after neutralization and decolorization, the resulting food additive polydextrose. This standard specifies the technical requirements and testing methods for food additive polydextrose. This notified draft standard will replace the current implementing national standard GB 25541-2010 (link in Chinese). The report provides an unofficial translation of the draft standard notified to WTO.

BEGIN TRANSLATION

National Food Safety Standard
Food Additive Polydextrose
(Draft for Comments)

Foreword

This standard replaces GB 25541-2010 National Food Safety Standard Food Additive Polydextrose.

As compared with GB 25541-2010, the following major changes are made to this specification:

- Normative citations are deleted,
- Product classifications are added,
- Sensory requirements and testing methods for liquid polydextrose are added,
- The physical and chemical indicators of liquid polydextrose are added, and the indicators and testing methods of dry substance (solids) are added,
- Ash content is changed to total ash content,
- GB 5009.75 is added as a new reference for the testing methods of lead,
- Determination methods for the content of polydextrose is revised and methods of high-performance liquid chromatograph is added,
- Description of the steps in the determination methods for pH value is revised.

1. Scope

This standard applies to polydextrose products that are mixed of glucose, sorbitol, and citric acid, or phosphoric acid in certain proportions, polymerized and refined at a high temperature, and the resulting polydextrose that, after neutralization and decolorization, serves as a food additive.

2. Product Classifications

2.1 The products are classified into polydextrose, post-neutralized polydextrose, and decolorized polydextrose according to different processes.

2.2 The products are classified into solid products and liquid products according to different forms.

3. Technical Requirements

3.1 Sensory requirements

Sensory requirements shall comply with provisions in Table 1.

Table 1: Sensory Requirements

Items	Requirements		Testing Methods
	Solid	Liquid	
Color	White to yellowish	Yellowish to yellow	Take a reasonable amount of the sample, place it in a clean dry white porcelain plate or in a colorless transparent glass container, observe its color and form under the natural light, and smell it.
Smell	No abnormal odor	No abnormal odor	
Form	Granular or powdery	Viscous and transparent liquid	

3.2 Physical and chemical indicators

Physical and chemical indicators shall comply with provisions in Table 2.

Table 2: Physical and Chemical Indicators

Items		Indicator				Testing Methods
		Polydextrose		Neutralized and decolorized polydextrose		
		Solid	Liquid	Solid	Liquid	
Polydextrose (on a dry and ash-free basis), *w*/%	≥	90.0				A.3 in Appendix A
Weight loss on drying, *w*/%	≤	4.0	/	4.0	/	Direct drying method in GB 5009.3
Dry substances (solids), w/%	≥	/	67.5	/	67.5	Specified in 7.4 in GB/T 23528.2
pH value		2.5~7.0		5.0~6.0	3.5~6.5	A.4 in Appendix A
Total ash content, *w*/%	≤	0.3		2.0		GB 5009.4
1,6-anhydro-D-dextrose (on a dry and ash-free basis), *w*/%	≤	4.0				A.5 in Appendix A
Glucose and sorbitol (on a dry and ash-free basis), *w*/%	≤	6.0				A.5 in Appendix A
5-hydroxymethylfurfural (on a dry and ash-free basis), *w*/%	≤	0.1		0.05		A.6 in Appendix A
Lead (Pb)/ (mg/kg or mg/L)	≤	0.5				GB 5009.75 or GB 5009.12

Appendix A

Testing Methods

A.1 General Rules

Reagents confirmed as analytically pure and the water as specified in GB/T 6682 are used in the analysis unless otherwise specified. If no other requirements are specified, standard titration solutions, standard solutions for impurities determination, reagents and products that are used in the analysis are prepared according to GB/T 601, GB/T 602, and GB/T 603 respectively. If it is not indicated which reagent is used for the preparation, all solutions used in the tests refer to aqueous solutions.

A.2 Identification Tests

A.2.1 Reagents and materials

A.2.1.1 Concentrated sulfuric acid

A.2.1.2 Acetone

A.2.1.3 Phenol solution: 50 g/L.

A.2.1.4 Copper citrate alkaline solutions: measure 173 g of sodium citrate ($C_6H_5Na_3O_7 \cdot 2H_2O$), 117 g of sodium carbonate ($Na_2CO_3 \cdot H_2O$), use about 700 mL of water to dissolve by heating. If necessary, use filter paper to filter the solution. Measure 17.3 g of copper sulfate ($CuSO_4 \cdot 5H_2O$), place it into another container, use about 100 mL of water to dissolve it, then slowly add this solution to the prepared solution above by steadily stirring the mixed solution. After the mixed solution is cooled, use water to dilute it until the volume reaches 1,000 mL and mix well.

A.2.2 Analytic steps

A.2.2.1 Take a drop of 100 g/L sample solution and add in 4 drops of phenol solution. If 15 drops of concentrated sulfuric acid are added in quickly, the color of the solution should turn into dark yellow or orange.

A.2.2.2 Take 1 mL of 100 g/L sample solution and add in 1 mL of acetone while vigorously stirring the mixed solution. The solution should be transparent. Add 2 mL of acetone to the transparent solution, and vigorously stir the mixed solution. The color of the solution should turn milky white and become turbid instantly.

A.2.2.3 Take 1 mL of 20 g/L sample solution, add in 4 mL of copper citrate alkaline solution, heat the mixed solution until it is boiled for 2 to 4 minutes, remove the heater, and put it still till clearance. The color of its upper layer of the clear liquid should turn into blue or bluish green.

A.3 Polydextrose Determination

A.3.1 High-performance liquid chromatograph method

A.3.1.1 Reagents and materials

A.3.1.1.1 The standard substance of 1,6-anhydro-D-dextrose (CAS No.: 498-07-7): purity ≥ 98.0%.

A.3.1.1.2 The standard substance of dextrose (α-D-dextrose): purity ≥ 98.0%.

A.3.1.1.3 The standard substance of sorbitol: purity ≥ 98.0%.

A.3.1.1.4 Sulfuric acid.

A.3.1.2 Instruments and equipment

A high-performance liquid chromatograph, with a refractive index detector.

A.3.1.3 Reference chromatographic conditions

A.3.1.3.1 Chromatographic column: styrene-divinylbenzene copolymer resin column of sulfuric acid type (with styrene as the monomer, divinylbenzene as the crosslinker, through size exclusion + ion exchange. The separation mode is: exclusion limit more than 1,000, theoretical tray number n ≥ 17,000), column length at 300 mm, column inner diameter at 8 mm, or any other chromatographic column with same effect.

A.3.1.3.2 Mobile phase: take 0.42 mL of sulfuric acid, dilute it with water until the volume reaches 1,000 mL, use 0.45 μm filter membrane to filter the solution, and degas it with ultrasonic wave for 15 minutes.

A.3.1.3.3 Column temperature: 60 ℃.

A.3.1.3.4 Flow rate: 0.5 mL/min.

A.3.1.3.5 Sample size: 20 μL.

A.3.1.4 Analytic steps

A.3.1.4.1 Preparation of standard solutions

Measure reasonable amount of standard substance of 1,6-anhydro-D-dextrose, dextrose (α-D-dextrose), and sorbitol, dissolve in water, prepare the standard solution in series of concentrations of 0.1 g/L, 0.2 g/L, 0.4 g/L, and 0.6 g/L respectively. Filter the solution with 0.45 μm filter membrane and keep for future use.

A.3.1.4.2 Preparation of sample solution

Measure about 1 g of the sample of polydextrose (accurate to 0.0001g), use water to dilute it until the volume reaches 25 mL. Filter the sample solution with 0.45 μm filter membrane and keep it for future use.

A.3.1.4.3 Determination

Determine standard solution in series of concentrations of 1,6-anhydro-D-dextrose, dextrose (α-D-dextrose), and sorbitol respectively under the reference chromatographic conditions specified in A.3.1.3. Take the peak areas of the standard solution as ordinates, series of concentrations (g/L) in the standard solutions as abscissas and draw the standard curves of 1,6- anhydro-D-dextrose, dextrose (α-D-dextrose), and sorbitol respectively.

Determine the sample solution under the reference chromatographic conditions specified in A.3.1.3 and analyze the chemical composition according to the retention times of the standard substances. See the appendix B for the chromatogram. Obtain the concentrations (g/L) of 1,6-anhydro-D-dextrose, dextrose, and sorbitol respectively in the sample solution according to the linear relationships between peak areas of the standard solution and concentrations in the standard solution. If the concentrations (g/L) of 1,6-anhydro-D-dextrose, dextrose, and sorbitol in the sample solution are outside the standard curves, the concentrations in the sample solution should be adjusted.

A.3.1.4.4 Results calculation

The polydextrose content X_1 (calculated on a dry and ash-free basis) in the sample solution is calculated according to formula (A.1):

$$X_1 = 100 - X_2 - X_3 \quad \text{……（A.1）}$$

The 1,6-anhydro-D-dextrose content X_2 (calculated on a dry and ash-free basis) in the sample solution is calculated according to formula (A.2):

$$X_2 = \frac{c_1}{c_2} \times 100\% \quad \text{(A.2)}$$

The dextrose and sorbitol content X_3 (calculated on a dry and ash-free basis) in the sample solution is calculated according to formula (A.3):

$$X_3 = X_4 + X_5 \quad \text{(A.3)}$$

The dextrose content X_4 (calculated on a dry and ash-free basis) in the sample solution is calculated according to formula (A.4):

$$X_4 = \frac{c_3}{c_2} \times 100\% \quad \text{(A.4)}$$

The sorbitol content X_5 (calculated on a dry and ash-free basis) in the sample solution is calculated according to formula (A.5):

$$X_5 = \frac{c_4}{c_2} \times 100\% \quad \text{(A.5)}$$

Where:
c_1 -- concentration of 1,6-anhydro-D-dextrose according to standard curve, expressed in (g/L),

c_2 -- concentration of the sample solution (calculated on a dry and ash-free basis, according to the weight losses on drying and the ash content in the sample), expressed in (g/L),

c_3 -- concentration (g/L) of dextrose (α-D-dextrose), obtained from the standard curve,

c_4 -- concentration (g/L) of sorbitol, obtained from the standard curve,

The calculation results are accurate to two decimals.

A.3.1.4.5 Accuracy

The test result is the arithmetic mean of parallel determination results. The absolute value of differences between the two independently determined results obtained under repetitive conditions should be no more than 5% of the arithmetic mean.

A.3.2 Spectrophotometer method

A.3.2.1 Reagents and materials

A.3.2.1.1 The standard substance of dextrose (α-D-dextrose): purity ≥98.0%.

A.3.2.1.2 Phenol.

A.3.2.1.3 Sulfuric acid.

A.3.2.1.4 Phenol solution: 4 g/mL; accurately measure 80 g of phenol, add in 20 mL of water to dilute it, and shake well.

A.3.2.2 Instruments and equipment

Spectrophotometer

A.3.2.3 Analytic steps

A.3.2.3.1 Preparation of standard dextrose solution

Measure a reasonable amount of the standard substance of dextrose (α-D-dextrose), dissolve it in water, and prepare the 0.2 mg/mL original standard solution. Use the original standard solution to prepare standard solutions in series of concentrations of 5 μg/mL, 10 μg/mL, 20 μg/mL, 30

μg/mL, 40 μg/mL, and 50 μg/mL respectively.

A.3.2.3.2 Preparation of sample solution

Measure about 0.25 g of the sample (accurate to 0.0001g), dissolve it in water and make volume reach and stay at 250 mL, shake well. Use a pipette to take 10.0 mL of the solution and add water to dilute it until the volume reaches 250 mL. The sample solution is prepared.

A.3.2.3.3 Drawing the standard curve of dextrose and determining the sample solution

Use pipettes to take 2.0 mL of the standard solutions of series of concentrations, sample solution, and distilled water (as blank contrast), put them into the 15 mL screw-cap vials that contain no acetone respectively, add 0.12 mL of phenol solution into each vial, put on the caps and shake gently. Remove the caps, immediately add 5.0 mL of sulfuric acid, put on the caps, and shake vigorously. Be remined to wear rubber gloves and other protective gear when operating on sulfuric acid.

Keep vials at room temperature for 45 minutes then choose a suitable spectrophotometer to determine light absorption values of the solution in every vial at 490 nm position. Use the mixed solution of phenol and sulfuric acid with distilled water as blank contrast solution. Repeat the test for three times to obtain average light absorption values of the standard solutions in series of concentrations and average light absorption values of the sample solution. Take average light absorption values of the standard solutions in series of concentrations as ordinates, the concentrations (μg /mL) in standard solutions as abscissas to draw the standard curve.

A.3.2.3.4 Results calculation

The polydextrose content (calculated on a dry and ash-free basis) X_1 is calculated according to formula (A.6):

$$X_1 = 1.05 \times \frac{100\% \times (A-Y)}{S \times c} - P_G - 1.11 \times P_L \quad \cdots\cdots\cdots\cdots\cdots\cdots\cdots\cdots\cdots\cdots \text{（A.6）}$$

Where:

A -- absorption value of the sample solution,

Y -- intercept of the standard cure,

S -- slope rate of the standard absorption value to dextrose concentration (μg/mL) standard curve, which is about 0.02,

c -- concentrations in the sample solution (calculated on a dry and ash-free basis according to the weight losses on drying and the ash content in the sample), expressed in μg/mL,

P_G, P_L -- content of dextrose and 1,6-anhydro-D-dextrose calculated in monomeric tests, expressed in %,

1.05 -- deducted correction factor,

1.11 -- conversion factor of 1,6-anhydro-D-dextrose.

The calculation results are accurate to two decimals.

A.3.2.3.5 Accuracy

The absolute value of the differences between the two independently determined results obtained under repetitive conditions should be no more than 10% of the arithmetic mean.

A.4 Determination of pH Values

A.4.1 Analytic steps

Measure a reasonable amount of the sample, use carbon dioxide-free aqueous solution to prepare the polydextrose solution of dry substance (solids) content is 10%, and use a pH meter to determine the results.

The determined results are accurate to one decimal.

Note: the carbon dioxide-free aqueous solution is prepared according to GB/T 603.

A.4.2 Accuracy

The absolute value of the differences between the two independently determined results obtained under repetitive conditions should be no more than 3% of the arithmetic mean.

A.5 Determination of 1,6-anhydro-D-dextrose, Dextrose, and Sorbitol

Use the method specified in A.3.1 for the determination and calculate 1,6-anhydro-D-dextrose content, dextrose (α-D-dextrose) content, and sorbitol content respectively.

A.6 Determination of 5-hydroxymethylfurfural

A.6.1 Instruments and equipment

Spectrophotometer

A.6.2 Analytic steps

A.6.2.1 Preparation of sample solution

Measure 1g of the polydextrose sample (accurate to 0.0001g), use water to dissolve it until the volume reaches 100 mL, stir well, and keep it for future use.

A.6.2.2 Determination

Choose a suitable spectrophotometer, use a 1cm quartz cuvette, and water as the blank contrast solution to determine the light absorption value of the sample solution at a wavelength of 283 nm.

A.6.3 Results calculation

The 5-hydroxymethylfurfural content (calculated on a dry and ash-free basis) X_6 is calculated according to formula (A.7):

$$X_6 = \frac{0.749 \times A}{c_3} \times 100\% \cdots\cdots (A.7)$$

Where:

A -- absorption value of the sample solution,

c_3 – concentration of the sample solution (calculated on a dry and ash-free basis according to the weight losses on drying and the ash content in the sample), expressed as mg/mL,

0.749 -- Combined proportional constant, including extinction factor, molecular weight, and conversion of units and volumes.

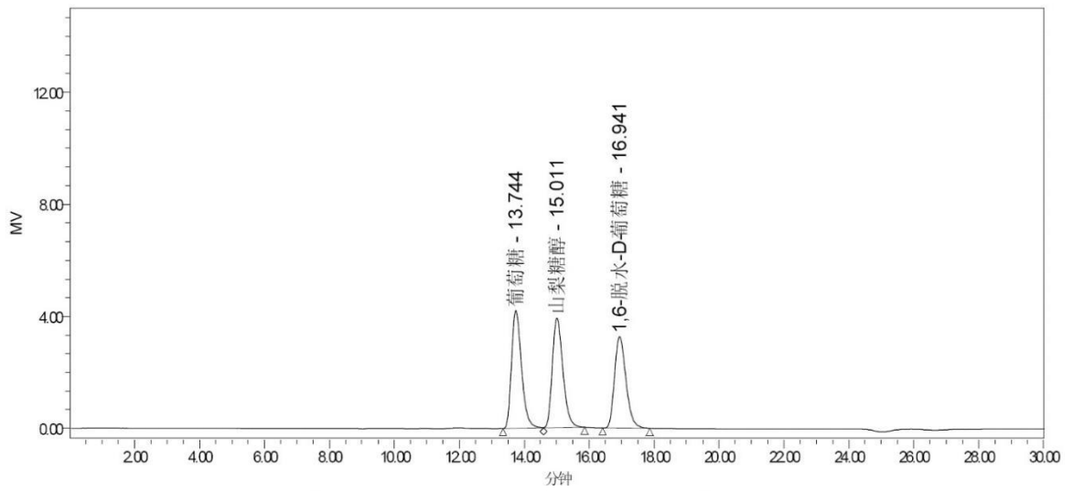
The calculation results are accurate to two decimals.

A.6.4 Accuracy

The absolute value of the differences between the two independently determined results obtained under repetitive conditions should be no more than 10% of the arithmetic mean.

Appendix B
Chromatogram Map in the High-performance Liquid Chromatograph Method for Determining of Content of Polydextrose

For the chromatogram maps of the standard substance and the reference sample solution in the high-performance liquid chromatograph method of determining polydextrose content, See Figures B.1 and B.2 respectively.



(Dextrose, Sorbitol, 1,6-Anhydro-Ddextrose)

Figure B.1: The reference liquid chromatogram map of the standard substance (0.36 mg/mL)

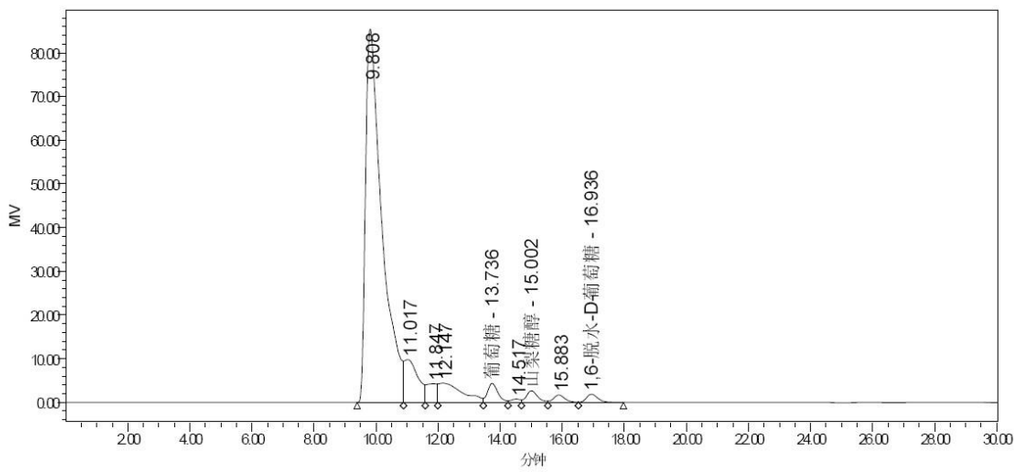


Figure B.2: The reference liquid chromatogram map of the sample (16 mg/mL)

Attachments:

No Attachments.