

Sorbitol Crystalline, NF/ FCC

(Excipient/ Food Use)

177410, 177430, 177440

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Description

Sorbitol Crystalline, is a white, hygroscopic powder and granular material. It is very soluble in water and slightly soluble in alcohol, in methanol, and in acetic acid. It has a sweet taste and not more than a slight, sweet odor. It is packed in tight containers.

General Characteristics

Formula	C ₆ H ₁₄ O ₆
Molecular Weight	182.17
pH (5 g/ 100ml water)	3.5-7.0
Solubility in water, maximum, at 20°C	70%
Calories per gram	2.6

Standard Specifications

Appearance	White free flowing powder and granules, essentially free of foreign matter
Odor	None
Identification	Meets NF/ FCC tests
Assay (anhydrous basis)	91.0 to 100.5%
Water	Maximum 1.5%
Residue on Ignition	Maximum 0.1%
Reducing Sugars	Maximum 0.3%
Total Sugars	Maximum 1.0%
pH (10% Solution)	3.5 - 7.0
Nickel	Maximum 1 ppm
Lead	Maximum 1 ppm
Microbial Limits:	
Total Aerobic Microbial Count	Maximum 1000 cfu/ ml
Yeast & Mold	Maximum 100 cfu/ ml

Ingredients

Sorbitol

CAS Number: 50-70-4

Regulatory Status

This food ingredient is Generally Recognized As Safe (GRAS) and complies with all the compendial requirements of the U.S. National Formulary and Food Chemical Codex. Please consult 21 CFR 184.1835 for current Good Manufacturing Practices.

Granulations

	USS Sieves (microns)	
Granular (177410)	On No. 10 (2000µ)	trace, Maximum
	Through No. 80 (177 µ)	10%, Maximum
Coarse Powder (177430)	On No. 40 (420µ)	3%, Maximum
	Through No. 200 (75 µ)	20%, Maximum
Powder (177440)	On No. 100 (149µ)	1%, Maximum

Packaging & Packaging Code

Granular	200 lb. drum	177410-2S
	2000 lb super sack	177410-4R
Coarse Powder	300 lb. drum	177430-V6
	1800 lb super sack	177430-7S
Powder	200 lb. drum	177440-2S

Storage & Shelf Life

Chemically, Sorbitol Crystalline, NF/ FCC, is very stable but has a tendency to absorb moisture. This may lead to caking. Cooler and lower humidity conditions are best. We thus recommend storing the material in sealed containers at 50% relative humidity or less and a room temperature of 25°C or cooler. Opened containers should be closed hermetically to prevent moisture absorption and caking.

The shelf life of Sorbitol Crystalline, NF/ FCC, is indefinite and depends upon the intended application's sensitivity to caking.

SC-001-100628



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Crystalline Sorbitol-Granular, NF/FCC
For Excipient/Food Use
(Product Code 177410)

Product Information

Crystalline Sorbitol-Granular, NF/FCC, is a white, hygroscopic powder and granular material. It is very soluble in water and slightly soluble in alcohol, in methanol, and in acetic acid. It has a sweet taste and not more than a slight, sweet odor. It is packed in tight containers.

Standard Specifications

Appearance	White free flowing powder/granules
Odor	None
Identification	Meets NF/FCC
Assay (anhydrous basis), %	91.0-100.5
Water, % Max.	1.5
pH (10% solution)	3.5-7.0
Residue on Ignition, % Max.	0.1
Reducing Sugars, % Max.	0.3
Total Sugars, % Max.	1.0
Nickel, ppm Max.	1
Lead, ppm Max.	1
Granulation (US Standard Mesh)	
On #10 (2000µ), Max.	Trace amount
Through #80 (177µ), % Max.	10

General Characteristics

Formula	C ₆ H ₁₄ O ₆
Molecular Weight	182.17
Solubility @ 20°C, % Max.	70
Calories/g (dry basis)	2.6

Ingredients

Sorbitol	CAS Number: 50-70-4
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Regulatory

Country of Origin: United States
GRAS Affirmation 21 CFR 184.1835
Meets NF and FCC specifications

Availability

Container	Container Code
200 lb. drums	2S
1500 lb. supersacks	3T
1800 lb. supersacks	7S
50 lb. bags	0H
50 lb. boxes	27

Microbiological Specifications (CFU/ml Max.)

Total Aerobic Bacteria	1000
Yeast	100
Mold	100

Storage/Shelf Life Guidelines

Chemically, Crystalline Sorbitol-Granular, NF/FCC, is very stable but has a tendency to absorb moisture which may lead to caking. We recommend storing the material in sealed containers at 50% relative humidity or less and a room temperature of 25°C or cooler. Opened containers should be closed hermetically to prevent moisture absorption and caking. The shelf life of Crystalline Sorbitol-Granular, NF/FCC, is indefinite and depends upon the intended application's sensitivity to caking. It is recommended that the product be retested after three years. It is recommended that the product be retested after three years.

Lot Coding

Bulk Drums & Supersacks

Example: D610131

D	Location Code
6	Last digit of the year
07	Two digit month
13	Two digit day
1	Packaging bin number

50 lb. bags & 50 lb. boxes

Example: W6101301

W	Location code
6	Last digit of year
10	Two digit month
13	Two digit day
0	Packaging bin number
1	Sequence batch number for the day

TECHNICAL DATA & INFORMATION

Date Approved
11/01/2016

Version
1.0

Document #
CBU.TS.SPEC.177410

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