

PRODUCT SPECIFICATIONS SHEET

GLYCOLYS® MAIZE

Definition

Product Identifier

Product name: GLYCOLYS® MAIZE

SODIUM STARCH GLYCOLATE (Type A): Sodium salt of a cross-linked partly O-carboxymethylated corn starch.

CAS No. 9063-38-1

INCI : SODIUM CARBOXYMETHYL STARCH

Specifications

A) CHARACTERS

APPEARANCE	White, fine powder, odourless
------------	----------------------------------

B) IDENTIFICATION

IDENTIFICATION TEST-A(*)	USP/NF	Conforms
IDENTIFICATION TEST-B(*)	USP/NF	Conforms
IDENTIFICATION TEST-C(*)	USP/NF	Conforms
IDENTIFICATION TEST-D(*)	USP/NF	Conforms

C) TESTS

pH	USP/NF	5.5 - 7.5
LOSS ON DRYING (as shipped)	USP/NF	10.0 % max.
SODIUM CONTENT	USP/NF	2.8 - 4.2 %
SODIUM CHLORIDE CONTENT	USP/NF	7.0 % max.
IRON(**)	USP/NF	20 mg/kg max.
SODIUM GLYCOLATE	USP/NF	2.0 % max.
PARTICLE SIZE (sieve)		
-RESIDUE ON 75 MICRONS		10.0 % max.
ETHANOL (residual solvent)	USP/NF	0.50 % max.

MICROBIOLOGICAL VALUES:

-TOTAL AEROBIC MICROBIAL COUNT	100 cfu/g max.
-TOTAL YEASTS AND MOULDS COUNT	10 cfu/g max.
-ESCHERICHIA COLI(**)	Not detected in 1g.
-SALMONELLA SPECIES(**)	Not detected in 10g.

GLYCOLYS® MAIZE

-STAPHILOCOCCUS AUREUS(**)

Not detected in 1g.

-PSEUDOMONAS AERUGINOSA(**)

Not detected in 1g.

- * Compliance data - Tests not performed .

- ** Monitoring plan

Indicatives Values

Solubility information : practically insoluble in methylene chloride.

Gives a translucent suspension in water.

Comments

Methods used by Roquette may be Ph.Eur. or USP/NF or internal validated methods which have been compared to the pharmacopeia monograph.

Conformity

Complies with the current USP/NF monographs requirements.

Storage

Storage in well-closed containers preferably protected from wide variations in temperature and humidity, which may cause caking.

Retest Date manufacturing date + 5 years.

Those date is for information only and may vary according to packaging type and manufacturing plant. Proper information is shown on labelling and Certificate of Analysis.

Disclaimer

The information provided in this Product Specification Sheet relates only to the specific product designated and may not be applicable when such product is used in combination with other materials or in any process.

All information and instructions provided in this Product Specification Sheet are based on the current state of our knowledge at the latest revision date indicated. It is the responsibility of the user to be aware of and to follow the regulations applying to our product for its possession, handling and use.

Notes : All the dates are formatted like YYYY/MM/DD.