

PRODUCT SPECIFICATION SHEET
MAIZE STARCH AMYLO N-400

Definition

Product identifier

Product name: MAIZE STARCH AMYLO N-400

CAS-No. 9005-82-7
EC No. 232-685-9

Specifications

Description (characters)

High amylose maize starch, separated from the grain of maize by a wet milling process.

Aspect	Very fine matt powder that creaks when pressed between the fingers.
Colour	White to slightly yellowish
Solubility	Practically insoluble in cold water and in ethanol 96%.

Identification

Identification test A	EP, NF	Complies
Identification test B	EP, NF	Complies
Identification test C	EP, NF	Complies

Physical and chemical values (tests)

Loss on drying	EP, NF	15,0 %(w/w) max.
pH	EP, NF	4,0 - 7,0
Sulphated ash	EP, NF	0,6 %(w/w) max.
Oxidizing substances	EP, NF	20 mg/kg max.
SO₂	EP, NF	50 mg/kg max.
Iron	EP, NF	10 mg/kg max.
Foreign matter	EP	Complies

Microbiological values

Total aerobic microbial count	1 000 /g max.
Total yeasts and moulds count	100 /g max.
Escherichia coli	Not detected in 1g
Salmonella	Not detected in 10g

Additional data

Comments

Methods used by ROQUETTE may be the Pharmacopoeia methods or alternative validated methods.

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Caption :

- EP stands for European Pharmacopoeia
- NF stands for National Formulary from USP - NF

Conformity

Legislation / specific regulations

Meets the requirements of the current monograph of:

- European Pharmacopoeia : MAIZE STARCH (0344)
- National Formulary from USP - NF : CORN STARCH

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When tested accordingly, this product complies with relevant monograph requirements. The compliance to the general chapters depends on plant manufacturing standards. This product is not recommended to be used as active ingredient since it is not fully manufactured according to pharma cGMPs . Please contact us for further information.

Storage

Storage conditions	The product durability may vary according to packaging type and manufacturing plant. Proper information is shown on labelling and CoA.
Storage conditions for PACK material	We recommend to preserve the product in its unopened original packaging, preferably protected from wide variations in temperature and humidity. Upon opening, use the product as quickly as possible to prevent moisture regain.
Expiry date of the packed product	Manufacturing date + 5 years, in its unopened packaging.

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. Analytical criteria are tested either on each batch or monitored or guaranteed, based on the Product Risk Analysis. For each batch, the status of the analysis may be indicated in the Certificate of Analysis. 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.

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