



# ROQUETTE

Offering the best of nature™

PRODUCT SPECIFICATION SHEET

## 400L-NF CORN STARCH

### Definition

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#### Product Identifier

**Product name:** 400L-NF CORN STARCH

Modified corn starch.  
CAS no. : 9005-25-8  
EINECS : 232-679-6

### Specifications

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#### A) CHARACTERS

**APPEARANCE** White powder.

#### B) IDENTIFICATION

**IDENTIFICATION TEST-A** COMPLIES  
**IDENTIFICATION TEST-B** COMPLIES  
**IDENTIFICATION TEST-C** COMPLIES

#### C) TESTS

**pH** 4.5 - 7.0  
**LOSS ON DRYING** 13.5 % max.  
**RESIDUE ON IGNITION** 0.5 % max.  
**IRON** 10 mg/kg max.  
**OXIDIZING SUBSTANCE** 20 mg/kg max.  
**SULFUR DIOXIDE** 50 mg/kg max.  
**RESIDUAL SOLVENTS** COMPLIES  
**FOREIGN MATTER** COMPLIES  
  
**PARTICLE SIZE (sieve)**  
- **RESIDUE ON 75 microns** 2.0 % max.  
  
**MICROBIOLOGICAL VALUES :**  
- **TOTAL AEROBIC MICROBIAL COUNT** 600 CFU/g max.  
- **TOTAL YEASTS COUNT** 20 CFU/g max.  
- **TOTAL MOULDS COUNT** 40 CFU/g max.  
- **COLIFORMS** 20 CFU/g max.



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- ESCHERICHIA COLI	Not detected in 10g
- SALMONELLA	Not detected in 10g
- STAPHYLOCOCCI	Not detected in 10g
- PSEUDOMONAS	Not detected in 10g

### Comments

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Methods used by Roquette may be the Pharmacopoeia methods or alternative validated methods which have been compared to the Pharmacopoeia methods.

Not intended for use in manufacture of parenteral dosage forms.

### Conformity

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#### Conforms to the current edition of

- National Formulary (NF)

### Disclaimer

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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.