

## STARLAC

### Definition

#### Product Identifier

**Product name:** STARLAC

SPRAY DRIED COUMPOUND:

- 85 PARTS LACTOSE MONOHYDRATE
  - 15 PARTS GMO FREE EXTRA WHITE NATIVE MAIZE STARCH
- CAS-No. 64044-51-5 / 9005-25-8

### Specifications

#### A) CHARACTERS

APPEARANCE	White or almost white odourless powder.
SOLUBILITY	Partially soluble in cold water, practically insoluble in ethanol 96%.

#### B) IDENTIFICATION

STARLAC® :

- IR-Spectroscopy COMPLIES

MAIZE STARCH:

- Test identification B	EP	COMPLIES
- Test identification C	EP	COMPLIES

#### C) PHYSICO-CHEMICAL VALUES

LACTOSE (on DS)	HPLC(*)	82.0 - 88.0 %
MAIZE STARCH (on DS)	Polarimetric(*)	12.0 - 18.0 %
LOSS ON DRYING	EP(*)	3 % max.
SULPHATED ASH	EP(*)	0.25 % max.
PARTICLE SIZE (Sieve)		
- residue on 32 microns		85 % min.
- residue under 160 microns		35 - 65 %
- residue on 250 microns		20 % max.

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(\*) See analytical monograph STARLAC, available on request.

### D) MICROBIOLOGICAL VALUES

- TOTAL AEROBIC MICROBIAL COUNT	1000 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT	100 CFU/g max.
- ESCHERICHIA COLI	Not detected in 1g
- SALMONELLA	Not detected in 10g

### Conformity

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#### EACH COMPONENT CONFORMS TO THE CURRENT EDITION OF

- European Pharmacopoeia (EP), LACTOSE MONOHYDRATE / MAIZE STARCH
- National Formulary (NF), LACTOSE MONOHYDRATE / CORN STARCH
- Japanese Pharmacopoeia (JP), LACTOSE HYDRATE / CORN STARCH

### Storage

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#### Chemical stability

manufacturing date + 3 years.

We recommend to preserve the product in its unopened original packaging, preferably protected from wide variations of temperature and humidity.

### 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.