

Certificate of Analysis



Product Code: 2001

Product Description: STARCH 1500® PARTIALLY PREGELATINIZED MAIZE STARCH 2001

Material Description:	White Powder	Ship To:	PT Menjangan Sakti ID
Lot No.:	IN551134	Bill To:	PT Menjangan Sakti ID
Date of Manufacture:	28-SEP-2023	Sales Order No.:	CCSP1989415
Re-evaluation Date:	27-SEP-2027	Customer PO No.:	PH-42309
Manufacturing Site:	Colorcon 3702 E 21st Street Indianapolis, IN 46218 United States	Customer Item:	N/A
		Shipped From:	Colorcon Inc. Indianapolis, Indiana

Test	Minimum	Maximum	Result	Method
COLD WATER SOLUBLES AVERAGE, %	10.0	18.0	12.1 %	IN-QAC-TM-5382
LOSS ON DRYING AVERAGE, %	7.00	11.00	8.89 %	IN-QAC-TM-5364
HEAVY METALS (S)	NMT 20		GM	CHP
IRON, %	NMT 0.0010		NMT 0.0010 %	USP/NF
OXIDIZING SUBSTANCES	NEGATIVE		NEGATIVE	USP/NF
SULPHUR DIOXIDE, %	NMT 0.001		GM	USP/NF
PH	4.5	7.0	5.6	USP/NF
RESIDUE ON IGNITION, %	0.0	0.5	0.1 %	USP/NF
PARTICLE SIZE THROUGH 100 MESH, %	90.0	100.0	95.9 %	IN-QAC-TM-5378
PARTICLE SIZE THROUGH 270 MESH, %	25.0	50.0	41.6 %	IN-QAC-TM-5378
IDENTIFICATION USP/NF	POSITIVE		POSITIVE	USP/NF
IDENTIFICATION PH EUR	POSITIVE		POSITIVE	PH EUR
FOREIGN MATTER	CONFORMS		CONFORMS	PH EUR
MICRO E. COLI	ABSENT		ABSENT	USP/NF
MICRO P. AERUGINOSA	ABSENT		GM	USP/NF

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MICRO S. AUREUS	ABSENT		GM		USP/NF
MICRO SALMONELLA	ABSENT		ABSENT		USP/NF
MICRO AEROBIC TPC, CFU	0	100	<10 CFU		USP/NF
MICRO M&Y, CFU	0	100	<10 CFU		USP/NF

- Compliance Statement : This Product meets all agreed upon specifications <2001>.

The above analytical data has been reviewed and authenticated electronically by an authorised representative of the Quality Unit as evidenced by the application of an electronic signature.

Approved By : Stephen Black **Date :** 09-OCT-2023
Electronic Signature ID : 5363233-4036397

This product complies with the requirements of the current NF, PhEur & ChP monographs for Pregelatinized Starch
This product is produced using identity preserved, non genetically enhanced maize.

GM: Manufacturer guarantees compliance based on process knowledge and audit testing.

- Additional Product Specific Regulatory and Quality Information is available via My Colorcon at <https://www.colorcon.com/regulatory-compliance/request-information>

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