

Product Specification

Product group: Starch
Brand name: Prejel PA5 PH
Product description: Pregelatinized potato starch
Article no.: 1229921
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Manufacturer: DFE Pharma GmbH & Co. KG, Goch, Germany.
Production site: Agglomix, Tilburg, the Netherlands.
Product name: Prejel PA5 PH.
Product description: Pregelatinized potato starch; a white or yellowish-white powder; swells in cold water and is insoluble in ethanol.
Conforms to USP-NF Pregelatinized Modified Starch, Ph. Eur. Starch, Pregelatinised, JPE Pregelatinized Starch and ChP Pregelatinized Starch monographs on the date of manufacture.

Physical-Chemical data:

	<u>Specification</u>
Identification A (USP-NF)	Pass
Identification A (Ph.Eur.)	Pass
Identification (1) (JPE)	Pass
Identification (Iodine reaction)- Identification B in USP-NF/Ph. Eur.; Identification (2) in JPE	Pass
Residue on ignition/ Sulphated ash	Max. 0.5 % w/w
Loss on Drying	Max. 13% w/w
pH	4.5-7.0
Heavy metals	Max. 20 ppm
Iron	Max. 20 ppm
Arsenic	Max. 2 ppm
Sulphur dioxide	Max. 30 ppm
Foreign matter	Pass
Oxidizing substances	Absent

Microbiological data:

	<u>Specification</u>
Total Aerobic Microbial Count	Max. 1000 cfu/g
Total Yeast and Mould Count	Max. 100 cfu/g
Escherichia coli	Negative in 1g
Salmonella species	Negative in 25g

Particle size

<u>Particle size</u>	<u>Specification</u>
(Sieve analysis) %< 125 µm	Min 80.0 %

Packaging : A white multi-layered paper bag with pre-inserted polyethylene inner liner, 25 kg net

Storage : Keep in original, unopened packing and away from strongly odorous materials.
Store at room temperature (normal warehouse conditions).

Shelf life : Product has a retest date of 36 months.

This document substitutes all previous versions issued for the brand names mentioned above.
We trust this information, which is made up to the best of our knowledge, will be helpful to you.

Name : Dr. Bastiaan Dickhoff
Job title : Director Innovation & Technical Solutions

Signature :



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