



# Product Specification

Product group: Superdisintegrants  
 Brand name: Primellose®  
 Article code: 743737  
 Product description: Croscarmellose Sodium  
 Document No.: PD-0047 Page 1 of 2

Production site: DFE Pharma BV, Foxhol, The Netherlands  
 Product name: Primellose® conforms to USP-NF, Ph.Eur., JP monograph, current at time of manufacture  
 Product description: White or greyish-white, hygroscopic powder  
 Residual Solvents  
 (CPMP/ICH/283/9): No Class 1, 2, 3 and other solvents than ethanol and water are used during production  
 Identification: Complies with Pharmacopoeia when tested

## **Physical-Chemical data:**

Loss on drying  
 Sodium glycolate and sodium chloride content  
 Content of water-soluble material  
 pH  
 Degree of substitution  
 Settling volume  
 Residue on ignition/Sulphated ash  
 Heavy metals  
 Ethanol (class 3 solvent)  
 Nitrite content (ppm)

## **Specification**

max. 7.0 %  
 max. 0.5 %  
 1.0 – 10.0 %  
 5.0 - 7.0  
 0.60 - 0.85  
 10.0 - 30.0 ml  
 14.0 - 28.0 %  
 max. 10 mg/kg  
 max. 6.0 %  
 reported value

## **Microbiological data:**

Total aerobic microbial count  
 Yeasts and Moulds  
 Escherichia coli  
 Staphylococcus aureus  
 Pseudomonas aeruginosa  
 Candida albicans  
 Salmonella

## **Specification**

max. 100 cfu/g  
 max. 20 cfu/g  
 negative in 10 g  
 negative in 10 g  
 negative in 10 g  
 negative in 1 g  
 negative in 10 g

## **Particle size** (Airjet sieve analysis, Alpine)

Particle size distribution % <45 µm  
 Particle size distribution % <75 µm  
 Particle size distribution % <125 µm

## **Specification**

65 - 85 %  
 min. 90 %  
 min. 98 %



## Product Specification

Product group: Superdisintegrants  
Brand name: Primellose®  
Article code: 743737  
Product description: Croscarmellose Sodium  
Document No.: PD-0047 Page 2 of 2

### Storage:

Keep in original, unopened packing and away from strongly odorous materials  
Temperature averaging between 5 and 25 °C, relative humidity of max. 70%.

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** :

A handwritten signature in blue ink that reads 'B. Dickhoff'.

This document is controlled by a validated, electronic system and is valid without signature.  
The above facsimile signature is only for display.