

FDA UNII - Numbers

Product group: Lactose, Inhalation, MCC,

Starch, Bipharma

and Superdisintegrants

Brand name: Lactohale®, Lactochem®,

Lactopress®, Pharmatose®, Respitose®, Solani Amylum, SuperTab®, SuperStarch®, Pharmacel®, Primojel®,

Pharmacel® sMCC 90,

Primellose®, BioHale® Sucrose, BioHale® Trehalose Dihydrate

Document No.: PD-0735 Page 1 of 2

Dear Customer,

Hereby we, DFE Pharma GmbH & Co. KG, provide you with the UNII Numbers (Unique Ingredient Identifier) attributed to our excipients according to the Substance Registration System of the FDA. The FDA defines the UNII as a non-proprietary, free, unique, unambiguous, non-semantic, alphanumeric identifier based on a substance's molecular structure and/or descriptive information.

Product Description	Brand Name	UNII No.
	Pharmatose®	
	Respitose® SV & ML	
	Lactohale®	
	Lactochem®	
	Lactopress® GR & SD	
Lactose Monohydrate	SuperTab [®] GR & SD	EWQ57Q8I5X
	Respitose® AN	
	SuperTab [®] AN	
Lactose Anhydrous	Lactopress® AN	₃ SY ₅ LH ₉ PMK
Sodium Starch Glycolate	Primojel [®]	5856J3G2A2
Croscarmellose Sodium	Primellose [®]	M28OL1HH48
Microcrystalline Cellulose	Pharmacel®	OP1R32D61U
Potato Starch and	Solani Amylum	
Pregelatinized Potato Starch	Prejel PA ₅ PH	8lo8gSAH3T
Partly Pregelatinized Maize Starch	SuperStarch®	O8232NY3SJ
Sucrose	BioHale® Sucrose	C151H8M554
	BioHale® Trehalose	
Trehalose dihydrate	Dihydrate	7YIN7J07X4
·	Pharmacel® sMCC 90	OP1R32D61U (Microcrystalline Cellulose)
Silicified Microcrystalline Cellulose		ETJ7Z6XBU4 (Silicon dioxide)



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This statement 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.

With kindest regards,

Name : Armand M. Janssen

Job title : QA Regulatory Affairs Officer

Signature

This document is controlled by a validated, electronic system and is valid without signature.

The above facsimile signature is only for display.