

## 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

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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 <sup>®</sup>   |   |
|                                       | Respitose® SV & ML        |   |
|                                       | Lactohale®                |   |
|                                       | Lactochem <sup>®</sup>    |   |
|                                       | Lactopress® GR & SD       |   |
| Lactose Monohydrate                   | SuperTab® GR & SD         | EWQ57Q8I5X                              |
|                                       | Respitose® AN             |   |
|                                       | SuperTab® AN              |   |
| Lactose Anhydrous                     | Lactopress® AN            | 3SY5LH9PMK                              |
| Sodium Starch Glycolate               | Primojel <sup>®</sup>     | 5856J3G2A2                              |
| Croscarmellose Sodium                 | Primellose <sup>®</sup>   | M28OL1HH48                              |
| Microcrystalline Cellulose            | Pharmacel <sup>®</sup>    | OP1R32D61U                              |
| Potato Starch and                     | Solani Amylum             |   |
| Pregelatinized Potato Starch          | Prejel PA <sub>5</sub> PH | 8lo89SAH3T                              |
| 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.