REACH - Statement

Product group: Starch, Lactose, Inhalation, Biopharma, MCC and Superdisintegrants

All products manufactured by DFE Pharma GmbH & Co. KG

Document No.: PD-0117

Dear Customer,

The REACH regulation of the European Union (Regulation (EC) 1907/2006 (consolidated)), regulates the registration, evaluation and approval of chemical substances for the EU market. The intention of the regulation is to assure that only substances that are safe for humans and the environment are circulated on the EU market.

Pharmaceutical products (and also food and feed products) have to fulfill only part of the requirements defined in the REACH regulation.

Registration Requirement:
The intended use of all DFE Pharma products is exempt from registration. According to Regulation (EC) No. 1907/2006, Art. 2 No. 5 (a) and (b), the provisions of Titles II (registration), V (downstream users), VI (evaluation) and VII (authorization) do not apply to the extent that a substance is used in medicinal products for human or veterinary use and to the extent that a substance is used in food or feedingstuffs.

- Lactose (Respitose®, Pharmatose®, SuperTab®, Lactochem®, Lactopress®,Lactohale®)
- Starch (Solani Amylum, Prejel PA5 PH)
- Sucrose (BioHale® Sucrose)
- Microcrystalline cellulose (Nutracel®, Pharmacel®)

In addition, listed above products do not need to be registered as lactose, starch, sucrose and cellulose pulp are included in Annex IV of Regulation (EC) No 1907/2006. Sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties, and thus the provisions of Titles II (registration), V (downstream users), and VI (evaluation) do not apply to these substances (Art. 2 No. 7 (a) of Regulation (EC) No 1907/2006).
Thus, mentioned products may be used in any application, even outside the scope of pharmaceutical manufacturing

- Silicified Microcrystalline cellulose (Pharmacel® sMCC 90):

This product is a mixture of 98% microcrystalline cellulose (no REACH registration required; because it is a natural polymer; cellulose pulp is also included in Annex IV of Regulation (EC) No 1907/2006) and 2% of Silicon dioxide (Aerosil 200, which has a REACH registration). For the mixture, there is thus no requirement for a REACH registration.
The product may be used in any application, even outside the scope of pharmaceutical manufacturing.

- Sodium starch glycolate (Primojel®), Croscarmellose sodium (Primellose®):

These products are polymers consisting of glucose monomers. For these products, there is no registration requirement. According to Regulation (EC) No. 1907/2006, Art. 2 No. 9, the provisions of Titles II (registration) and VI (evaluation) do not apply to polymers.
Thus, mentioned products may be used in any application, even outside the scope of pharmaceutical manufacturing. DFE Pharma, however, does not in general promote the use of these products outside the pharmaceutical (and if applicable food) area.

DFE Pharma GmbH & Co. KG
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- Trehalose (BioHale® Trehalose Dihydrate):

BioHale® Trehalose purified by other solvents than water requires a REACH registration when used outside the scope of food and pharmaceutical products. This use is not recommended by DFE Pharma.

Information Requirement:

For pharmaceutical products exists an information requirement. DFE Pharma meets the information requirement by providing you (on request) with Safety Information Data Sheets.

Information from Suppliers:

DFE Pharma has chosen its suppliers with great care and trusts them to fulfill the legal requirements. Data have been collected from suppliers to ensure that their products comply with the requirements of the REACH regulation (if applicable). This approach will be continued for all new products sourced from approved suppliers as well as for selection of new suppliers.

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 : Lorina Bisharat
Job title : Regulatory Affairs Manager
Signature :

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The above facsimile signature is only for display.

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