Dioxins

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

All products manufactured by DFE Pharma GmbH & Co. KG

Document No.: PD-0101

Dear Customer,

Dioxins and dioxin-like-PCBs have greater affinity for lipid like media; they are therefore only found in the fat-containing part of a product. All the excipients mentioned above are more or less hydrophilic, carbohydrate based, or contain negligible fat content and therefore are not at risk for contamination with this group of contaminants.

Regulation (EU) 2023/915 sets maximum levels for dioxins and related contaminants in certain food categories, including foods of animal origin such as raw milk and dairy products, as well as vegetable oils and fats, and food intended for infants and young children. Lactose is manufactured from whey, which is derived from bovine milk and therefore falls within the scope of this regulation. The remaining excipients listed above are not subject to specific legal limits for dioxins and related contaminants under this regulation.

Dioxins and dioxin-like-PCBs are monitored in the EU and in New Zealand through official contaminant surveillance programs that analyze agro-alimentary raw materials, including raw milk. In addition, our raw material suppliers conduct their own contaminant monitoring in accordance with their quality and compliance obligations, and this monitoring is verified as part of our supplier qualification processes.

On this basis, we herewith certify that the above mentioned products comply with Regulation (EU) 2023/915 on maximum levels for dioxins and related contaminants, as applicable.

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 :

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

DFE Pharma GmbH & Co. KG
Kleyer Strasse 187, 47574 Goch, Germany, P.O. Box 20 21 20, 47568 Goch, Germany, T. +49 2823 9288 770, F. +49 2823 9288 7799

The document is an uncontrolled copy and is valid only at the time of distribution. Timestamp: 18-11-2026; 18:50 UTC

Release date: 23-02-2026