Contaminants Statement
(EU)

Product group:	Lactose and Inhalation Produced in Europe
Brand name:	Pharmatose®, Respitose®, SuperTab®, Lactochem®, Lactopress®, Lactohale®, Lactose DT
Document No.:	PD-0123

Dear Customer,

Herewith, we inform you about the maximum level of some potential contaminants present in the above mentioned products, as listed below:

Mycotoxins	
Aflatoxin M1	Max. 0.35 µg /kg [1,2)]
Dioxins and PCBs	
Sum of dioxins (WHO-PCDD/F-TEQ)	Max. 2.0 pg/g fat, based on monitoring raw milk [1)]
Sum of dioxins and dioxin-like PCBs (WHO-PCDD/F-PCB-TEQ)	Max. 4.0 pg/g fat, based on monitoring raw milk [1)]
Sum of PCB28, PCB52, PCB101, PCB138, PCB153 and PCB180 (ICES-6)	Max. 40 ng/g fat, based on monitoring raw milk [1)]
Others	
Pesticides	In compliance with 396/2005/EC, based on testing raw milk [3)]
Antibiotics	Not detectable, based on testing raw milk [4)]
Radioactivity (Cs 134/Cs 137)	Max. 1000 Bq/kg, based on monitoring raw milk [5)]

1) Regulation (EU) No 2023/915 on maximum levels for certain contaminants in food.
2) The legal requirements of aflatoxin M1 apply to raw milk. For powders, a reconstitution factor of 7 is used.
3) Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin, as amended.
4) Delvotest, detection limits based on Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as amended.
5) Regulation (Euratom) 2016/52 laying down maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency.

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.

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