



To whom it may concern

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Quality Unit / Regulatory Affairs

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Page 1/2
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Revision 39

Undesired Substances

MEGGLE Products:

- Lactose Monohydrate (Ph. Eur. / USP-NF / JP): CapsuLac[®] 60, FlowLac[®] 90, FlowLac[®] 100, GranuLac[®] 70, GranuLac[®] 80, GranuLac[®] 140, GranuLac[®] 200, GranuLac[®] 230, PrismaLac[®] 40, SacheLac[®] 80, SorboLac[®] 400, SpheroLac[®] 100, Tablettose[®] 70, Tablettose[®] 80, Tablettose[®] 100
- Lactose Monohydrate (USP-NF / Ph. Eur. / JP): Lactose monohydrate Low Endotoxin
- Inhaler Grade Lactose Monohydrate (USP-NF / Ph. Eur. / JP): InhaLac[®] 70, InhaLac[®] 120, InhaLac[®] 140, InhaLac[®] 150, InhaLac[®] 160, InhaLac[®] 230, InhaLac[®] 250, InhaLac[®] 251, InhaLac[®] 300, InhaLac[®] 400, InhaLac[®] 500
- Co-processed excipients: Cellactose[®] 80, CombiLac[®], MicroceLac[®] 100, RetaLac[®], Reta M[®], StarLac[®]

The mentioned substances mentioned in the list on page 2 are neither used as ingredients and technical aids nor are contained in ingredients or technical aids as intentionally added substances.

Manufacturing of lactose includes refining whereby processing aids (activated carbon and inorganic filter auxiliaries) are added to a hot solution of the unrefined lactose. With cooling, the desired crystals grow and the regular structure of the crystal tends to favour the desired material and exclude other kinds of particles and impurities. Thus, refining is a purification process leading to a higher purity.

The other compounds in co-processed excipients are also purified substances.

Best regards

MEGGLE GmbH & Co. KG


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Page 2/2

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Undesired Substance¹ List

Active pharmaceutical ingredients	Flavourings, perfumes	Polybrominated Diphenyl Ethers
Alkyl phenols and their ethoxylates	Flavouring substances ²	Polychlorinated Biphenyls
Amines	Formaldehyde and its donor substances	Polychlorinated Phenoxyphenols
Aminopolycarboxylic acids (EDTA etc.)	Fruits and vegetables, all types	Polysaccharides ³ other than composition ⁴
Antioxidants	Fumaric acid and its esters	Polysorbates
Asbestos	Fungi	Preservatives
Azo dyes	Gelatin	Protein, hydrolysed protein, all types
Azoles ⁵	Glycerol	Purine alkaloids
Benzoic acid, its salt and acid derivates	Glycols, and their esters	Pyrrrolizidine alkaloids
Benzoin	Heavy Metals	Quaternary Ammonium Compounds
Benzophenone	Herbs, spices, all types	Salicylates
Benzyl alcohol	Human origin material	Silanes
Bergamot oil	Hydrazines	Silicones
Biogenic amines	Iodine	Substances prohibited etc. in food ⁶
Biocides	Lanolin	Sugar alcohols other than composition ⁷
Bisphenols and their derivates	Lectines	Sulfonic acids, its salts and acid derivates
Boron, boric acid, borates	Lysozyme	Sulfuric acid, its salts and acid derivates
Coatings	Melamine, Cyanuric acid	Sulfurous acid, its salts and acid derivates
Cocamides	Mica Ester	Sulphur
Colophony	Monosaccharides	SVHC-substances ⁸
Colours	Natamycin	Sweeteners
Coniferyl Alcohol	Nitrates	Talc
Cyclodextrins	Nitrites	Thiocyanates
Dehydroacetic acid	Nitrosamines	Thiuram disulphides
Diacetyl	Oils and fats, vegetable and animal	Tributyltin
Dimethyl fumarate	Oilseeds ⁹	Triglycerides
Dioxins	Oligo- and polypeptides	Volatile Organic Compounds
Disaccharides other than lactose	Organic poly- and their monomers ¹⁰	Yeast
Emulsifiers (Lecithin etc.)	Parabens	
Ethanol	Peru balsam	
Fatty acids and their esters	Phenylalanine	
Fibers other than composition ¹¹	Phthalates	

¹ The list includes derived products as far as applicable.

² for EU: incl. substances mentioned in Regulation (EC) No 1334/2008, Annex I and Regulation (EC) No 1223/2009, Annex III Ref. numbers 67 – 92.

³ incl. starch, cellulose, glycogen, chitin, dextran, chitosan, pectin, inulin, xanthan, arabinogalactan, galactomannan, alginate, carrageenan, guaran, carubin.

⁴ cellulose in Cellactose[®] 80; microcrystalline cellulose in CombiLac[®], MicroceLac[®] 100; maize starch in CombiLac[®], StarLac[®], HPMC in RetaLac[®], Reta M[®]

⁵ pyrrole, imidazole, pyrazole, triazoles, tetrazole, pentazole, oxazole, isoxazole, oxadiazoles, thiazole, isothiazole, thiadiazoles and the successively reduced analogues (azolines and azolidines).

⁶ substances whose use in foods is prohibited, restricted or under community scrutiny (Regulation (EC) 1925/2006, Annex III in the current version)

⁷ mannitol in Reta M[®]

⁸ for EU: current [ECHA Candidate List of Substances of Very High Concern](#).

⁹ e.g. poppy seed, sunflower seed, linseed.

¹⁰ incl. PE, PP, PVC, PS, PET and their monomers ethene, propene, vinyl chloride, styrene, terephthalic acid, ethylene glycol.

¹¹ cellulose in Cellactose[®] 80; microcrystalline cellulose in CombiLac[®], MicroceLac[®] 100; HPMC in RetaLac[®], Reta M[®]