



To whom it may concern

Dr. Stefan Dreiheller
Quality Unit / Regulatory Affairs

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Revision 38

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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Undesired Substance¹ List

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

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[®]