



To whom it may concern

Dr. Stefan Dreiheller
Quality Unit

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Doc.-No. EIP-0065
Revision 40

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

A handwritten signature in purple ink that reads "i. V. Stefan Dreiheller".

Dr. Stefan Dreiheller

Regulatory Affairs / Specification Management



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Undesired Substance¹ List

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

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 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[®]