



To whom it may concern

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Quality Unit / Regulatory Affairs

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Doc.-No. EIP-0065
Revision 35

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[®] 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 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

represented by MEGGLE Verwaltungs GmbH


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Undesired Substance¹ List

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

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

⁴ incl. starch, cellulose, glycogen, chitin, dextran, chitosan, pectin, inulin, xanthan, arabinogalactan, galactomannan, alginate, carrageenan, guaran, carubin.

⁵ cellulose in Cellactose[®] 80; microcrystalline cellulose in CombiLac[®], MicroceLac[®] 100; maize starch in CombiLac[®], StarLac[®], HPMC in RetaLac[®], Reta M[®]

⁶ mannitol in Reta M[®]

⁷ for EU: current [ECHA Candidate List of Substances of Very High Concern](#).

⁸ e.g. poppy seed, sunflower seed, linseed.

⁹ incl. PE, PP, PVC, PS, PET and their monomers ethene, propene, vinyl chloride, styrene, terephthalic acid, ethylene glycol.

¹⁰ cellulose in Cellactose[®] 80; microcrystalline cellulose in CombiLac[®], MicroceLac[®] 100; HPMC in RetaLac[®], Reta M[®]