



An die interessierte Partei / To whom it may concern

Dr. Stefan Dreiheller
Quality Unit / Regulatory Affairs

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Doc.-No. EIP-0025
Revision 29

Undesired Substances

MEGGLE products:

- Lactose Monohydrate Ph. Eur. / USP-NF / JP: CapsuLac[®] 60, FlowLac[®] 90, FlowLac[®] 100, GranuLac[®] 70, 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: InhaLac[®] 70, InhaLac[®] 120, InhaLac[®] 140, InhaLac[®] 150, InhaLac[®] 160, InhaLac[®] 230, InhaLac[®] 250, InhaLac[®] 251, InhaLac[®] 400, InhaLac[®] 500, Lactose monohydrate Low Endotoxin
- Anhydrous Lactose USP-NF / Ph. Eur. / JP: DuraLac[®] H
- Co-processed excipients: Cellactose[®] 80, CombiLac[®], MicroceLac[®] 100, RetaLac[®], 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 purified substances, also.

Freundliche Grüße / Best regards

Molkerei MEGGLE Wasserburg GmbH & Co. KG


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Undesired Substance¹ List

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

Remarks:

¹ The list includes derived products as far as applicable.

² Cereals containing gluten, Crustaceans, Eggs, Fish, Peanuts, Soybeans, Nuts, Celery, Mustard, Sesame seeds, Sulphur dioxide / Sulphites, Lupins, Molluscs, Buckwheat, Bee Pollen, Propolis, Mango, Peach, Pork, Tomato, Latex.

³ Pyrrole, imidazole, pyrazole, triazoles, tetrazole, pentazole, oxazole, isoxazole, oxadiazoles, thiazole, isothiazole, thiadiazoles and the successively reduced analogues (azolines and azolidines).

⁴ Maize starch in StarLac[®].

⁵ Incl. substances mentioned in Regulation (EC) No 1334/2008, Annex I and Regulation (EC) No 1223/2009, Annex III Ref. numbers 67 – 92.

⁶ Incl. poppy seed, sunflower seed, linseed.

⁷ Incl. PE, PP, PVC, PS, PET and their monomers ethene, propene, vinyl chloride, styrene, terephthalic acid, ethylene glycol.

⁸ Incl. starch, cellulose, glycogen, chitin, dextran, chitosan, pectin, inulin, xanthan, arabinogalactan, galactomannan, alginate, carrageenan, guaran, carubin.

⁹ Cellulose in Cellactose[®] 80; Microcrystalline Cellulose in CombiLac[®], MicroceLac[®] 100; Maize Starch in CombiLac[®], StarLac[®], HPMC in RetaLac[®].

¹⁰ Current [ECHA Candidate List of Substances of Very High Concern](#) .