



An die interessierte Partei / To whom it may concern

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Quality Unit / Regulatory Affairs

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Revision 25

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[®] 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 Substance List

Alkyl phenols and their ethoxylates	Flavouring substances ¹	Polybrominated diphenyl ethers
Amines	Formaldehyde and its donor substances	Polychlorinated Biphenyls
Antioxidants	Fumaric acid and its esters	Polychlorinated Phenoxyphenols
Artificial sweeteners	Gelatin, hydrolyzed gelatin	Polysaccharides other than composition ³
Asbestos	Glycerin	Preservatives
Azo dyes	Glycols	Propolis
Benzoic acid	Heavy Metals	Purine alkaloids
Benzoin	Iodine	Pyrrrolizidine alkaloids
Benzophenone	Isothiazolinones	Royal Jelly
Bergamot oil	Lanolin	Salicylates
Biogenic amines	Latex, Natural Rubber	Silanes
Biocides	Lectines	Silicones
Bisphenols and their derivates	Melamine, Cyanuric acid	Sugar alcohols
Boron or borates	Mica Ester	Sulfates
Cocamides	Monosaccharides	Sulfonic acids
Colophony	Natamycin	Sulfurous acid and its salts
Colours	Nitrates	Sulfur
Coniferyl Alcohol	Nitrites	Talc
Dehydroacetic acid	Oligo- and polypeptides	Thiocyanates
Diacetyl	Organic poly- and their monomers ²	Thiuram disulfides
Dimethylfumarate	Parabenes	Tributyltin
Dioxins	Peru balsam	Triglycerides
Disaccharides (other than lactose)	Phenols (Mono-, Di-, Tri- etc.)	Vegetable oil
Ethanol	Phenylalanin	Volatile Organic Compounds
Fatty acids and their esters	Phthalates	Yeast
Flavourings, perfumes	Pollen	

Remarks

¹ incl. substances mentioned in Regulation (EC) No 1334/2008, Annex I and Regulation (EC) No 1223/2009, Annex III Ref. numbers 67 – 92

² incl. PE, PP, PVC, PS, PET and their monomers ethene, propene, vinyl chloride, styrene, terephthalic acid, ethylene glycol.

³ e.g. glycogen, chitin, dextran, chitosan, pectin, inulin, xanthan, arabinogalactan, galactomannan, alginate, carrageenan, guaran, carubin