



An die interessierte Partei / To whom it may concern

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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 below 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


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Undesired Substance List

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

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