



An die interessierte Partei / To whom it may concern

Dr. Stefan Dreiheller
Quality Unit / Regulatory Affairs

Date of issue: 12.10.2018
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Doc.-No. EIP-0025
Revision 22

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

Remarks

¹ incl. Substances mentioned in Ref. numbers 67 – 92 in Annex III to [Regulation \(EC\) No 1223/2009](#):

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