



To whom it may concern

**Dr. Stefan Dreiheller**  
Quality Unit / Regulatory Affairs

Date of issue: 18.08.2020  
Page 1/2  
Doc.-No. EIP-0025  
Revision 32

## Undesired Substances

MEGGLE Products:

- Lactose Monohydrate (Ph. Eur. / USP-NF / JP): CapsuLac<sup>®</sup> 60, FlowLac<sup>®</sup> 90, FlowLac<sup>®</sup> 100, GranuLac<sup>®</sup> 70, GranuLac<sup>®</sup> 80, GranuLac<sup>®</sup> 140, GranuLac<sup>®</sup> 200, GranuLac<sup>®</sup> 230, PrismaLac<sup>®</sup> 40, SacheLac<sup>®</sup> 80, SorboLac<sup>®</sup> 400, SpheroLac<sup>®</sup> 100, Tablettose<sup>®</sup> 70, Tablettose<sup>®</sup> 80, Tablettose<sup>®</sup> 100
- Lactose Monohydrate (USP-NF / Ph. Eur. / JP): Lactose monohydrate Low Endotoxin
- Inhaler Grade Lactose Monohydrate (USP-NF / Ph. Eur. / JP): InhaLac<sup>®</sup> 70, InhaLac<sup>®</sup> 120, InhaLac<sup>®</sup> 140, InhaLac<sup>®</sup> 150, InhaLac<sup>®</sup> 160, InhaLac<sup>®</sup> 230, InhaLac<sup>®</sup> 250, InhaLac<sup>®</sup> 251, InhaLac<sup>®</sup> 400, InhaLac<sup>®</sup> 500
- Co-processed excipients: Cellactose<sup>®</sup> 80, CombiLac<sup>®</sup>, MicroceLac<sup>®</sup> 100, RetaLac<sup>®</sup>, StarLac<sup>®</sup>

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.

Best regards

**MEGGLE GmbH & Co. KG**

  
Dr. Stefan Dreiheller



Date of issue: 18.08.2020

Page 2/2

Doc.-No. EIP-0025

Revision 32

## Undesired Substance<sup>1</sup> List

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

### Remarks:

<sup>1</sup> The list includes derived products as far as applicable.

<sup>2</sup> Pyrrole, imidazole, pyrazole, triazoles, tetrazole, pentazole, oxazole, isoxazole, oxadiazoles, thiazole, isothiazole, thiadiazoles and the successively reduced analogues (azolines and azolidines).

<sup>3</sup> Maize starch in StarLac<sup>®</sup>.

<sup>4</sup> Incl. substances mentioned in Regulation (EC) No 1334/2008, Annex I and Regulation (EC) No 1223/2009, Annex III Ref. numbers 67 – 92.

<sup>5</sup> Incl. poppy seed, sunflower seed, linseed.

<sup>6</sup> Incl. PE, PP, PVC, PS, PET and their monomers ethene, propene, vinyl chloride, styrene, terephthalic acid, ethylene glycol.

<sup>7</sup> Incl. starch, cellulose, glycogen, chitin, dextran, chitosan, pectin, inulin, xanthan, arabinogalactan, galactomannan, alginate, carrageenan, guaran, carubin.

<sup>8</sup> Cellulose in Cellactose<sup>®</sup> 80; Microcrystalline Cellulose in CombiLac<sup>®</sup>, MicroceLac<sup>®</sup> 100; Maize Starch in CombiLac<sup>®</sup>, StarLac<sup>®</sup>, HPMC in RetaLac<sup>®</sup>.

<sup>9</sup> Current [ECHA Candidate List of Substances of Very High Concern](#).