



Undesired Substances

MEGGLE Products:

- Lactose Monohydrate: CapsuLac® 60, FlowLac® 90, FlowLac® 90 MS, FlowLac® 100, FlowLac® 100 MS, FlowLac® 100 SD, GranuLac® 70, GranuLac® 70 MS, GranuLac® 80, GranuLac® 140, GranuLac® 140 S, GranuLac® 200, GranuLac® 200 MS, GranuLac® 200 S, GranuLac® 230, InhaLac® 70, InhaLac® 120, InhaLac® 140, InhaLac® 145, InhaLac® 150, InhaLac® 160, InhaLac® 180, InhaLac® 230, InhaLac® 240, InhaLac® 251, InhaLac® 300, InhaLac® 400, InhaLac® 500, Lactose Monohydrate 200 Mesh IP, Lactose Monohydrate Impalpable, Lactose Monohydrate Low Endotoxin, PrismaLac® 40, SacheLac® 80, SorboLac® 400, SpheroLac® 100, Tablettose® 70, Tablettose® 80, Tablettose® 100, Tablettose® 100 MS

- Co-processed Excipients: Cellactose® 80, CombiLac®, MicroceLac® 100, MicroceLac® Plus, RetaLac®, StarLac®

All "Low Nitrite" Grades are included.

The 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 in MEGGLE Products.

Manufacturing of MEGGLE Lactose Monohydrate Products 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 MEGGLE Co-processed Excipients are also purified substances.

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List of Undesired Substances¹

Active pharmaceutical ingredients	Fatty acids	Polyalcohols ¹³
Alkyl phenols	Flavour enhancers ⁶	Polychlorinated Phenoxyphenols
Amines	Flavouring substances ⁷	Polysaccharides ¹⁴
Aminopolycarboxylic acids (EDTA etc)	Flavourings, perfumes	Polysorbates
Animal-derived materials ²	Fruits and vegetables, all types ⁸	Preservatives ¹⁵
Antioxidants ³	Fumaric acid and its esters	Protein, hydrolysed protein, all types
Asbestos	Fungi	Purine alkaloids
Azo dyes	Gelatin	Pyrrolizidine alkaloids
Azoles ⁴	Hazardous Substances ⁹	Salicylic acid
Benzoin	Herbs, spices, all types	Silanes
Benzophenone	Human origin material	Silicones
Benzyl alcohol	Hydrazines	Substances prohibited etc. in food ¹⁶
Bergamot oil	Iodine	Sulfonic acids
Biocides ⁵	Lanolin	Sulfuric acid
Biogenic amines	Lectines	Sulfurous acid
Bisphenols	Lysozyme	Sulphur
Boron, boric acid, borates	Mica Ester	SVHC-substances ¹⁷
Coatings	Monosaccharides	Sweeteners
Cocamides	Nitrates	Talc
Colophony	Nitrites	Thiocyanates
Colours	Oils and fats, vegetable and animal	Thiuram disulphides
Coniferyl Alcohol	Oilseeds ¹⁰	Titanium dioxide
Cyclodextrins	Oligo- and polypeptides	Tributyltin
Dehydroacetic acid	Organic poly- and their monomers ¹¹	Triglycerides
Diacetyl	Peroxides	Volatile Organic Compounds
Disaccharides other than lactose	Persistent Organic Pollutants ¹²	Yeast
Emulsifiers (Lecithin etc)	Peru balsam	
Ethanol	Phthalates (DEHP etc)	

¹ The list includes derived products, e.g. salts, esters etc. as far as applicable The list does not apply to substances under the MEGGLE Monitoring Program.

² Material other than MEGGLE Products themselves derived from any species incl. *Sus* ssp. (pork), *Bos* ssp. (bovine), *Gallus* ssp. (chicken)

³ All types, e.g. BHA, BHT

⁴ Pyrrole, imidazole, pyrazole, triazoles, tetrazole, pentazole, oxazole, isoxazole, oxadiazoles, thiazole, isothiazole, thiadiazoles and the successively reduced analogues (azolines and azolidines).

⁵ All types, e.g. formaldehyde and its donor substances, tributyltin etc

⁶ All types, e.g. glutamate salts

⁷ For EU: incl. substances mentioned in Regulation (EC) No 1334/2008, Annex I (e.g. Vanillin) and Regulation (EC) No 1223/2009, Annex III Ref. numbers 67 – 92.

⁸ incl. carrot, cinnamon, cocoa, coriander, legumes, maize, *umbelliferae*

⁹ Hazardous Substances of any type (e.g. CMR substances) as defined according Regulation (EC) No 1272/2008 (European GHS law)

¹⁰ e.g. poppy seed, sunflower seed, linseed.

¹¹ incl. PE, PP, PVC, PS, PET and their monomers ethene, propene, vinyl chloride, styrene, terephthalic acid, ethylene glycol

¹² As mentioned in Regulation (EU) 2019/1021

¹³ All types, e.g. diethylene glycol, ethylene glycol, propylene glycol, glycerol, sorbitol, mannitol

¹⁴ All types e.g. glycogen, chitin, dextran, chitosan, pectin, inulin, xanthan, arabinogalactan, galactomannan, alginate, carrageenan, guar gum, carubin other than composition: Cellulose in Cellactose[®] 80; Microcrystalline Cellulose in CombiLac[®], MicroceLac[®] 100; Maize Starch in CombiLac[®], StarLac[®], HPMC in Retalac[®]

¹⁵ All types, e.g. benzoic acid, sorbic acid, their salts, parabens, cresols, quaternary ammonium compounds, thiomersal etc.

¹⁶ Substances whose use in foods is prohibited, restricted or under community scrutiny (Regulation (EC) 1925/2006, Annex III in the current version)

¹⁷ For EU: current ECHA Candidate List of Substances of Very High Concern.

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