

INFORMATION

Quality / Regulatory Affairs



EIP-0065

Revision 49

Date of issue: 17.01.2024

1/2

Undesired Substances

MEGGLE Products:

- Lactose Monohydrate: CapsuLac[®] 60, FlowLac[®] 90, FlowLac[®] 90 MS, FlowLac[®] 100, FlowLac[®] 90 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[®] 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, RetaLac[®], StarLac[®]

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 lactose 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 also purified substances.

This MEGGLE Information was electronically released and is valid without signature.



List of Undesired Substances¹

Active pharmaceutical ingredients	Flavouring substances ⁶	Peru balsam
Alkyl phenols	Flavourings, perfumes	Pesticides
Amines	Fruits and vegetables, all types	Phthalates (DEHP etc)
Aminopolycarboxylic acids (EDTA etc)	Fumaric acid and its esters	Polyalcohols ¹⁴
Antioxidants	Fungi	Polychlorinated Phenoxyphenols
Asbestos	Gelatin	Polycyclic aromatic hydrocarbons (PAHs) ¹⁵
Azo dyes	Hazardous Substances ⁷	Polysaccharides ¹⁶ other than composition ¹⁷
Azoles ²	Herbs, spices, all types	Polysorbates
Benzoin	Human origin material	Preservatives ¹⁸
Benzophenone	Hydrazines	Protein, hydrolysed protein, all types
Benzyl alcohol	Iodine	Purine alkaloids
Bergamot oil	Lanolin	Pyrrolizidine alkaloids
Biocides ³	Lectines	Salicylic acid
Biogenic amines	Lysozyme	Silanes
Bisphenols	Melamine, Cyanuric acid	Silicones
Boron, boric acid, borates	Metals and other elements ⁸	Substances prohibited etc. in food ¹⁹
Coatings	Mica Ester	Sulfonic acids, its salts and acid derivatives
Cocamides	Monosaccharides	Sulfuric acid, its salts and acid derivatives
Colophony	Mycotoxins ⁹	Sulfurous acid, its salts and acid derivatives
Colours	Nitrates	Sulphur
Coniferyl Alcohol	Nitrites	SVHC-substances ²⁰
Cyclodextrins	Nitrosamines	Sweeteners
Dehydroacetic acid	Oils and fats, vegetable and animal	Talc
Diacetyl	Oilseeds ¹⁰	Thiocyanates
Dioxins and PCBs ⁴	Oligo- and polypeptides	Thiuram disulphides
Disaccharides other than lactose	Organic poly- and their monomers ¹¹	Titanium dioxide
Emulsifiers (Lecithin etc)	Perchlorate	Tributyltin
Ethanol	Perfluoroalkylated substances ¹²	Triglycerides
Fatty acids	Peroxides	Volatile Organic Compounds
Fibres other than composition ⁵	Persistent Organic Pollutants ¹³	Yeast

¹ The list includes derived products, e.g. salts, esters as far as applicable

² Pyrrole, imidazole, pyrazole, triazoles, tetrazole, pentazole, oxazole, isoxazole, oxadiazoles, thiazole, isothiazole, thiazolidines and the successively reduced analogues (azolines and azolidines).

³ All types, e.g. formaldehyde and its donor substances, tributyltin etc

⁴ As mentioned in Regulation (EU) 2023/915

⁵ Cellulose in Cellactose[®] 80; Microcrystalline Cellulose in CombiLac[®], MicroLac[®] 100; HPMC in RetaLac[®]

⁶ For EU: incl. substances mentioned in Regulation (EC) No 1334/2008, Annex I and Regulation (EC) No 1223/2009, Annex III Ref. numbers 67 – 92.

⁷ Hazardous Substances of any type (e.g. CMR substances) as defined according Regulation (EC) No 1272/2008 (European GHS law)

⁸ As mentioned in Regulation (EU) 2023/915, namely Pb, Cd, Hg, As

⁹ Aflatoxins, Ochratoxin A, Patulin, Deoxynivalenol, Zearalenone, Fumonisin, Citrinin, Ergot sclerotia and ergot alkaloids

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) 2023/915

¹³ As mentioned in Regulation (EU) 2019/1021

¹⁴ All types, e.g. diethylene glycol, ethylene glycol, propylene glycol, glycerol, sorbitol, mannitol

¹⁵ As mentioned in Regulation (EU) 2023/915

¹⁶ incl. starch, cellulose, glycogen, chitin, dextran, chitosan, pectin, inulin, xanthan, arabinogalactan, galactomannan, alginate, carrageenan, guar gum, carubin

¹⁷ Cellulose in Cellactose[®] 80; Microcrystalline Cellulose in CombiLac[®], MicroLac[®] 100; Maize Starch in CombiLac[®], StarLac[®], HPMC in RetaLac[®]

¹⁸ All types, e.g. benzoic acid, sorbic acid, their salts, parabens, cresols, quaternary ammonium compounds, thiomersal etc.

¹⁹ Substances whose use in foods is prohibited, restricted or under community scrutiny (Regulation (EC) 1925/2006, Annex III in the current version)

²⁰ For EU: current ECHA Candidate List of Substances of Very High Concern.

This MEGGLE Information was electronically released and is valid without signature.