



## Undesired Substances

MEGGLE Products:

- Lactose Monohydrate: CapsuLac<sup>®</sup> 60, FlowLac<sup>®</sup> 90, FlowLac<sup>®</sup> 90 MS, FlowLac<sup>®</sup> 100, FlowLac<sup>®</sup> 100 MS, FlowLac<sup>®</sup> 100 SD, GranuLac<sup>®</sup> 70, GranuLac<sup>®</sup> 70 MS, GranuLac<sup>®</sup> 80, GranuLac<sup>®</sup> 140, GranuLac<sup>®</sup> 140 S, GranuLac<sup>®</sup> 200, GranuLac<sup>®</sup> 200 MS, GranuLac<sup>®</sup> 200 S, GranuLac<sup>®</sup> 230, InhaLac<sup>®</sup> 70, InhaLac<sup>®</sup> 120, InhaLac<sup>®</sup> 140, InhaLac<sup>®</sup> 150, InhaLac<sup>®</sup> 160, InhaLac<sup>®</sup> 180, InhaLac<sup>®</sup> 251, InhaLac<sup>®</sup> 300, InhaLac<sup>®</sup> 400, InhaLac<sup>®</sup> 500, Lactose Monohydrate 200 Mesh IP, Lactose Monohydrate Impalpable, Lactose Monohydrate Low Endotoxin, 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, Tablettose<sup>®</sup> 100 MS

- Co-processed Excipients: Cellactose<sup>®</sup> 80, CombiLac<sup>®</sup>, MicroceLac<sup>®</sup> 100, RetaLac<sup>®</sup>, StarLac<sup>®</sup>

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.

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## List of Undesired Substances<sup>1</sup>

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

<sup>1</sup> The list includes derived products, e.g. salts, esters 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> All types, e.g. formaldehyde and its donor substances, tributyltin etc

<sup>4</sup> As mentioned in Regulation (EU) 2023/915

<sup>5</sup> Cellulose in Cellactose<sup>®</sup> 80; Microcrystalline Cellulose in CombiLac<sup>®</sup>, MicroceLac<sup>®</sup> 100; HPMC in RetaLac<sup>®</sup>

<sup>6</sup> 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.

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

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

<sup>9</sup> Aflatoxins, Ochratoxin A, Patulin, Deoxynivalenol, Zearalenone, Fumonisin, Citrinin, Ergot sclerotia and ergot alkaloids

<sup>10</sup> e.g. poppy seed, sunflower seed, linseed.

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

<sup>12</sup> As mentioned in Regulation (EU) 2023/915

<sup>13</sup> All types, e.g. diethylene glycol, ethylene glycol, propylene glycol, glycerol, sorbitol, mannitol

<sup>14</sup> As mentioned in Regulation (EU) 2023/915

<sup>15</sup> incl. starch, cellulose, glycogen, chitin, dextran, chitosan, pectin, inulin, xanthan, arabinogalactan, galactomannan, alginate, carrageenan, guar gum, carubin

<sup>16</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>17</sup> All types, e.g. benzoic acid, sorbic acid, their salts, parabens, cresols, quaternary ammonium compounds, thiomersal etc.

<sup>18</sup> Substances whose use in foods is prohibited, restricted or under community scrutiny (Regulation (EC) 1925/2006, Annex III in the current version)

<sup>19</sup> For EU: current ECHA Candidate List of Substances of Very High Concern.

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