

## INFORMATION

Quality Management



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### Undesired Substances

MEGGLE USA Products:

- Lactose Monohydrate: GranuLac® 70 US, GranuLac® 140 US, GranuLac® 200 US

- Anhydrous Lactose: DuraLac® H

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 USA 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.

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

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

<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> As mentioned in Regulation (EU) 2019/1021

<sup>14</sup> All types, e.g. diethylene glycol, ethylene glycol, propylene glycol, glycerol, sorbitol, mannitol

<sup>15</sup> As mentioned in Regulation (EU) 2023/915

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

<sup>17</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>18</sup> All types, e.g. benzoic acid, sorbic acid, their salts, parabens, cresols, quaternary ammonium compounds, thiomersal etc.

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

<sup>20</sup> For EU: current ECHA Candidate List of Substances of Very High Concern.

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