

# 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>7</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>15</sup>
Animal-derived materials <sup>2</sup>	Fungi	Polychlorinated Phenoxyphenols
Antioxidants	Gelatin	Polycyclic aromatic hydrocarbons (PAHs) <sup>16</sup>
Asbestos	Hazardous Substances <sup>8</sup>	Polysaccharides <sup>17</sup> other than composition <sup>18</sup>
Azo dyes	Herbs, spices, all types	Polysorbates
Azoles <sup>3</sup>	Human origin material	Preservatives <sup>19</sup>
Benzoin	Hydrazines	Protein, hydrolysed protein, all types
Benzophenone	Iodine	Purine alkaloids
Benzyl alcohol	Lanolin	Pyrrolizidine alkaloids
Bergamot oil	Lectines	Salicylic acid
Biocides <sup>4</sup>	Lysozyme	Silanes
Biogenic amines	Melamine, Cyanuric acid	Silicones
Bisphenols	Metals and other elements <sup>9</sup>	Substances prohibited etc. in food <sup>20</sup>
Boron, boric acid, borates	Mica Ester	Sulfonic acids, its salts and acid derivatives
Coatings	Monosaccharides	Sulfuric acid, its salts and acid derivatives
Cocamides	Mycotoxins <sup>10</sup>	Sulfurous acid, its salts and acid derivatives
Colophony	Nitrates	Sulphur
Colours	Nitrites	SVHC-substances <sup>21</sup>
Coniferyl Alcohol	Nitrosamines	Sweeteners
Cyclodextrins	Oils and fats, vegetable and animal	Talc
Dehydroacetic acid	Oilseeds <sup>11</sup>	Thiocyanates
Diacetyl	Oligo- and polypeptides	Thiuram disulphides
Dioxins and PCBs <sup>5</sup>	Organic poly- and their monomers <sup>12</sup>	Titanium dioxide
Disaccharides other than lactose	Perchlorate	Tributyltin
Emulsifiers (Lecithin etc)	Per- and polyfluoroalkylated substances <sup>13</sup>	Triglycerides
Ethanol	Peroxides	Volatile Organic Compounds
Fatty acids	Persistent Organic Pollutants <sup>14</sup>	Yeast
Fibres other than composition <sup>6</sup>		

<sup>1</sup> The list includes derived products, e.g. salts, esters as far as applicable

<sup>2</sup> Material other than MEGGLE USA Products themselves derived from any species incl. *Sus* ssp. (pork), *Bos* ssp. (bovine)

<sup>3</sup> Pyrrole, imidazole, pyrazole, triazoles, tetrazole, pentazole, oxazole, isoxazole, oxadiazoles, thiazole, isothiazole, thiadiazoles and the successively reduced analogues (azolines and azolidines).

<sup>4</sup> All types, e.g. formaldehyde and its donor substances, tributyltin etc

<sup>5</sup> Also mentioned in Regulation (EU) 2023/915 on maximum levels for certain contaminants in food

<sup>6</sup> Cellulose in Cellactose<sup>®</sup> 80; Microcrystalline Cellulose in CombiLac<sup>®</sup>, MicroceLac<sup>®</sup> 100; HPMC in RetaLac<sup>®</sup>

<sup>7</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>8</sup> Hazardous Substances of any type (e.g. CMR substances) as defined according Regulation (EC) No 1272/2008 (European GHS law)

<sup>9</sup> Also mentioned in Regulation (EU) 2023/915, on maximum levels for certain contaminants in food namely Pb, Cd, Hg, As

<sup>10</sup> Aflatoxins, Ochratoxin A, Patulin, Deoxynivalenol, Zearalenone, Fumonisin, Citrinin, Ergot sclerotia and ergot alkaloids

<sup>11</sup> e.g. poppy seed, sunflower seed, linseed.

<sup>12</sup> incl. PE, PP, PVC, PS, PET and their monomers ethene, propene, vinyl chloride, styrene, terephthalic acid, ethylene glycol

<sup>13</sup> Also mentioned in Regulation (EU) 2023/915 on maximum levels for certain contaminants in food

<sup>14</sup> As mentioned in Regulation (EU) 2019/1021

<sup>15</sup> All types, e.g. diethylene glycol, ethylene glycol, propylene glycol, glycerol, sorbitol, mannitol

<sup>16</sup> Also mentioned in Regulation (EU) 2023/915 on maximum levels for certain contaminants in food

<sup>17</sup> incl. starch, cellulose, glycogen, chitin, dextran, chitosan, pectin, inulin, xanthan, arabinogalactan, galactomannan, alginate, carrageenan, guar gum, carubin

<sup>18</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>19</sup> All types, e.g. benzoic acid, sorbic acid, their salts, parabens, cresols, quaternary ammonium compounds, thiomersal etc.

<sup>20</sup> Substances whose use in foods is prohibited, restricted or under community scrutiny (Regulation (EC) 1925/2006, Annex III in the current version)

<sup>21</sup> For EU: current ECHA Candidate List of Substances of Very High Concern.

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