

# INFORMATION

Quality Management



EIP-0065-USA

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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>9</sup>                    | Peru balsam  |
| Alkyl phenols                              | Flavourings, perfumes                                 | Pesticides   |
| Amines                                     | Fruits and vegetables, all types <sup>10</sup>        | Phthalates (DEHP etc)  |
| Aminopolycarboxylic acids (EDTA etc)       | Fumaric acid and its esters                           | Polyalcohols <sup>18</sup>   |
| Animal-derived materials <sup>2</sup>      | Fungi   | Polychlorinated Phenoxyphenols                                     |
| Antioxidants <sup>3</sup>                  | Gelatin   | Polycyclic aromatic hydrocarbons (PAHs) <sup>19</sup>              |
| Asbestos                                   | Hazardous Substances <sup>11</sup>                    | Polysaccharides <sup>20</sup> other than composition <sup>21</sup> |
| Azo dyes                                   | Herbs, spices, all types                              | Polysorbates   |
| Azoles <sup>4</sup>                        | Human origin material                                 | Preservatives <sup>22</sup>  |
| Benzoin                                    | Hydrazines  | Protein, hydrolysed protein, all types                             |
| Benzophenone                               | Iodine  | Purine alkaloids   |
| Benzyl alcohol                             | Lanolin   | Pyrrrolizidine alkaloids   |
| Bergamot oil                               | Lectines  | Salicylic acid   |
| Biocides <sup>5</sup>                      | Lysozyme  | Silanes  |
| Biogenic amines                            | Melamine, Cyanuric acid                               | Silicones  |
| Bisphenols                                 | Metals and other elements <sup>12</sup>               | Substances prohibited etc. in food <sup>23</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>13</sup>                              | Sulfurous acid, its salts and acid derivatives                     |
| Colophony                                  | Nitrates  | Sulphur  |
| Colours                                    | Nitrites  | SVHC-substances <sup>24</sup>                                      |
| Coniferyl Alcohol                          | Nitrosamines  | Sweeteners   |
| Cyclodextrins                              | Oils and fats, vegetable and animal                   | Talc   |
| Dehydroacetic acid                         | Oilseeds <sup>14</sup>                                | Thiocyanates   |
| Diacetyl                                   | Oligo- and polypeptides                               | Thiuram disulphides  |
| Dioxins and PCBs <sup>6</sup>              | Organic poly- and their monomers <sup>15</sup>        | Titanium dioxide   |
| Disaccharides other than lactose           | Perchlorate   | Tributyltin  |
| Emulsifiers (Lecithin etc)                 | Per- and polyfluoroalkylated substances <sup>16</sup> | Triglycerides  |
| Ethanol                                    | Peroxides   | Volatile Organic Compounds   |
| Fatty acids                                | Persistent Organic Pollutants <sup>17</sup>           | Yeast  |
| Fibres other than composition <sup>7</sup> |   |  |
| Flavour enhancers <sup>8</sup>             |   |  |

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

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

<sup>3</sup> All types, e.g. BHA, BHT

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

<sup>5</sup> All types, e.g. formaldehyde and its donor substances, tributyltin etc

<sup>6</sup> Also mentioned in Regulation (EU) 2023/915 on maximum levels for certain contaminants in food

<sup>7</sup> Cellulose in Cellactose<sup>®</sup> 80; Microcrystalline Cellulose in CombiLac<sup>®</sup>, MicroceLac<sup>®</sup> 100; HPMC in RetaLac<sup>®</sup>

<sup>8</sup> All types, e.g. glutamate salts

<sup>9</sup> 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.

<sup>10</sup> incl. carrot, cinnamon, cocoa, coriander, legumes, maize, *umbelliferae*

<sup>11</sup> Hazardous Substances of any type (e.g. CMR substances) as defined according Regulation (EC) No 1272/2008 (European GHS law)

<sup>12</sup> As mentioned in Regulation (EU) 2023/915, namely Pb, Cd, Hg, As

<sup>13</sup> Aflatoxins, Ochratoxin A, Patulin, Deoxynivalenol, Zearalenone, Fumonisin, Citrinin, Ergot sclerotia and ergot alkaloids

<sup>14</sup> e.g. poppy seed, sunflower seed, linseed.

<sup>15</sup> incl. PE, PP, PVC, PS, PET and their monomers ethene, propene, vinyl chloride, styrene, terephthalic acid, ethylene glycol

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

<sup>17</sup> As mentioned in Regulation (EU) 2019/1021

<sup>18</sup> All types, e.g. diethylene glycol, ethylene glycol, propylene glycol, glycerol, sorbitol, mannitol

<sup>19</sup> Also mentioned in Regulation (EU) 2023/915 on maximum levels for certain contaminants in food

<sup>20</sup> incl. starch, cellulose, glycogen, chitin, dextran, chitosan, pectin, inulin, xanthan, arabinogalactan, galactomannan, alginate, carrageenan, guar gum, carubin

<sup>21</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>22</sup> All types, e.g. benzoic acid, sorbic acid, their salts, parabens, cresols, quaternary ammonium compounds, thiomersal etc.

<sup>23</sup> Substances whose use in foods is prohibited, restricted or under community scrutiny (Regulation (EC) 1925/2006, Annex III in the current version)

<sup>24</sup> For EU: current ECHA Candidate List of Substances of Very High Concern.

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