



To whom it may concern

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Doc.-No. EIP-0065 -USA
Revision 5

Undesired Substances

MEGGLE Products:

- Lactose Monohydrate (USP-NF / Ph. Eur. / JP): GranuLac® 70 US, GranuLac® 140 US, GranuLac® 200 US
- Anhydrous Lactose (USP-NF / Ph. Eur. / JP): DuraLac® H

The mentioned 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.

Manufacturing 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.

Best regards

MEGGLE USA inc.



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Undesired Substance¹ List

Alkyl phenols and their ethoxylates	Flavourings, perfumes	Phenylalanine
Amines	Flavouring substances ²	Phthalates
Antioxidants	Formaldehyde and its donor substances	Polybrominated Diphenyl Ethers
Asbestos	Fruits and vegetables, all types	Polychlorinated Biphenyls
Azo dyes	Fumaric acid and its esters	Polychlorinated Phenoxyphenols
Azoles ³	Fungi	Polysaccharides ⁴
Benzoic acid	Gelatin	Preservatives
Benzoin	Glycerol	Protein, hydrolysed protein, all types
Benzophenone	Glycols	Purine alkaloids
Bergamot oil	Heavy Metals	Pyrrrolizidine alkaloids
Biogenic amines	Herbs, spices, all types	Salicylates
Biocides	Hydrazines	Silanes
Bisphenols and their derivates	Iodine	Silicones
Boron or borates	Lanolin	Sugar alcohols
Coatings	Lectines	Sulphates
Cocamides	Lysozyme	Sulfonic acids
Colophony	Melamine, Cyanuric acid	Sulphurous acid and its salts
Colours	Mica Ester	Sulphur
Coniferyl Alcohol	Monosaccharides	SVHC-substances ⁵
Dehydroacetic acid	Natamycin	Sweeteners
Diacetyl	Nitrates	Talc
Dimethyl fumarate	Nitrites	Thiocyanates
Dioxins	Nitrosamines	Thiuram disulphides
Disaccharides other than lactose	Oils and fats, vegetable and animal	Tributyltin
Emulsifiers (Lecithin etc.)	Oilseeds ⁶	Triglycerides
Ethanol	Oligo- and polypeptides	Volatile Organic Compounds
Fatty acids and their esters	Organic poly- and their monomers ⁷	Yeast
Fibers other than composition	Parabens	
Flavour enhancers	Peru balsam	

¹ The list includes derived products as far as applicable.

² 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.

³ pyrrole, imidazole, pyrazole, triazoles, tetrazole, pentazole, oxazole, isoxazole, oxadiazoles, thiazole, isothiazole, thiadiazoles and the successively reduced analogues (azolines and azolidines).

⁴ incl. starch, cellulose, glycogen, chitin, dextran, chitosan, pectin, inulin, xanthan, arabinogalactan, galactomannan, alginate, carrageenan, guaran, carubin.

⁵ for EU: current [ECHA Candidate List of Substances of Very High Concern](#).

⁶ e.g. poppy seed, sunflower seed, linseed.

⁷ incl. PE, PP, PVC, PS, PET and their monomers ethene, propene, vinyl chloride, styrene, terephthalic acid, ethylene glycol.