



To whom it may concern

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Doc.-No. EIP-0025 -USA
Revision 4

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

Remarks:

¹ The list includes derived products as far as applicable.

² Pyrrole, imidazole, pyrazole, triazoles, tetrazole, pentazole, oxazole, isoxazole, oxadiazoles, thiazole, isothiazole, thiadiazoles and the successively reduced analogues (azolines and azolidines).

³ Incl. poppy seed, sunflower seed, linseed.

⁴ Incl. PE, PP, PVC, PS, PET and their monomers ethene, propene, vinyl chloride, styrene, terephthalic acid, ethylene glycol.

⁵ Incl. starch, cellulose, glycogen, chitin, dextran, chitosan, pectin, inulin, xanthan, arabinogalactan, galactomannan, alginate, carrageenan, guaran, carubin.