

# INFORMATION

Quality / Regulatory Affairs



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## Residual Solvents

Ph. Eur. General Texts 5.4; USP-NF General Chapter <467>; JP General Tests 2.46, ICH Guideline Q3C (R9)

MEGGLE Product:

Co-processed Excipient: StarLac®

The MEGGLE Product is a co-processed, directly compressible spray agglomerate containing

- 85 % Lactose Monohydrate (Ph. Eur. / USP-NF / JP) and

- 15 % Maize Starch (Ph. Eur. / USP-NF / JP).

Starting material Lactose Monohydrate (Ph. Eur. / USP-NF / JP):

Raw materials, manufacturing process and product do not contain organic solvents listed as class 1, 2, 3 solvents in the mentioned documents.

Starting material Maize Starch (Ph. Eur. / USP-NF / JP):

According to the confirmation of the supplier, organic solvents listed as class 1, 2, 3 solvents in the mentioned documents are not used in the manufacturing process. The product may contain traces of class 3 solvent acetic acid, a by-product of the bacterial treatment of the starch slurry with peracetic acid.

The supplier certifies that delivered batches have an acceptable concentration level < 5000 ppm and therefore is not required to be quantified.

Note: The monographs require "Oxidising substances: maximum 20 ppm, calculated as H<sub>2</sub>O<sub>2</sub>". This is equivalent to "maximum 35 ppm, calculated as peracetic acid", i.e. 26 ppm acetic acid.

StarLac®:

In the manufacturing process (spray-drying of suspension), only demineralised water is used.

Organic solvents listed as Class 1, Class 2 or Class 3 solvents or any other solvents are not used and are therefore "not likely to be present".

*This MEGGLE Information was electronically released and is valid without signature.*