



To whom it may concern

Dr. Stefan Dreiheller
Quality Unit / Regulatory Affairs

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GRAS / Inactive Ingredient Database (IID)

MEGGLE Product: CombiLac®

The product is a co-processed, directly compressible spray agglomerate comprising 70 % Lactose Monohydrate (Ph. Eur. / USP-NF / JP), 25 % Microcrystalline Cellulose (Ph. Eur. / USP-NF / JP) and 10 % Maize Starch (Ph. Eur. / USP-NF / JP). The components conform to the monograph "Lactose Monohydrate" or "Microcrystalline Cellulose" or "Maize Starch" of Ph. Eur., USP-NF and JP. The monographs have undergone pharmacopoeial harmonisation.

Lactose is "Affirmed GRAS" as in compliance with FCC monograph "Lactose" and 21 CFR §168.122

Cellulose, microcrystalline and cornstarch are listed in the United States FDA SCOGS (GRAS) database, both with the Type of Conclusion:

"There is no evidence in the available information on [substance] that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when they are used at levels that are now current or might reasonably be expected in the future."

The three compounds are listed on the United States FDA Inactive Ingredients Database.

Best regards

MEGGLE GmbH & Co. KG


Dr. Stefan Dreiheller