



To whom it may concern

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GRAS / Inactive Ingredient Database (IID)

MEGGLE Product: Reta M[®]

The product is a co-processed, directly compressible spray agglomerate comprising 50 % Mannitol (Ph. Eur. / USP-NF / JP) and 50 % Hypromellose (Ph. Eur. / USP-NF / JP). The components conform to the monograph "Mannitol" or "Hypromellose" of Ph. Eur., USP-NF and JP. The monographs have undergone pharmacopoeial harmonisation.

Mannitol is "Affirmed GRAS" as in compliance with 21 CFR §180.25.

Mannitol is listed in the United States FDA SCOGS (GRAS) database 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."

Hydroxypropylmethyl cellulose is listed in the United States FDA SCOGS (GRAS) database 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 both compounds are listed on the United States FDA Inactive Ingredients Database.

Best regards

MEGGLE GmbH & Co. KG

represented by MEGGLE Verwaltungs GmbH


Dr. Stefan Dreiheller