



To whom it may concern

Dr. Stefan Dreiheller
Quality Unit / Regulatory Affairs

Date of issue: 02.02.2021
Page 1/1
Doc.-No. EIP-7060
Revision 2

Melamine

FDA Guidance for Industry: Pharmaceutical Components at Risk for Melamine Contamination

MEGGLE Product: Reta M[®]

The product is a co-processed, directly compressible spray agglomerate comprising
- 50 % Mannitol (Ph. Eur. / USP-NF / JP) and
- 50 parts Hypromellose (Ph. Eur. / USP-NF / JP).

The product is neither covered by the definition for an “at-risk component” as referenced in footnote 3 of the FDA Guidance nor the components are listed as “at-risk pharmaceutical components”.

Best regards

MEGGLE GmbH & Co. KG
represented by MEGGLE Verwaltungs GmbH

Dr. Stefan Dreiheller