



An die interessierte Partei / To whom it may concern

Dr. Stefan Dreiheller
Quality Unit / Regulatory Affairs

Date of issue: 19.11.2015
Page 1/1
Doc.-No. EIP-5007
Revision 2

GRAS, IID

Meggle products:

Co-processed excipients: RetaLac[®]

The product is a co-processed excipient and a spray dried mixture of 50 parts Lactose Monohydrate Ph. Eur. / USP-NF / JP and 50 parts Hypromellose Ph. Eur. / USP-NF / JP.

Lactose complies with FCC monograph 'Lactose' and 21CFR 168.122 Standard of Identity and therefore is affirmed GRAS.

Hypromellose (Hydroxypropylmethyl cellulose) is listed in the United States FDA SCOGS (GRAS) database.

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

Freundliche Grüße / Best regards

Dr. Stefan Dreiheller