



To whom it may concern

**Dr. Stefan Dreiheller**  
Quality Unit / Regulatory Affairs

Date of issue: 01.07.2020  
Page 1/1  
Doc.-No. EIP-2007  
Revision 3

## **GRAS / Inactive Ingredient Database (IID)**

MEGGLE Product: Cellactose® 80

The product is a co-processed, directly compressible spray agglomerate comprising 75 % Lactose Monohydrate (Ph. Eur. / USP-NF / JP) and 25 % Cellulose Powder (Ph. Eur. / USP-NF / JP). The components conform to the monograph "Lactose Monohydrate" or "Cellulose Powder" 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

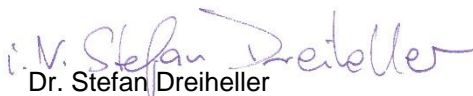
Cellulose is listed in the United States FDA SCOGS (GRAS) database with the Type of Conclusion:

*"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**

  
Dr. Stefan Dreiheller