



An die interessierte Partei / To whom it may concern

Dr. Stefan Dreiheller
Quality Unit / Regulatory Affairs

Date of issue: 28.01.2016
Page 1/1
Doc.-No. EIP-6030
Revision 1

Suitability as ingredient in food products

Meggler products:

- Co-processed excipients: CombiLac[®]

CombiLac[®] is a spray-dried mixture of

- 70 parts Lactose Monohydrate Ph. Eur. / USP-NF / JP (**Lactose**),
- 20 parts Cellulose Microcrystalline Ph. Eur. / USP-NF / JP (**MCC**) and
- 10 parts Maize Starch Ph. Eur. / USP-NF (**MS**)

The product is manufactured as excipients for pharmaceutical industry. The compounds conform to the relevant monographs as mentioned above.

The use of the product for which other regulations are applicable underlies the responsibility of the customer.

In the following, the status regarding food regulation of the components is described.

Lactose is the natural occurring sugar of milk (milk sugar). It is gained from whey via crystallization, washing and refining. It is regarded as food (dairy product or sugar).

For the sake of completeness: Lactose is not a food additive. The Regulation (EU) No 231/2012 and Regulation (EC) No. 1333/2008 are not applicable.

Lactose conforms to the current EU and German food regulations and is suitable for human consumption.

MCC complies with the specification for E 460 (i) in Regulation (EU) No. 231/2012 laying down specifications for food additives. Regarding the use in food, the Regulation (EC) No. 1333/2008 has to be considered.

MCC conforms to the current EU and German food regulations and is suitable for human consumption.

MS is the natural occurring carbohydrate in maize. It is regarded as food.

For the sake of completeness: Starch is not a food additive. The Regulation (EU) No 231/2012 and Regulation (EC) No. 1333/2008 are not applicable.

MS conforms to the current EU and German food regulations and is suitable for human consumption.

Freundliche Grüße / Best regards

Dr. Stefan Dreiheller