

INFORMATION

Quality / Regulatory Affairs



EIP-0058

Revision 13

Date of issue: 17.01.2024

1/1

Packaging Material

MEGGLE Products:

- Lactose Monohydrate: CapsuLac[®] 60, FlowLac[®] 90, FlowLac[®] 90 MS, FlowLac[®] 100, FlowLac[®] 90 MS, FlowLac[®] 100 SD, GranuLac[®] 70, GranuLac[®] 70 MS, GranuLac[®] 80, GranuLac[®] 140, GranuLac[®] 140 S, GranuLac[®] 200, GranuLac[®] 200 MS, GranuLac[®] 200 S, GranuLac[®] 230, InhaLac[®] 70, InhaLac[®] 120, InhaLac[®] 140, InhaLac[®] 145, InhaLac[®] 150, InhaLac[®] 160, InhaLac[®] 180, InhaLac[®] 230, InhaLac[®] 251, InhaLac[®] 300, InhaLac[®] 400, InhaLac[®] 500, Lactose Monohydrate 200 Mesh IP, Lactose Monohydrate Impalpable, Lactose Monohydrate Low Endotoxin, PrismaLac[®] 40, SacheLac[®] 80, SorboLac[®] 400, SpheroLac[®] 100, Tablettose[®] 70, Tablettose[®] 80, Tablettose[®] 100, Tablettose[®] 100 MS
- Co-processed Excipients: Cellactose[®] 80, CombiLac[®], MicroceLac[®] 100, RetaLac[®], StarLac[®]

In the absence of regulatory guidance regarding packaging material for excipients, the consistent legal framework for food contact materials provides a basis for the evaluation of primary packaging material with respect to migration and safety for solid excipients.

The packaging material used for the MEGGLE Products is produced in accordance with

- Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food,

The packaging material is in accordance with

- Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food as well as with legislation ("Specific measures") based on this Regulation, in particular
- Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food,

and all other legal requirements of Germany and EU laid down for packaging material which is intended to come into direct contact with food.

This MEGGLE Information was electronically released and is valid without signature.