

INFORMATION

Quality / Regulatory Affairs



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1/1

Allergen Information

MEGGLE Products:

Lactose Monohydrate: Tablettose® 70, Tablettose® 80, Tablettose® 100, Tablettose® 100 MS

An allergen management as part of the HACCP System is installed. The allergen management system comprises the scope of considered allergens, working principles regarding allergens in raw material, transport and manufacturing as well as information of customers about allergenic ingredients and potential allergenic cross contamination.

Allergens and products thereof	Allergens Present as Intentionally Added Ingredient(s) and/or "Product as such" + (Yes) / - (No)		Cross- Contamination
	Material	Production Equipment	

Legal EU Allergens (Regulation (EU) No 1169/2011)

Cereals containing gluten	-		-	-
Crustaceans	-		-	-
Eggs	-		-	-
Fish	-		-	-
Peanuts	-		-	-
Soybeans	-		-	-
Milk incl. lactose	+	Product as such	+	n.a.
Nuts	-		-	-
Celery	-		-	-
Mustard	-		-	-
Sesame seeds	-		-	-
Sulphur dioxide, sulphites	-		-	-
Lupins	-		-	-
Molluscs	-		-	-

The product is manufactured on dedicated equipment for lactose and lactose-based excipients. Cleaning validation/verification incl. EU allergens is installed.

Cross contamination status is integral part of the installed Change Control System. Any change of the above cross contamination status triggers adequate customer information.

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