

INFORMATION

Quality / Regulatory Affairs



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Revision 11

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1/1

Allergens

MEGGLE Product:

Co-processed Excipient: CombiLac®

The MEGGLE Allergen Concept is an integral part of the installed HACCP System. The concept describes the scope of the considered allergens, working principles regarding presence of allergens in raw material, on equipment/production lines and during storage and transport as well as measures to prevent cross contaminations and information of customers about allergenic ingredients and potential allergenic cross contamination.

Allergens and products thereof	Present in Material (Intentionally Added) + Yes / - No	Potential Presence ¹ on		Cross- Contamination + Yes / - No / N/A Not applicable
		Line	Site	
		+ Authorised / - Forbidden		

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	-		-	-	-

Additional FAO/WHO-Allergens²

Buckwheat	-		-	-	not evaluated
Pine nuts	-		-	-	not evaluated

¹ Authorised allergens **may be** present on line / site. This **does not mean** that the listed allergens are actually present at the time of publication. Forbidden allergens **are not** present on line / site at any time.

² Within prevalence group 1. See [here](#) for additional information.

The MEGGLE Product is manufactured on multipurpose equipment. Cleaning validation/verification incl. allergens is installed.

Cross contamination status is integral part of the installed Change Control System and is evaluated on the VITAL procedure of The Allergen Bureau in the current version. Changes regarding cross contamination status (Column "Cross Contamination") are in the scope of the installed Change Control System and are communicated.

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