



To whom it may concern

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Quality Unit / Regulatory Affairs

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Allergen Information

MEGGLE Product:

Inhaler Grade Lactose Monohydrate (USP-NF / Ph. Eur. / JP): InhaLac® 70, InhaLac® 120, InhaLac® 140, InhaLac® 150, InhaLac® 160, InhaLac® 230, InhaLac® 250, InhaLac® 251

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. No other products are processed .

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

Best regards

MEGGLE GmbH & Co. KG


Dr. Stefan Dreiheller