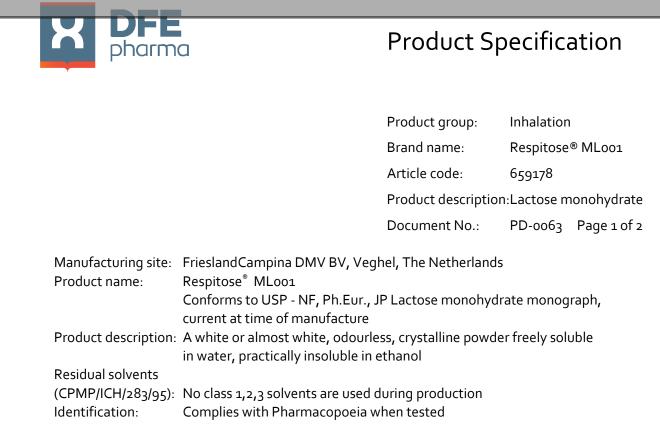
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Specification

Water (KF) Loss on drying	4.5 - 5.5 % max. 0.5 %
Specific optical rotation: [α] ²⁰ _D anhydrous basis	+54.4° to +55.9°
Residue on ignition/Sulphated ash	max. 0.1 %
Proteins and Light Absorbing Impurities	
[A] 1%, 1 cm at 270 - 300 nm	max. 0.07
[A] 1%, 1 cm at 210 - 220 nm	max. 0.25
Appearance of solution (Ph.Eur.)	Clear and not more coloured than ref. BY 7
•	Clear and not more coloured than ref. BY 7 Clear and colourless or nearly colourless
Appearance of solution (Ph.Eur.)	
Appearance of solution (Ph.Eur.) Clarity and Colour of Solution	Clear and colourless or nearly colourless
Appearance of solution (Ph.Eur.) Clarity and Colour of Solution [A] 10%, 1 cm at 400 nm	Clear and colourless or nearly colourless max. 0.04
Appearance of solution (Ph.Eur.) Clarity and Colour of Solution [A] 10%, 1 cm at 400 nm Acidity or Alkalinity (ml 0.1 N NaOH/6 g)	Clear and colourless or nearly colourless max. 0.04 max. 0.4 ml
Appearance of solution (Ph.Eur.) Clarity and Colour of Solution [A] 10%, 1 cm at 400 nm Acidity or Alkalinity (ml 0.1 N NaOH/6 g) Heavy metals	Clear and colourless or nearly colourless max. 0.04 max. 0.4 ml

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Brand name:	Respitose	® ML001
Article code:	659178	
Product description:Lactose monohydrate		
Document No.:	PD-0063	Page 2 of 2

Particle size distribution	on (Air jet sieve)		
	% < 45 μm	40 - 60	
	% < 100 μm	min. 75	
	% < 150 μm	min. 90)
	% < 315 μm	min. 10	0
Laser diffraction (dry)			
	dio	3 - 7 µm	
	d50	37 - 61 µ	เm
	d9o	124 - 19	4 µm
Morphology & shape		Premille	ed Tomahawk
Endotoxins		max.	5 EU/g
Total aerobic microbia	alcount	max.	10 cfu/g
Yeasts and moulds			<u> </u>
	anati na kanatania	max.	5
Bile-tolerant gram-ne	gative bacteria	neg. in	4 x 1 g
E. coli		neg. in	10 g
St. aureus		neg. in	10 g
Pseudomonas aerugir	iosa	neg. in	10 g
Salmonella		neg. in	50 g

Packaging: Polyethylene inner liner in a HDPE drum, 50 kg net

Storage:Keep in original, unopened packing and away from strongly odorous materials.Store at room temperature (normal warehouse conditions), allowing temporary
excursions from these conditions

This document substitutes all previous versions issued for the brand names mentioned above. We trust this information, which is made up to the best of our knowledge, will be helpful to you.

Name	: Rutger Drost
Job title	: Global Marketing, Innovation & Technology Director
Signature	:/ / /

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