Product Specification

Product group:	Inhalation
Brand name:	Respitose® SV010
Article code:	0659177
Product description:	Lactose monohydrate
Document No.:	PD-0082 Page 1 of 2

Manufacturing site:	FrieslandCampina DMV BV, Veghel, The Netherlands
Product name:	Respitose® SV010
Conforms to	USP – NF (requirements for inhalation use),Ph.Eur., JP, ChP Lactose monohydrate monograph, current at time of manufacture
Product description:	A white or almost white, crystalline powder freely soluble in water, practically insoluble in ethanol
Residual solvents	(ICH Guideline Q3C, USP General Chapter <467>, and Ph. Eur. General Chapter 5.4.): No class 1,2,3 solvents are used during production

	Specification
Infrared absorption Spectrum / Id A	Conforms to reference
Water (KF)	4.5 - 5.5 % (m)
Appearance of solution	Not more intensely coloured than ref. BY 7
Lactose Colour of Solution	Nearly colourless
Lactose Clarity of Solution	Clear
Proteins and Light Absorbing Impurities	
[A] 1%, 1 cm at 210 - 220 nm	max. 0.25
[A] 1%, 1 cm at 270 - 300 nm	max. 0.07
[A] 10%, 1 cm at 400 nm	max. 0.04
Acidity or Alkalinity	max. 0.4 ml 0.1 N NaOH/6 g
Specific optical rotation: $[\alpha]^{20}_{D}$ anhydrous basis	+54.4° to +55.9°
Heavy metals	max. 5 ppm
Loss on drying	max. 0.5 % (m)
Residue on ignition/Sulphated ash	max. 0.1 % (m)
Related sugars:	
Glucose	max. 200 ppm
Galactose	max. 200 ppm
Arsenic	max. 2 ppm
Assay by HPLC	98.0 – 102.0 %
Identification by HPLC	Pass
Related substances by HPLC	max. 0.5 % w/w

DFE Pharma GmbH & Co. KG
Kleyer Strasse 187, 47574 Goch, Germany, P.O. Box 20 21 20, 47568 Goch, Germany, T. +49 2823 9288 770, F. +49 2823 9288 7799

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Release date: 03-09-2026

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Particle shape and morphology		Premilled Tomahawk
Particle size distribution: Laser diffraction (Dry)	d10	35 - 65 µm
	d50	95 - 125 µm
	d90	160- 190 µm
	Span	Reported Value

Total aerobic microbial count	max. 10 cfu/g
Total yeasts and moulds	max. 10 cfu/g
Escherichia coli	neg. in 10 g
Salmonella	neg. in 50 g
Bile-tolerant gram-negative bacteria	neg. in 4 x 1 g
Pseudomonas aeruginosa	neg. in 10 g
Staphylococcus aureus	neg. in 10 g
Bacterial Endotoxin	max. 5 EU/g
Burkholderia cepacia	neg. in 10 g

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

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 : Dr. Bastiaan Dickhoff
Job title : Director Innovation & Technical Solutions

Signature : 

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DFE Pharma GmbH & Co. KG
Klever Strasse 187. 47574 Goch. Germany. P.O. Box 20 21 20. 47568 Goch. Germany. T. +49 2823 9288 770. F. +49 2823 9288 7799

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