

SPECIFICATION DATA SHEET

SynBalance[®] Premix14 Smoky Quartz

Blend of freeze-dried probiotics

Strains Origin	Concentration		
Human	50 billion CFU/g		

ANALYTICAL SPECIFICATION					
Parameter	Unit	Requirement	Method		
PHYSICAL-CHEMICAL					
Appearance	-	Powder	IO 07-06A		
Colour	-	White cream to beige	IO 07-06A		
Odour	-	Characteristic	IO 07-06A		
Loss on drying (105°C)	%	<u><</u> 5,0	Ph.Eur. 2.2.32		

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Water activity	_	<u><</u> 0,25	IO 07-06AL
	MICROBIOLOGICA		
Total LAB count	CFU/g	<u>></u> 0,5 E+11	IO 07-06T
Non LAB count	CFU/g	<u><</u> 1.000	ISO 13559 + confirmatory catalase test
Yeasts & Moulds	CFU/g	<u><</u> 100	ISO 21527-2
Enterobacteriaceae*	CFU/g	<u><</u> 100	ISO 21528-2
Escherichia coli beta glucuronidase positive*	CFU/g	<u><</u> 10	UNI ISO 16649-2
Staphylococci coagulase positive*	CFU/g	<u><</u> 10	ISO 6888-1
Salmonella*	25g	Absence	UNI EN ISO 6579-1
Listeria monocytogenes*	25g	Absence	ISO 11290-1

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*Analysis verified/performed following an internal analytical plan and through the application of appropriate statistical process control method. The term "Complies" will be reported in the certificate of analysis of the batches not included in the above-mentioned plan.

Excipient: Maltodextrin

(Corn starch could be found in negligible amount as excipient of the original strains).

Storage: Store in original sealed containers at -18°C, in a dry place, repaired from light or humidity sources.

Period of best use: 18 months from production date, in sealed original container, if stored as described above.

Roelmi HPC Technical Department

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THE PRESENT DOCUMENT SUBSTITUTES AND CANCELS THE PREVIOUS VERSION

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