Buckton Scott Deutschland

TECHNICAL DATA SHEET

PROPOLIS RE 1:1 DE
PR2610

Raw material: Crude propolis

Ratio raw material / final product: 1 to 1 (a)

Extraction solvent(s): Ethanol, water 30 : 70 (V/V)

Carrier(s): Wheat maltodextrin

Part used: Resin

DESCRIPTION

	Specifications	Methods and references
Appearance	*Hygroscopic powder with presence eof natural black dots*	
Color	*Off-white to beige*	
Odor	*Characteristic*	
Taste	*Characteristic*	
Solubility	*To be tested following the degree of incorporation*	

ANALYSES

	Specifications		Method and reference
	Min	Max	
Loss on drying [%] (11)	-	*6.00*	*MO-183 - Eur. Ph. (01/2008:20817) and (02/2008:20816)*
Bulk density	*0.30*	*0.70*	*MO-181 - Eur. Ph. (04/2019:20934)*
Total ash content [%] (11)	-	*< 8.00*	*MO-01 - Muffle furnace, Eur. Ph. (01/2008:20416), "Total ash" adapted monograph*
pH (1% in demineralized water) (11)	*3.0*	*6.5*	*MO-03 - pH-meter, Eur. Ph. (07/2016:20203),"Potentiometric determination of pH" monograph*
Screening [% < 500 µm]	*95.0*	-	*MO-184 - Granulometer, internal method*

CONTAMINANTS

	Specifications		Method and reference
	Min	Max	
Pb content [ppm] (4)	-	*< 3.00*	*AE-01 - ICP, internal method*
Cd content [ppm] (4)	-	*< 1.00*	*AE-01 - ICP, internal method*
Hg content [ppm] (4)	-	*< 0.10*	*AE-01 - ICP, internal method*

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INFORMATION ABOVE AS RECEIVED FROM OUR SUPPLIER

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Pesticides content [ppm] (4)	*< Residual Maximum Limit fixed in European regulation 396/2005 and its modifications*		*AE-02 - GC-MSMS/LC-MSMS, internal method*
Benzo(a)pyrene content [ppb] (4)	-	*< 10.0*	*AE-03 - GC-MS-MS, internal method*
Pahs (sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene) content [ppb] (4)	-	*< 50.0*	*AE-03 - GC-MS-MS, internal method*

MICROBIOLOGY	**Specifications**		**Method and reference**
	Min	**Max**	
Total aerobic microbial count [CFU/g] (1)	-	*< 10 000*	*AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)*
Total yeasts/moulds count [CFU/g] (1)	-	*< 100*	*AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)*
Salmonella content [/25g]	*Absent*		*AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)*
Bile-tolerant Gram negative bacteria content [CFU/g]	-	*< 100*	*AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)*
Escherichia coli content [/g]	*Absent*		*AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)*

(1) Acceptable maximal count: 5 times the acceptance criterion according to Eur. Ph. VIII° Ed. 5.1.8 Category B
(11) First ten batches
(4) HACCP based control plan defined annually according to risk analysis

Best before/ DMD (in months) : *24*

Storage conditions: *Store in closed original packaging at 5 to 25°C in a dry place and protected from light.*

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Complementary data	*(a): Variable indicative ratio depending on productions and / or variability of the raw material. Non contractual data*

This reference is neither an Active Pharmaceutical Ingredient nor an excipient for pharmaceutical use Responsibility of final labelling lies with the company placing the final product on the market.
- According to Regulation 1999/3/EC, and its modifications, has not been ionized.
- According to the Regulations 2001/18/EC, 1829/2003 and 1830/2003, and its modifications, the above mentioned item does not contain deliberately added GMO. (fortuitous or technically inevitable traces could be detected at less than 0,9%)
- The product does not contain TSE/BSE substances