

TECHNICAL DATA SHEET

GRAPE SE 45% DE PR5226

Botanical kind:	Vitaceae Vitis vinifera L.
Part of the plant:	Seed
Extraction solvent(s):	Ethanol, water 30 : 70 (V/V)
Carrier(s):	Wheat maltodextrin

DESCRIPTION

	Specifications	Methods and references
Appearance	<i>Powder</i>	
Color	<i>Brown to red brownish</i>	
Taste	<i>Characteristic, astringent</i>	
Solubility	<i>To be tested following the degree of incorporation</i>	

ANALYSES

	Specifications		Method and reference
	Min	Max	
Oligomeric proanthocyanidins (OPCs) content [%]	45.00	-	<i>MO-07 - UV-Vis, internal method</i>
Identification (raw material) (4)	<i>Complies with the phytochemical profile of Vitaceae Vitis vinifera L., seed</i>		<i>AE-11 - HPLC or HPTLC, internal method</i>
Loss on drying [%] (11)	-	8.00	<i>MO-249 - Desiccator, internal method</i>
Bulk density	0.30	0.70	<i>MO-181 - Eur. Ph. (04/2019:20934)</i>
pH (1% in demineralized water) (11)	2.5	6.5	<i>MO-03 - pH-meter, Eur. Ph. (07/2016:20203), "Potentiometric determination of pH" monograph</i>
Screening [% < 500 µm]	100	-	<i>MO-184 - Granulometer, internal method</i>

CONTAMINANTS

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

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Pesticides content [ppm] (4)	<i><Residual Maximum Limit fixed in European regulation 396/2005 and its modifications (product code: 0151000 or 0630000)</i>	<i>AE-02 - GC-MSMS/LC-MSMS, internal method</i>
Benzo(a)pyrene content [ppb] (4)	-	<i>< 10.0</i>
Pahs (sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene) content [ppb] (4)	-	<i>< 50.0</i>

MICROBIOLOGY	Specifications		Method and reference
	Min	Max	
Total aerobic microbial count [CFU/g] (1)	-	<i>< 10 000</i>	<i>MO-191 - Pétrifilm TM / ISO 4833</i>
Total yeasts/moulds count [CFU/g] (1)	-	<i>< 100</i>	<i>MO-192 - Pétrifilm TM / AOAC 997.02</i>
Salmonella content [/25g]	<i>Absent</i>		<i>MO-193 - TECRA TM / ISO 6579</i>
Enterobacteria content [CFU/g]	-	<i>< 100</i>	<i>MO-194 - Pétrifilm TM ISO 21528-2</i>
Escherichia coli content [CFU/g]	-	<i>< 10</i>	<i>MO-195 - Pétrifilm TM / ISO 16649-2</i>

(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/ 24

DMD (in months) :

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**

- 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.*
- *Complies with French decrees (2006-352 and 24th June 2014).*
 - *According to Regulation 1999/3/EC, and its modifications, the product has not been ionized.*
 - *According to the Regulations 2001/18/EC, 1829/2003 and 1830/2003, and its modifications, the product 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.*