

TECHNICAL DATA SHEET

ORGANIC HORSE CHESTNUT SE 4 - 6 % DE PR8640

Organic labelling regulation
((UE) 2018/848 - art.32):

BIO = DE-ÖKO-039

Botanical kind:

Organic Sapindaceae Aesculus hippocastanum L.

Part of the plant:

Seed

Extraction solvent(s):

Ethanol, Water 70:30 (V/V)

Carrier(s):

Organic maltodextrin

DESCRIPTION

	Specifications	Methods and references
Appearance	<i>Powder</i>	
Color	<i>Dark beige to brown</i>	
Water solubility	<i>Water soluble</i>	<i>MO-186 - Solubility, Eur. Ph. (04/2022:51100), "Characters section in monographs" monograph</i>

ANALYSES

	Specifications		Method and reference
	Min	Max	
Anhydrous aescin content [%]	4.00	6.00	<i>MO-27 - UV-Vis, Fr. Ph. (1992), "Extrait de marron d'Inde (sec)" monograph</i>
Esculin content [ppm] (4)	<i>Indicative value</i>		<i>AE-21 - HPLC, internal method</i>
Identification (raw material) (4)	<i>Complies</i>		<i>MO-70 - TLC, Fr. Ph. (1995), "Marron d'Inde" monograph</i>
Loss on drying [%] (11)	-	8.00	<i>MO-183 - Eur. Ph. (01/2008:20817) and (02/2008:20816)</i>
Bulk density	0.30	0.70	<i>MO-181 - Eur. Ph. (04/2019:20934)</i>
pH (1% in demineralized water) (11)	3.0	6.5	<i>MO-03 - pH-meter, Eur. Ph. (07/2016:20203), "Potentiometric determination of pH" monograph</i>
Screening [% < 500 µm]	95.0	-	<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>

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INFORMATION ABOVE AS RECEIVED FROM OUR SUPPLIER

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As content [ppm] (4)	-	< 1.00	AE-01 - ICP, internal method
Pesticides content [ppm] (4)	detection limit		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/ 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, 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*