

TECHNICAL DATA SHEET

SHADDOCK SE 4:1 DE PR4184

Botanical kind:	Rutaceae Citrus maxima (Burm) Merr. (=Citrus decumana L.) (=Citrus grandis L.)
Part of the plant:	Seed
Ratio plant / final extract:	4 to 1 (a)
Extraction solvent(s):	Water
Carrier(s):	Wheat maltodextrin

DESCRIPTION	Specifications	Methods and references
Appearance	<i>Powder</i>	
Color	<i>White to dark beige</i>	
Solubility	<i>To be tested following the degree of incorporation</i>	

ANALYSES	Specifications		Method and reference
	Min	Max	
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)	2.5	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] (2)	-	< 3.00	<i>AE-01 - ICP, internal method</i>
Cd content [ppm] (2)	-	< 1.00	<i>AE-01 - ICP, internal method</i>
Hg content [ppm] (2)	-	< 0.10	<i>AE-01 - ICP, internal method</i>
Pesticides content [ppm] (2)	<i>< Residual Maximum Limit fixed in European regulation 396/2005 and its modifications</i>		<i>AE-02 - GC-MSMS/LC-MSMS, internal method</i>
Benzo(a)pyrene content [ppb] (2)	-	< 10.0	<i>AE-03 - GC-MS-MS, internal method</i>

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Pahs (sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene) content [ppb] (2)	-	< 50.0	AE-03 - GC-MS-MS, internal method
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MICROBIOLOGY	Specifications		Method and reference
	Min	Max	
Total aerobic microbial count [CFU/g] (1)	-	< 10 000	MO-191 - Pétrifilm TM / ISO 4833
Total yeasts/moulds count [CFU/g] (1)	-	< 100	MO-192 - Pétrifilm TM / AOAC 997.02
Salmonella content [/25g]	Absent		MO-193 - TECRA TM / ISO 6579
Enterobacteria content [CFU/g]	-	< 100	MO-194 - Pétrifilm TM ISO 21528-2
Escherichia coli content [CFU/g]	-	< 10	MO-195 - Pétrifilm TM / ISO 16649-2

(1) Acceptable maximal count: 5 times the acceptance criterion according to Eur. Ph. VIII° Ed. 5.1.8 Category B

(11) First ten batches

(2) On request with additional cost

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.

Complementary data

(a): Variable indicative raw material 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, 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.