

Article no. (manufacturer / supplier):	CPE--03287
Identification of the substance or preparation:	Aspalathus linearis extract
REACH registration No.:	None
Use of the substance / preparation:	Active Pharmaceutical Ingredient
Supplier (manufacturer/importer/downstream user/distributor):	
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	Only available during office hours (GMT + 2:00)

A: PHYSICAL/ CHEMICAL/ MICROBIOLOGICAL CHARACTERISTICS

LATIN NAME OF PLANT MATERIAL USED	<i>Aspalathus linearis</i> (Burm.f.) R.Dahlgren
PART OF PLANT USED (DRUG: root, leaves...)	Leaf of the plant
GEOGRAPHICAL ORIGIN OF THE PLANT	Throughout South Africa
COMMON NAME	Green Rooibos
SITE OF MANUFACTURING (CITY, COUNTRY)	Paarl, South Africa
APPEARANCE (Colour, taste, odour)	A reddish green powder.
KIND OF EXTRACTION (FOR EXTRACTS ONLY): (i.e. water, hydro-alcoholic)	Spray dried Hydro-alcoholic extract
EXTRACTION RATIO	5:1
EXCIPIENT USED (%) (Maltodextrin, Lactose....)	100% Native
SUBSIDIARY SUBSTANCES	No preservatives or production additives
SOLUBILITY (water, ethanol, chloroform, hexane....)	Sparingly soluble in water between 15°C and 25°C
IDENTIFICATION i.e. method used (IR, UV; HPLC)	Thin layer chromatography; FT-IR
ASSAY (HPLC)	Aspalathin – Batch specific determination
MOISTURE (%) (Loss on drying)	≤ 5.0 % (m/m)
SOLVENT RESIDUES (%)	Ethanol < 0.5 %
SIEVE ANALYSIS (< 0.315 mm)	< 5.0 % (m/m)
BULK DENSITY	Batch specific determination

HEAVY METALS	PARAMETERS
Lead	< 5.0 mg/kg
Cadmium	< 0.2 mg/kg
Mercury	< 0.10 mg/kg
Arsenic	< 1.0 mg/kg

PESTICIDES	PARAMETERS
Pesticides	Meets Ph. Eur. requirements

AFLATOXINS	PARAMETERS
Aflatoxin B1	< 2.0 µg/ kg
Total aflatoxins (B1, B2, G1 and G2)	< 4.0 µg/ kg

MICROBIOLOGY	PARAMETERS
Total aerobic count	< 2 000 cfu/g
Total combined yeast and mould	< 100 cfu/g
Bile tolerant gram negative bacteria	< 100 cfu/g
<i>Escherichia coli</i>	Absent/g
<i>Salmonella spp.</i>	Absent/25g

B. REGULATORY DATA

1. Food allergen information: According to Regulation (EC) No 1169/2011, of ingredients present in food stuff, and amendments

	<u>Substances</u>	ALLERGENS		
		Present in the product (+/-)	Present in the site (+/-)	Risk of cross-contamination (+/-)
01	Cereals containing gluten and products thereof	-	-	-
02	Crustaceans and products thereof	-	-	-
03	Eggs and products thereof	-	-	-
04	Fish and products thereof	-	+	-
05	Peanuts and products thereof	-	-	-
06	Soya beans and products thereof	-	+	-
07	Milk and products thereof (including lactose)	-	+	-
08	Nuts and products thereof	-	+	-
09	Celery and products thereof	-	-	-
10	Mustard and products thereof	-	-	-
11	Sesame seeds and products thereof	-	-	-
12	Lupine and products thereof	-	-	-
13	Molluscs and products thereof	-	-	-
14	Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO ₂	-	+	< 10 ppm

2. Statement in accordance with Commission Decisions 1999/724/EC and 1997/534/EC

Statement regarding Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE) free	
<p>We hereby confirm that the materials used in the manufacturing process of the product are of plant origin and not from cattle, sheep, goat or other animals. There is no contact with any animal during the processing of this product.</p> <p>There is therefore no likelihood of any BSE and TSE transmitters. No actives are suspected to be present in the product either. Therefore, transmission of BSE and TSE via the mentioned product is not expected to occur.</p> <p>This confirmation is valid for all ingredients including additives and flavours.</p>	
_____ 21 June 2016 Date	_____ <i>R. Longrigg</i> Signature, stamp

3. Statement in accordance with Regulation 1829/2003/EC and 1830/2003/EC

Statement regarding Genetically modified organisms	
<p>We hereby confirm that, to our present knowledge, the product mentioned above does not contain genetically modified raw materials according to:</p> <p>REGULATION (EC) No 1829/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003 on genetically modified food and feed and the</p> <p>REGULATION (EC) No 1830/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and amending Directive 2001/18/EC</p> <p>The production process is mechanical and therefore does not utilise any genetically modified organisms. The product is immediately packed upon completion of production, in a way that eliminates contamination of any form and therefore during production or transportation cannot be contaminated by any foreign material including GMO's This confirmation is valid for all ingredients including additives and flavours.</p>	
<p>21 June 2016</p> <p>_____</p> <p>Date</p>	<p><i>R. Longrigg</i></p> <p>_____</p> <p>Signature, stamp</p>

C. ADDITIONAL CERTIFICATION (Religious statements)

Halaal Status	Certified
Kosher / Beth Din Status	Certified

D. SPECIAL NUTRITION STATUS

Nutrition for vegetarians	The material is free from meat, fish, shellfish and their products
Nutrition for vegans	The material is free from animal components (including honey)

E. SAFETY STATEMENT

Oral use for human consumption (Food)	Reported to be safe
Possible side effects	None Known
Possible adverse interactions (Compound, food or drug)	Reported to be safe