	TECHNICAL DATA SHEET	Doc No.	TDS-CPE03287-02
		Linked Doc	SDS-CPE03287 PS-CPE03287 AR-CPE03287
Afriplex™ GRT (Green Rooibos Tea extract)		Effective date	June 2019
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Article no. (manufacturer / supplier): Identification of the substance or preparation: REACH registration No.: Supplier (manufacturer/importer/downstream user/distributor): Address: Telephone: Fax No: Department responsible for information: E-mail: Emergency telephone:	CPE03287 Afriplex™ GRT Extract None Afriplex (Pty) Ltd 10 De Vreugde Crescent Dal Josaphat Paarl, 7646 South Africa +27-21-872 4976 +27-21-872 4930 Quality Assurance Department: CheryldeneM@afriplex.co.za +27-21-872 4976 Only available during office hours (GMT + 2:00)
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A: PHYSICAL/ CHEMICAL/ MICROBIOLOGICAL CHARACTERISTICS

Raw material Latin name of plant material used Part of plant used (drug: root, leaves...) Geographical origin of the plant Trade name Common name Site of manufacturing (city, state) Appearance (colour, taste, odour) Kind of extraction (for extracts only): Excipient used (%) (maltodextrin, lactose...) Processing aids	Green unfermented Rooibos <i>Aspalathus linearis</i> (Burm.f.) R.Dahlgren herba sicc Leaves and stems Southern Africa Afriplex™ GRT Extract Green Rooibos Extract Paarl, South Africa Reddish brown fine powder Hydro-alcoholic (60%) None None
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PRODUCT SPECIFICATION

Physical and Chemical Specifications

Parameter	Specification	Test Method
Characteristics and Appearance	Reddish brown fine powder. Aroma is typical to rooibos.	WHO/Pharm/92.599/rev 1 page 10
Solubility	Sparingly soluble in water, 1g in 100 ml	Ph. Eur. General notice Part II
Identification (FT-IR)	≥ 95,00% similarity to reference	SOP-QC023
Identification (TLC)	The Rf bands of the sample corresponds to the Rf bands of the reference sample.	Ph. Eur. 2.2.27
Assay by HPLC	Aspalathin – Batch specific determination	Ph. Eur. 2.2.29
Moisture (%) (Loss on drying)	≤ 5 % (m/ m)	Ph. Eur. 2.2.32
Bulk Density	Batch specific	Ph. Eur. 2.9.34


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Sieve (<0,315 mm)	< 5,0 % (m/m)	<i>Ph. Eur.</i>
Residual Solvent	≤ 0,5 % EtOH	<i>Ph. Eur. 2.4.24</i>
Total Aflatoxins (B1, G1, B2, G2)	< 4,0 µg/ g	<i>Ph. Eur. 2.8.18</i>
Aflatoxin B1	< 2,0 µg/ g	<i>Ph. Eur. 2.8.18</i>
Pesticides	Meets Ph. Eur. requirements	<i>Ph. Eur. 2.8.13</i>

Microbial Specifications

Parameter	Specification	Test Method
Total Aerobic Count	< 2 000 cfu/ g	<i>Ph. Eur. 2.6.31; Ph. Eur. 2.6.12-13</i>
Yeast & Mould	< 100 cfu/ g	<i>Ph. Eur. 2.6.31; Ph. Eur. 2.6.12-13</i>
Bile-tolerant gram-negative bacteria	<100 cfu/ g	<i>Ph. Eur. 2.6.31</i>
<i>Escherichia coli</i>	Absent / g	<i>Ph. Eur. 2.6.31; Ph. Eur. 2.6.12-13</i>
<i>Staphylococcus aureus</i>	Absent / g	<i>Ph. Eur. 2.6.31</i>
Salmonella spp.	Absent /25 g	<i>Ph. Eur. 2.6.31; Ph. Eur. 2.6.12-13</i>

Heavy Metal Specifications

Parameter	Specification	Test Method
Lead	< 5,00 mg/ kg	<i>Ph. Eur. 2.4.8</i>
Cadmium	< 1,00 mg/ kg	<i>Ph. Eur. 2.4.8</i>
Mercury	< 0,10 mg/ kg	<i>Ph. Eur. 2.4.8</i>
Arsenic	< 1,00 mg/ kg	<i>Ph. Eur. 2.4.8</i>

STORAGE CONDITIONS & PRECAUTIONS

Shelf life	23 months – excluding month of manufacturing
Recommended storage conditions	Closed, protect from moisture, light and high temperatures
Precautions	None


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B. REGULATORY DATA

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

ALLERGENS				
	Substances	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	-	+	<10ppm

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>	
<u>10 June 2019</u> Date	 Signature, stamp


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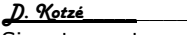
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3. Statement in accordance with Regulation 1829/2003/EC and 1830/2003/EC

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</p> <p>This confirmation is valid for all ingredients including additives and flavours.</p>	
<u>10 June 2019</u> Date	 Signature, stamp

4. Statement in accordance with Regulation (EC) 1881/2006 and 594/2012/EC

Statement regarding Melamine	
<p>We hereby confirm that, to our present knowledge, the product mentioned above does not contain melamine according to:</p> <p>REGULATION (EC) No (EC) 1881/2006 and 594/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 July 2012 on the maximum levels of the contaminants ochratoxin A, non-dioxin-like PCBs and melamine in foodstuffs.</p> <p>Afriplex does not add any products containing melamine during the manufacture, storage or packaging of our products. While Afriplex does not specifically test for the presence of melamine we have no reason to believe it is present in any of our products.</p> <p>This confirmation is valid for all ingredients.</p>	
<u>10 June 2019</u> Date	 Signature, stamp


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5. Statement in accordance with Regulation (EC) 1169/2011

Statement regarding Engineered Nanomaterial	
<p>We hereby confirm that, to our present knowledge, the product mentioned above does not contain nanomaterial according to:</p> <p>REGULATION (EC) No (EC) 1169/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2011 on the provision of food information to consumers.</p> <p>Afriplex does not use ingredients in the form of engineered nanomaterials during the manufacture, storage or packaging of our products.</p>	
<u>10 June 2019</u> Date	<u>J. Kotzé</u> Signature, stamp

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

Checked by Quality Control:	Checked by Quality Assurance:
	
Date: 12 June 2019	Date: 14 June 2019
Approved by Regulatory Department:	
	
Date: 14 June 2019	

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