Afriplex™ GRT
(Green Rooibos Tea extract)

A: PHYSICAL/ CHEMICAL/ MICROBIOLOGICAL CHARACTERISTICS

Raw material
Green unfermented Rooibos
Aspalathus linearis (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

Latin name of plant material used
Aspalathus linearis (Burm.f.) R.Dahlgren

Part of plant used (drug: root, leaves...)
Leaves and stems

Geographical origin of the plant
Southern Africa

Trade name
Afriplex™ GRT Extract

Common name
Green Rooibos

Site of manufacturing (city, state)
Paarl, South Africa

Appearance (colour, taste, odour)
Reddish brown fine powder

Kind of extraction (for extracts only):
Hydro-alcoholic (60%)

Excipient used (%)(maltodextrin, lactose....)
None

Processing aids
None

PRODUCT SPECIFICATION

Physical and Chemical Specifications

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

14/06/2019 10:58
IMPORTANT NOTE TO USER: Unless otherwise documented, printed documents are not controlled.
Afriplex
10 De Vreugde Crescent, Paarl, 7646, South Africa Tel: +27 21 872 4976 Fax: +27 21 872 4930
Afriplex™ GRT
(Green Rooibos Tea extract)

Effective date: June 2019

Linked Doc: SDS-CPE03287
PS-CPE03287
AR-CPE03287

Afriplex Pharmaceuticals (Pty)Ltd.
10 De Vreugde Crescent, Paarl, 7646, South Africa
Tel: +27 21 872 4976 Fax: +27 21 872 4930

**Sieve (<0,315 mm)**: < 5.0 % (m/m)  
**Residual Solvent**: ≤ 0.5 % EtOH  
**Total Aflatoxins (B1, G1, B2, G2)**: < 4.0 µg/ g  
**Aflatoxin B1**: < 2.0 µg/ g  
**Pesticides**: Meets Ph. Eur. requirements

**Microbial Specifications**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
<th>Test Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Aerobic Count</td>
<td>&lt; 2 000 cfu/ g</td>
<td>Ph. Eur. 2.6.31; Ph. Eur. 2.6.12-13</td>
</tr>
<tr>
<td>Yeast &amp; Mould</td>
<td>&lt; 100 cfu/ g</td>
<td>Ph. Eur. 2.6.31; Ph. Eur. 2.6.12-13</td>
</tr>
<tr>
<td>Bile-tolerant gram-negative bacteria</td>
<td>&lt;100 cfu/ g</td>
<td>Ph. Eur. 2.6.31</td>
</tr>
<tr>
<td><em>Escherichia coli</em></td>
<td>Absent / g</td>
<td>Ph. Eur. 2.6.31; Ph. Eur. 2.6.12-13</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em></td>
<td>Absent / g</td>
<td>Ph. Eur. 2.6.31</td>
</tr>
<tr>
<td><em>Salmonella spp.</em></td>
<td>Absent /25 g</td>
<td>Ph. Eur. 2.6.31</td>
</tr>
</tbody>
</table>

**Heavy Metal Specifications**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
<th>Test Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead</td>
<td>&lt; 5.00 mg/ kg</td>
<td>Ph. Eur. 2.4.8</td>
</tr>
<tr>
<td>Cadmium</td>
<td>&lt; 1.00 mg/ kg</td>
<td>Ph. Eur. 2.4.8</td>
</tr>
<tr>
<td>Mercury</td>
<td>&lt; 0.10 mg/ kg</td>
<td>Ph. Eur. 2.4.8</td>
</tr>
<tr>
<td>Arsenic</td>
<td>&lt; 1.00 mg/ kg</td>
<td>Ph. Eur. 2.4.8</td>
</tr>
</tbody>
</table>

**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

<table>
<thead>
<tr>
<th>Substances</th>
<th>Present in the product (+/-)</th>
<th>Present in the site (+/-)</th>
<th>Risk of cross-contamination (+/-)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cereals containing gluten and products thereof</td>
<td>-</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Crustaceans and products thereof</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Eggs and products thereof</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Fish and products thereof</td>
<td>-</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Peanuts and products thereof</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Soya beans and products thereof</td>
<td>-</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Milk and products thereof (including lactose)</td>
<td>-</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Nuts and products thereof</td>
<td>-</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Celery and products thereof</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Mustard and products thereof</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Sesame seeds and products thereof</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Lupine and products thereof</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Molluscs and products thereof</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO₂</td>
<td>-</td>
<td>+</td>
<td>&lt;10ppm</td>
</tr>
</tbody>
</table>


Statement regarding Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE) free

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.

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.

This confirmation is valid for all ingredients including additives and flavours.

10 June 2019
D. Kotzé
Date Signature, stamp

Statement regarding Genetically Modified Organisms

We hereby confirm that, to our present knowledge, the product mentioned above does not contain genetically modified raw materials according to:

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


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.

10 June 2019
Date

D. Kotzé
Signature, stamp


Statement regarding Melamine

We hereby confirm that, to our present knowledge, the product mentioned above does not contain melamine according to:


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.

This confirmation is valid for all ingredients.

10 June 2019
Date

D. Kotzé
Signature, stamp
5. Statement in accordance with Regulation (EC) 1169/2011

Statement regarding Engineered Nanomaterial

We hereby confirm that, to our present knowledge, the product mentioned above does not contain nanomaterial according to:


Afriplex does not use ingredients in the form of engineered nanomaterials during the manufacture, storage or packaging of our products.

10 June 2019

D. Kotzé

Date
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: Tanya Oosthuizen
Date: 12 June 2019

Checked by Quality Assurance: Marlie le Roux
Date: 14 June 2019

Approved by Regulatory Department:

Date: 14 June 2019