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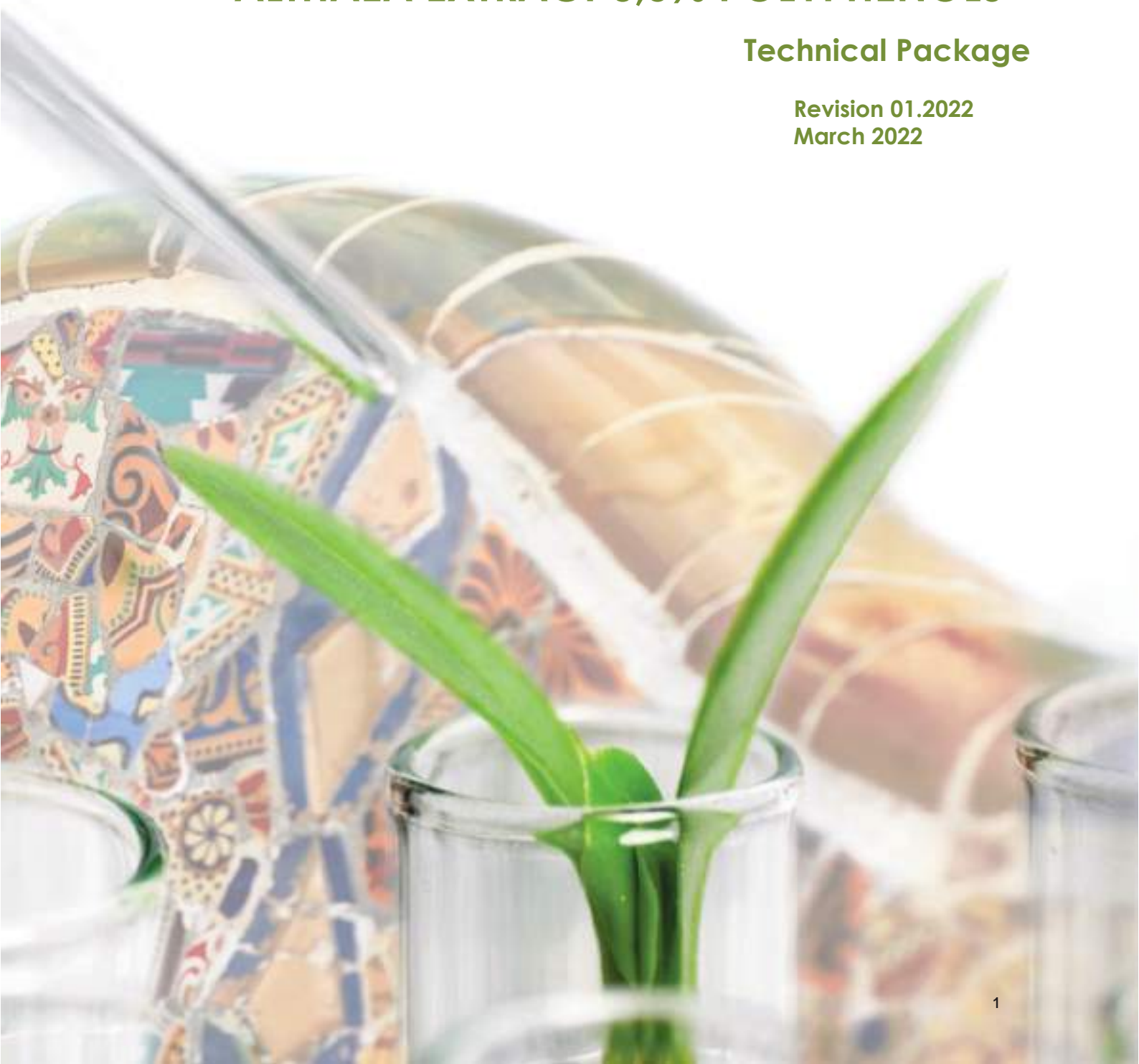
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sb select botanical
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ALTHAEA EXTRACT 0,5% POLYPHENOLS

Technical Package

**Revision 01.2022
March 2022**



TECHNICAL DATA PACKAGE

ALTHAEA EXTRACT 0,5%

POLYPHENOLS

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TECHNICAL DATA SHEET

Product name: **ALTHAEA DRY EXTRACT 0.5% POLYPHENOLS**

Product Code: **ID-0008-0122-P**

Botanical name: *Althaea officinalis* L.

Part Used: Root

Storage: Keep container tightly sealed and store in a dry place in closed original container.

Excipients: Maltodextrin, Silicon dioxide

Shelf life: 3 years

ANALYSIS	METHODS	SPECIFICATIONS
Description		
Appearance	Visual	Ochre coloured powder
Odour & Taste	Organoleptic	Characteristic
Extraction solvent		Ethanol/Water
Ratio plant/extract		3-5:1
Identification		
Thin layer chromatography -TLC	Eur.Ph. current monograph "1856"- Identification C	Raw material complies reference
Physico-Chemical		
Loss on drying (% w/w)	USP <731>	≤5,0
Total ash (% w/w)	USP <561>	≤15,0
Bulk density (g/ml)	USP <616>	≥0,30
Tapped density (g/ml)	USP <616>	≥0,40
Particle size (% w/w)	USP <786>-Through 180 µm	≥95
Solubility		Partially soluble in hydroalcoholic solutions
Assay		
Total polyphenols (dry basis) (% w/w)	UV-Vis	≥0,50
Residual Solvents		
Ethanol (ppm)	GC (Acc.CHMP/ICH/ 82260/2006 guidelines)	≤5000
Microbiology Quality		
Total aerobic microbial count (TAMC) (CFU/g)	USP <61>	≤10000
Total combined yeasts/moulds count (TYMC) (CFU/g)	USP <61>	≤100
Bile-tolerant gram-negative bacteria (CFU/g)	USP <62>	≤100
<i>Escherichia coli</i> (g)	USP <62>	Absence 1
<i>Salmonella</i> (g)	USP <62>	Absence 25
Contaminants		
Pesticides	GC-MS/LC-MS	Complies USP <561>
Lead (ppm)	Raw material-I.C.P-MS	≤0,5
Cadmium (ppm)	Raw material-I.C.P-MS	≤0,2
Mercury (ppm)	Raw material-I.C.P-MS	≤0,1
Arsenic (ppm)	Raw material-I.C.P-MS	≤0,5

Specification Nº/version:202203/01

SELECT BOTANICAL, S.L. Office: C/Borí i Fontestà, 49 08017 Barcelona Telf.: +34 93 3621223 Fax: +34 93 3621224

Manufacturing plant: Polígono Industrial de Buñuel Calle B, Nº5 31540 Buñuel (Navarra) - SPAIN

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ALTHAEA EXTRACT 0,5% POLYPHENOLS

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TECHNICAL DATA SHEET

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Benzopyrene (ppb)	GC-MS	≤10,0
4 PAH's (ppb)	GC-MS	≤50,0
Aflatoxin B1 (ppb)	Raw material-Eur.Ph.ed.2.8.18	≤2,0
Aflatoxins B1,B2,G1,G2 (ppb)	Raw material-Eur.Ph.ed.2.8.18	≤4,0

Contaminants: analysis by monitoring system in external homologated laboratory

Sum of 4PAH (benzo(a)pyrene, benz(a)anthracene, benzo(a)fluoranthene, chrysene)

Product manufactured in Spain

Plant & Biomass origin: Europe



Allergen Information Statement

Name of the product: **ALTHAEA DRY EXTRACT 0.5%**

Allergen list according Annex II of the Regulation 1169/2011 and amendments	Product ingredient	Is this allergen present in the same manufacturing facility?	Risk of cross contamination (raw material, storage, transport)	Conclusion of the contamination risk
	Y/N	Y/N	Y/N	
Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof	N	N	N	N
Crustaceans and products thereof	N	N	N	N
Eggs and products thereof	N	N	N	N
Fish and products thereof	N	N	N	N
Peanuts and products thereof	N	N	N	N
Soybeans and products thereof	N	Y (soy Isoflavones extract)	N	N
Milk and products thereof (including lactose)	N	N	N	N
Nuts i. e. Almond (<i>Amygdalus communis</i> L.), Hazelnut (<i>Corylus avellana</i>), Walnut (<i>Juglans regia</i>), Cashew (<i>Anacardium occidentale</i>), Pecan nut (<i>Carya illinoensis</i> (Wangenh.) K. Koch), Brazil nut (<i>Bertholletia excelsa</i>), Pistachio nut (<i>Pistacia vera</i>), Macadamia nut and Queensland nut (<i>Macadamia ternifolia</i>) and products thereof	N	N	N	N
Celery and products thereof	N	N	N	N
Mustard and products thereof	N	N	N	N
Lupine and products thereof	N	N	N	N
Molluscs and products thereof	N	N	N	N
Sesame seeds and products thereof	N	N	N	N
Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO ₂ ."	N	N	N	N



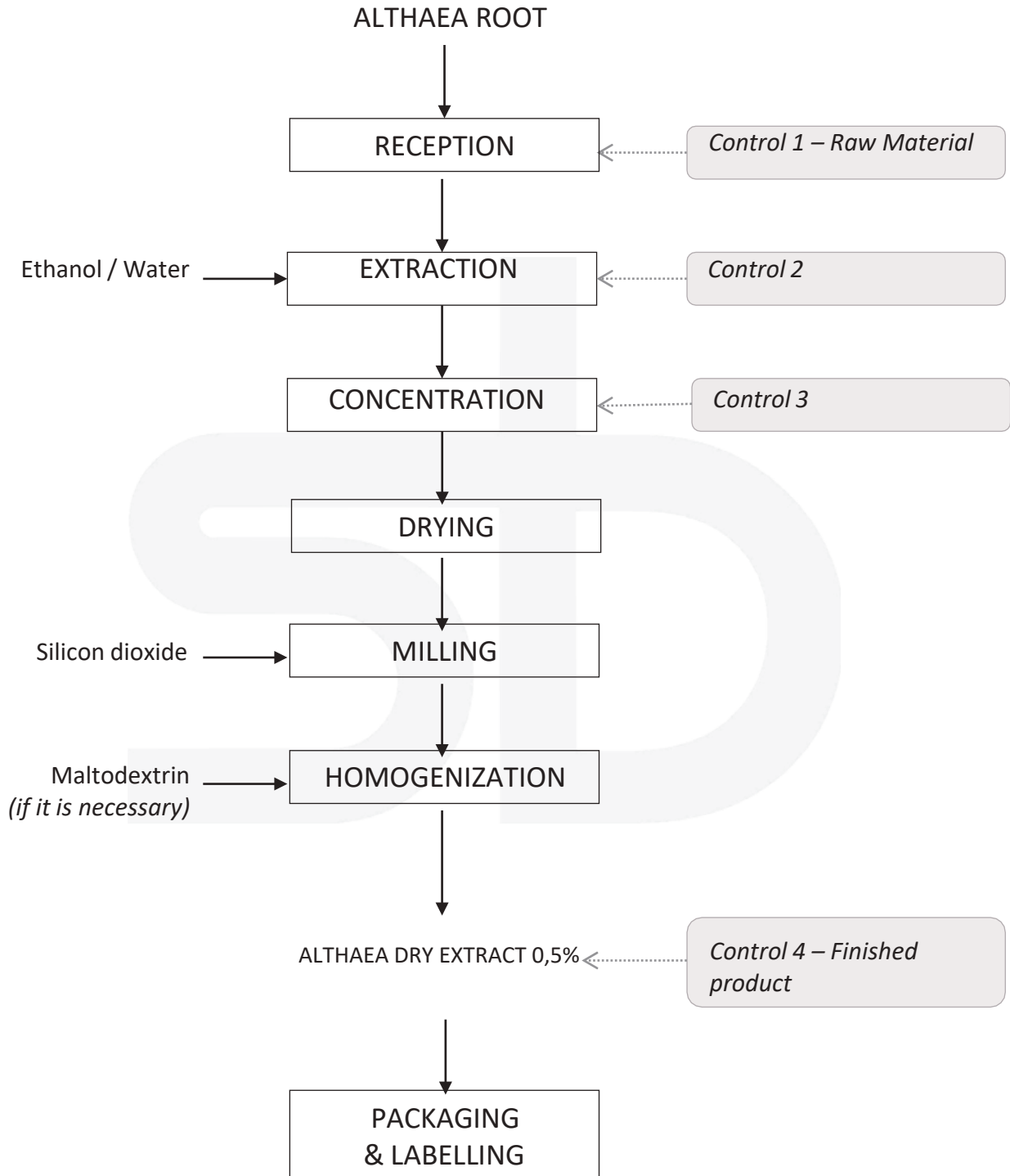
Núria Gómez
 Regulatory Affairs Technician
 SELECT BOTANICAL S.L.
 15th February 2021

SELECT BOTANICAL, S.L. Office: C/Borí i Fontestà, 49 – 08017 Barcelona Telf.: +34 93 3621223 Fax: +34 93 3621224
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**ALTHAEA EXTRACT
Manufacturing Flow Chart**



SELECT BOTANICAL, S.L. Office: C/Borí i Fontestà, 49 – 08017 Barcelona Telf.: +34 93 3621223 Fax: +34 93 3621224
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ALTHAEA EXTRACT 0,5% POLYPHENOLS

Revision 01.2022 // March 2022

MATERIAL SAFETY DATA SHEET ACCORDING TO THE REGULATION 453/2010

ALTHAEA DRY EXTRACTVersion 3 / Page 1 of 7
Revision Date: 08/11/2019
Printing date: 08/11/2019

1. IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY**1.1. Product Identifier:****Common name:** ALTHAEA DRY EXTRACT 0,5%**1.2. Relevant identified uses of the substance or mixture and uses advised against:****Use of the substance:** Pharmaceutical, Food supplement and cosmetic industry**1.3. Details of the supplier of the Safety Data Sheet.****Company name:** SELECT BOTANICAL, S.L.**Company address:** C/ Bori i Fontestà, n° 49
08017 Barcelona-SPAIN**Phone number:** +34 93 362 12 23**Fax number:** +34 93 362 12 24**E-mail:** sb@selectbotanical.com**1.4. Telephone number****Please contact:** + 34 933 621 223**Opening hours:** From 9:00 to 18:00 (CET)
Monday to Friday

2. HAZARDS IDENTIFICATION**2.1. Classification according to Regulation (EC) No 1272/2008**

None, if it is used as the intended purpose.

2.2. Labelling according to Regulation (EC) No 1272/2008 [CLP]

None, if it is used as the intended purpose.

2.3. Other hazards

None, if it is used as the intended purpose.

3. COMPOSITION/INFORMATION ON INGREDIENTS**3.1. Substance**

Not applicable

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ALTHAEA DRY EXTRACT

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3.2. Mixtures

SUBSTANCE NAME	CAS No	EC No	Classification acc. to EC regulation 1272/2008 (CLP)
ALTHAEA OFFICINALIS ROOT EXTRACT	73049-65-7	277-254-6	Not classified
MALTODEXTRIN	9050-36-6	232-940-4	Not classified
SILICON DIOXIDE	112945-53-5 7631-86-9	231-545-4	Not classified

Additional information

Full text of hazards statements, see section 16.

4. FIRST AID MEASURES
4.1. Description of First aid Measures
General information:

In case of adverse health effects seek medical advice.

Following inhalation:

After prolonged or massive inhalation of the powder, remove from the exposure to fresh air. Get medical attention for any breathing difficulty.

Following skin contact:

Rinse with running water.

Following eye contact:

Rinse immediately with plenty of running water (for 10 minutes).Get medical attention, it is necessary.

Following ingestion:

After massive ingestion, rinse the mouth. Drink 1-2 glasses of water, and get medical attention, it is necessary.

4.2. Most important symptoms and effects, both acute and delayed

No data available

4.3. Indication of any immediate medical attention and special treatment needed

No data available

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ALTHAEA DRY EXTRACTVersion 3 / Page 3 of 7
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5. FIRE-FIGHTING MEASURES:**5.1. Extinguishing media:**Water spray jet.
Extinguishing powder**5.2. Special hazards arising from the substance**

Carbon monoxide may be formed during combustion.

5.3. Advice for fire-fighters

Special protective equipment for firefighter: Wear self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES**6.1. Personal precautions, protective equipment and emergency procedures**

Avoid dust formation.

6.2. Environmental precautions

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

6.3. Methods and material for containment and cleaning up

Remove mechanically.

6.4. Reference to other sections

Personal protection equipment: see section 8

7. HANDLING AND STORAGE**7.1. Precaution for safe handling:**Minimize dust formation and accumulation.
Use adequate ventilation.
Avoid open flames and sources of ignition**7.2. Conditions for safe storage, including any incompatibilities**Store in a tightly sealed container
Store in a cool, dry well-ventilated place in closed original container at recommended temperature < 30°C and away from heat and direct sun light**7.3. Specific end use(s)**Pharmaceutical, Food supplements and cosmetic industry

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ALTHAEA DRY EXTRACT

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

No data available

8.2. Exposure controls

Additional information for systems design:

Ensure good ventilation/suction at the workplace

Respiratory protection:

Use precaution to avoid inhalation.

In absence of suitable containment facilities, a dust mask should be worn when handling small quantities of material. For larger quantities, a dust respirator is recommended.

Hand protection:

Wear protective gloves.

Eye protection:

Wear safety glasses.

General protection and hygiene measures

Immediately remove soiled or soaked clothing

Wash hands before work breaks and after finishing work

Do not eat, drink or smoke while working

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state: Solid

Appearance: Powder

Odour: Characteristic

Colour: Brown powder

9.2. Other information

Non available

10. STABILITY AND REACTIVITY

10.1. Reactivity:

This product presents no significant reactivity hazard.

10.2. Chemical Stability

No data available

MATERIAL SAFETY DATA SHEET ACCORDING TO THE REGULATION 453/2010

ALTHAEA DRY EXTRACTVersion 3 / Page 5 of 7
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10.3. Possibility of hazardous reactions

This product presents no significant reactivity hazard.

10.4. Conditions to avoid

Avoid temperatures over 30°C, open flames and sources of ignition. Keep away from heat and direct sun light.

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

Carbon monoxide may be formed during combustion

11. TOXICOLOGICAL INFORMATION**11.1. Information on toxicological effects****General toxicological information**

No data available

12. ECOLOGICAL INFORMATION**12.1. Toxicity**

No data available

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

No data available

12.6. Other adverse effects

No data available

MATERIAL SAFETY DATA SHEET ACCORDING TO THE REGULATION 453/2010**ALTHAEA DRY EXTRACT**Version 3 / Page 6 of 7
Revision Date: 08/11/2019
Printing date: 08/11/2019**13. DISPOSAL CONSIDERATIONS****13.1. Waste treatment methods****Product disposal:**

Collection and delivery to recycling enterprise or other official elimination institution.

Package disposal:

Disposal must be made according to official regulations

14. TRANSPORT INFORMATION**14.1. UN number**RID: Not relevant
ADR: Not relevant
IMDG: Not relevant
ICAO-TI/IATA-DGR: Not relevant**14.2. UN proper shipping name**RID: Not relevant
ADR: Not relevant
IMDG: Not relevant
ICAO-TI/IATA-DGR: Not relevant**14.3. Transport hazard class**RID: Not relevant
ADR: Not relevant
IMDG: Not relevant
ICAO-TI/IATA-DGR: Not relevant**14.4. Packing group**RID: Not relevant
ADR: Not relevant
IMDG: Not relevant
ICAO-TI/IATA-DGR: Not relevant**14.5. Environmental hazards**RID: Not relevant
ADR: Not relevant
IMDG: Not relevant
ICAO-TI/IATA-DGR: Not relevant

MATERIAL SAFETY DATA SHEET ACCORDING TO THE REGULATION 453/2010

ALTHAEA DRY EXTRACTVersion 3 / Page 7 of 7
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14.6. Special precautions for user

Not hazardous according to RID/ADR, GGVS/GGVE, ADNR, IMDG, ICAO-TI/IATA-DGR.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC CodeNot applicable

15. REGULATORY INFORMATION**15.1. Safety, health and environmental regulations/legislation specific for the substance**

EU Regulations:

- Contains no substances with annex XVII restrictions
- Contains no substances on the REACH Candidate list
- Contains no REACH Annex XIV substances

15.2. Chemical safety assessmentA chemical safety assessment has not been carried out for the mixture

16. OTHER INFORMATION

This MSDS was revised according to Regulation (EC) No 1272/2008.

The information contained herein is based on the current state of knowledge and describes the product from the standpoint of appropriate precautions for use, handling, transport and storage. There is no guarantee of product properties.

SELECT BOTANICAL expressly disclaims any responsibility for the marketing of the product and/or use with respect to the information. This information above is believed to be accurate and represents the best information currently available to us.

The conditions of use are beyond the scope of SELECT BOTANICAL. The user is responsible for verifying the data on the present MSDS and determining whether the product is suitable for your particular purpose and assume all risk of use, handling and disposal of waste.

This information relates only to the product and does not relate to the combinations that can be made from this or processes that can be included.

STATEMENT SUMMARY

We, Select Botanical, hereby declare that **ALTHAEA EXTRACT 0,5% POLYPHENOLS** is manufactured in accordance with the following guidelines:

- Botanical source: *Althaea Officinalis L.*
- Country of Origin of Botanical source (Biomass): Europe
- Country of Origin of Product: Spain
- No animal derived products have been used in the manufacture of the above material. The above product does not enter in contact with animal derived material. For this reason, the above product is free from components which can cause Bovine Spongiform Encephalopathy (BSE) or Transmissible Spongiform Encephalopathy (TSE).
- The above material has not been genetically modified or exposed to genetically modified organisms during the production process and is therefore GMO free (EU Reg. 1829/2003 & 1830/2003).
- Only the following organic solvents are used in the manufacturing process: Ethanol
- The above material complies with the pesticides limits set forth by USP<561>
- The above material complies with the California Proposition 65 and is safe for human consumption.
- The above material complies with Aflatoxin limits fixed by USP.
- The above material and its constituents are naturally free of products containing gluten.
- The above material and its constituents is free of Melamine and PCB's.
- This material has not been tested on animals.
- This material is suitable for vegetarian and vegan consumption.
- The product does not contain any ingredient specified in Annex II of Allergen Regulation (UE) n°1169/2011: wheat, rye, barley, oat, spelt, kamut, crustacean, egg, fish, peanut, soybean, milk, nuts (almonds, hazelnuts, walnuts, cashew, pecan nuts, brazil nuts, pistachio nuts, macadamia), celery, mustard, sesame seeds, lupin, molluscs and products made thereof.
- The above material has not been irradiated per 7 CFR 205.105(f) requirements with understanding that "irradiation" shall be defined as outlined in 21 CFR 179.26.
- The above material and its raw material has not been treated with ethylene oxide (ETO) or any other chemical sterilization agent.
- At no point in the process is the above extract derived from, produced using, or handled with sewage sludge, as defined in 7 CFR 205.105(g).
- The above material neither contains nor comes in contact with banned substances listed by NSF, NFL, and WADA.
- The above material is Kosher certified, and meets Sharia dictates although not Halal certified.
- The above material has been affirmed as GRAS by FDA (21 CFR 172.510).

The **Althaea Extract 0,5% Polyphenols** is composed by the following:

- Native extract: 50-80%
- Maltodextrine: 20-50% with following characteristics: Corn, Food Grade, European origin.
- Silicon Dioxide: 0-2% with following characteristics: Food Grade, European origin.

Typical nutritional data for the above material are as follows:

PARAMETER	RESULT	UNITS
Energy	43	kCal/100g
Protein	<15	%
Fat content	<6	%
Carbohydrates	<85	%

ALTHAEA EXTRACT 0,5% POLYPHENOLS

Shelf-life: 3 years.

Storage Conditions: Keep container tightly sealed and store in a dry place in closed original container.



Pilar Alonso Sanchez
Head of Quality Assurance
Select Botanical
19.03.2022

Exclusive Distribution by:

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