

# **CERTIFICATE OF ANALYSIS**

PRODUCT NAME : STEARIC ACID BP POWDER - PRODUCT SYNONYM : STEARIC ACID 1843 POWDER

BATCH NUMBER : 4414101

BEST BEFORE : NOVEMBER 2023

MANUFACTURING SITE: LIPIDCHEM

TEST	UNIT	SPECIFICATION	RESULT
Freezing Point (Id A)	°C	54 - 56	55.8
Iodine Value	gl2/100g	1.0 max	0.31
Acid Value (Id B)	mg KOH/g	206 - 210	208.40
Colour Lovibond	Yellow 5.25"	5.0 max	0.7
Colour Lovibond	Red 5.25"	0.5 max	0.1
Water Content	%	0.2 max	0.04
Composition C18	%	40 - 60	45.11
Composition C16+C18	%	90 min	99.51
Identification C		Complies with monograph	Complies
Appearance		$Y_7$ or $BY_7$	< Y <sub>7</sub>
Appearance at 20 °C		Complies	Complies
Acidity		Complies with monograph	Complies
Nickel	ppm	1.0 max	Not detected (<0.02)
Heavy Metal as Pb	ppm	10 max	Not detected (<0.02)
Arsenic *	ppm	3.0 max	Not detected (<0.05)
Lead *	ppm	1.0 max	Not detected (<0.02)
Mercury *	ppm	0.1 max	Not detected (<0.02)
Cadmium *	ppm	1.0 max	Not detected (<0.02)
Unsaponifiable Matter *	%	1.5 max	0.3
Residue on Ignition	%	0.1 max	<0.01
Residual Solvent (5.4)		Complies	Complies
Solubility		Practically insoluble in water; soluble in ethanol (96%) and in light petroleum.	Complies

Note:

Parameter mark with (\*) shall be tested and reported quarterly.

Material Tested according to Ph Eur 1474.

Material complies with Stearic Acid 50 Ph Eur 1474 & E 570 according to EU 231/2012



Date: Feb 20, 2020

Our Ref: LSB/2K20-02/MKR-UK/SA50P/517

Product Name: STEARIC ACID POWDER
Product Synonym: STEARIC ACID BP POWDER

# 1) PESTICIDE / FUNGICIDE / MYCOTOXIN / DIOXIN / NANOMATERIALS

To the best of our knowledge based on our understanding of the process and raw materials, our Stearic Acid Powder does not contain Pesticides, Fungicide, Mycotoxin, Dioxin and Nanomaterials. Thus, we would not expect any of these materials to be present in our product.

## 2) BSE/TSE FREE CERTIFICATION

The Stearic Acid Powder is a non-animal sourced material. It is made from raw material of vegetable origin (Palm Oil or Elaeis Guineensis) and does not contact with any animal source material during processing. We hereby certify our Stearic Acid Powder is completely BSE/TSE Free.

#### 3) LATEX STATEMENT

We hereby certify that the Steric Acid Powder we manufacture does not contain Latex as ingredient or come into contact during manufacturing process.

# 4) PROP 65 STATEMENT

The Stearic Acid Powder does not contain any hazardous materials listed in the California Proposition 65.

## 5) RESIDUAL SOLVENT STATEMENT

The Stearic Acid Powder manufacturing and/or cleaning processes do not involve any class 1, 2 or 3 solvents as ingredient or come into contact during processing. Therefore, we certify that the Stearic Acid Powder is free from any solvents and its residue.

Stearic acid powder statement

# 6) GMP STATEMENT ON MANUFACTURING

The manufacturer certifies that the methods used in and the facilities and controls used for the manufacture, processing, packaging and holding of the product are according to the current Good Manufacturing Practices.

## 7) DMF FILED

Our Stearic Acids C1843 & C1890 are filed with FDA under type IV US DMF No. 23613.

# 8) AFLATOXIN & DIOXIN STATEMENT

Based on our best knowledge of manufacturing and handling raw materials and finished products, the Stearic Acid Powder does not contain aflatoxins and dioxin. Thus, we would not expect any of these materials to be present in our product.

## 9) GMO STATEMENT

Based on our best knowledge the Stearic Acid Powder is none genetically modified organisms nor does it contain any genetically modified organisms.

## 10) ALLERGEN STATEMENT

The Stearic Acid Powder does not contain any of the following allergens under EU Directive 2003/89/EC and amendments: Cereals Containing Gluten and its Products, Eggs and its Products, Fish and its Products, Crustaceans and its Products, Peanuts and its Products, Any Type of Nut and its Products, Soybeans and its Products, Milk and its Products, Celery and its Products, Mustard and its Products, Sesame and its Products.

# 11) MELAMINE STATEMENT

Based on our best knowledge of manufacturing and handling raw materials and finished products, we do not use or add any Melamine in our process. Therefore, we certify that our Stearic Acid Powder is free from Melamine.

Stearic acid powder statement

# 12) NON-IRRIDATED & NON-ETO MATERIAL STATEMENT

We hereby declare that the Stearic Acid Powder produced by us has never been irradiated, or treated with ETO (Ethylene Oxide), and never exposed to radioactive or high frequency electrical charge.

# 13) SHELF LIFE

Expiration period is 2 years from the manufactured date. The product should be stored at room temperature and under shade.

It is certified that the above information is correct.

Stearic acid powder statement



STEARIC ACID BP POWDER RSPO MB

Page: 1

Compilation date: 12/11/2008

**Revision date:** 09/05/2018

Revision No: 3

## Section 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product name: STEARIC ACID BP POWDER RSPO MB

REACH registered number(s): NOT REACH REGISTERED - EXEMPTION APPLIES FOR CERTAIN APPLICATIONS

CAS number: 67701-03-5 EINECS number: 266-928-5 Product code: WAXSTEA

Synonyms: STEARIC ACID AND PALMITIC ACID

OCTADECANOIC ACID AND HEXADECANOIC ACID

STEARIC ACID 1843 POWDER

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of substance / mixture: From 01/06/2018, only REACH exempt uses permitted (food, pharmaceutical, feed and

flavour)

## 1.3. Details of the supplier of the safety data sheet

Company name: MADAR Corporation Limited

19-20 Sandleheath Industrial Estate

Fordingbridge Hampshire SP6 1PA

**Tel:** +44 (0)1425 655555

Email: sales@madarcorporation.co.uk

## 1.4. Emergency telephone number

Emergency tel: +44 (0) 1425 655555

(office hours only)

# **Section 2: Hazards identification**

#### 2.1. Classification of the substance or mixture

Classification under CLP: This product has no classification under CLP.

#### 2.2. Label elements

Label elements: This product has no label elements.

## STEARIC ACID BP POWDER RSPO MB

Page: 2

#### 2.3. Other hazards

Other hazards: Combustible. In use, may form flammable / explosive dust-air mixture.

PBT: This product is not identified as a PBT/vPvB substance.

#### Section 3: Composition/information on ingredients

#### 3.1. Substances

Chemical identity: STEARIC ACID BP POWDER RSPO MB

**CAS number:** 67701-03-5 **EINECS number:** 266-928-5

REACH registered number(s): NOT REACH REGISTERED - EXEMPTION APPLIES FOR CERTAIN APPLICATIONS

Contains: Stearic Acid and Palmitic Acid

#### Section 4: First aid measures

#### 4.1. Description of first aid measures

**Skin contact:** Wash immediately with plenty of soap and water. **Eye contact:** Bathe the eye with running water for 15 minutes.

Ingestion: Wash out mouth with water.

Inhalation: Consult a doctor.

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

**Skin contact:** There may be mild irritation at the site of contact.

**Eye contact:** There may be irritation and redness. **Ingestion:** There may be irritation of the throat.

Inhalation: There may be irritation of the throat with a feeling of tightness in the chest.

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

Immediate / special treatment: Not applicable.

#### Section 5: Fire-fighting measures

# 5.1. Extinguishing media

Extinguishing media: Suitable extinguishing media for the surrounding fire should be used.

#### 5.2. Special hazards arising from the substance or mixture

Exposure hazards: In combustion emits toxic fumes. May form flammable / explosive dust-air mixture.

# 5.3. Advice for fire-fighters

Advice for fire-fighters: Wear self-contained breathing apparatus. Wear protective clothing to prevent contact

with skin and eyes.

# Section 6: Accidental release measures

## STEARIC ACID BP POWDER RSPO MB

Page: 3

## 6.1. Personal precautions, protective equipment and emergency procedures

**Personal precautions:** Refer to section 8 of SDS for personal protection details.

#### 6.2. Environmental precautions

Environmental precautions: Do not discharge into drains or rivers.

#### 6.3. Methods and material for containment and cleaning up

Clean-up procedures: Wash the spillage site with large amounts of water.

#### 6.4. Reference to other sections

Reference to other sections: Refer to section 8 of SDS.

#### Section 7: Handling and storage

#### 7.1. Precautions for safe handling

**Handling requirements:** Avoid the formation or spread of dust in the air.

#### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Store in a cool, well ventilated area.

Suitable packaging: In bulk liquid store at about 5-10 deg C above melting point. Temperature higher than

necessary degrades quality at rates dependent on time and temperature.

# 7.3. Specific end use(s)

Specific end use(s): No data available.

# Section 8: Exposure controls/personal protection

#### 8.1. Control parameters

Workplace exposure limits: No data available.

#### **DNEL/PNEC Values**

**DNEL / PNEC** No data available.

## 8.2. Exposure controls

**Engineering measures:** Ensure there is sufficient ventilation of the area. **Respiratory protection:** Respiratory protective device with particle filter.

Hand protection: Protective gloves.

Eye protection: Safety glasses. Ensure eye bath is to hand.

**Skin protection:** Protective clothing.

#### Section 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

State: Powder Colour: White

Odour: Barely perceptible odour

## STEARIC ACID BP POWDER RSPO MB

Page: 4

Evaporation rate: Negligible

Oxidising: Non-oxidising (by EC criteria)

Solubility in water: Insoluble

Also soluble in: Most organic solvents.

Boiling point/range°C: >300 Melting point/range°C: 55-60

Flash point°C: >200 Autoflammability°C: >300

9.2. Other information

Other information: No data available.

#### Section 10: Stability and reactivity

## 10.1. Reactivity

**Reactivity:** Stable under recommended transport or storage conditions.

#### 10.2. Chemical stability

Chemical stability: Stable under normal conditions.

## 10.3. Possibility of hazardous reactions

Hazardous reactions: Hazardous reactions will not occur under normal transport or storage conditions.

Decomposition may occur on exposure to conditions or materials listed below.

#### 10.4. Conditions to avoid

Conditions to avoid: Heat.

# 10.5. Incompatible materials

Materials to avoid: Strong oxidising agents. Strong acids.

## 10.6. Hazardous decomposition products

Haz. decomp. products: In combustion emits toxic fumes.

## **Section 11: Toxicological information**

#### 11.1. Information on toxicological effects

## **Toxicity values:**

Route	Species	Test	Value	Units
ORL	RAT	LD50	>10000	mg/kg

#### **Excluded hazards for substance:**

Hazard	Route	Basis
Acute toxicity (ac. tox. 4)	-	No hazard: calculated
Acute toxicity (ac. tox. 3)	-	No hazard: calculated

## STEARIC ACID BP POWDER RSPO MB

Page: 5

Acute toxicity (ac. tox. 2)	-	No hazard: calculated
Acute toxicity (ac. tox. 1)	-	No hazard: calculated
Skin corrosion/irritation	-	No hazard: calculated
Serious eye damage/irritation	-	No hazard: calculated
Respiratory/skin sensitisation	-	No hazard: calculated
Germ cell mutagenicity	-	No hazard: calculated
Carcinogenicity	-	No hazard: calculated
Reproductive toxicity	-	No hazard: calculated
STOT-single exposure	-	No hazard: calculated
STOT-repeated exposure	-	No hazard: calculated
Aspiration hazard	-	No hazard: calculated

#### Symptoms / routes of exposure

**Skin contact:** There may be mild irritation at the site of contact.

**Eye contact:** There may be irritation and redness. **Ingestion:** There may be irritation of the throat.

**Inhalation:** There may be irritation of the throat with a feeling of tightness in the chest.

#### **Section 12: Ecological information**

## 12.1. Toxicity

Ecotoxicity values: No data available.

#### 12.2. Persistence and degradability

Persistence and degradability: Biodegradable.

# 12.3. Bioaccumulative potential

Bioaccumulative potential: No bioaccumulation potential.

## 12.4. Mobility in soil

Mobility: Non-volatile. Insoluble in water. Floats on water.

#### 12.5. Results of PBT and vPvB assessment

PBT identification: This product is not identified as a PBT/vPvB substance.

# 12.6. Other adverse effects

Other adverse effects: Negligible ecotoxicity.

# Section 13: Disposal considerations

## 13.1. Waste treatment methods

Disposal operations: Transfer to a suitable container and arrange for collection by specialised disposal

company. Deposit into or on to land (e.g. landfill, etc.)

Disposal of packaging: Dispose of as normal industrial waste.

NB: The user's attention is drawn to the possible existence of regional or national

regulations regarding disposal.

## STEARIC ACID BP POWDER RSPO MB

Page: 6

#### **Section 14: Transport information**

Transport class: This product does not require a classification for transport.

#### **Section 15: Regulatory information**

# 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

## 15.2. Chemical Safety Assessment

Chemical safety assessment: A chemical safety assessment has not been carried out for the substance or the mixture

by the supplier.

#### **Section 16: Other information**

#### Other information

Other information: This safety data sheet is prepared in accordance with Commission Regulation (EU) No

2015/830.

\* indicates text in the SDS which has changed since the last revision.

Legal disclaimer: The above information is believed to be correct but does not purport to be all inclusive

and shall be used only as a guide. This company shall not be held liable for any

damage resulting from handling or from contact with the above product.



#### PRODUCT SPECIFICATION

**OLSABPRSPO** 

**Description:** Stearic Acid BP Powder

**RSPO Mass Balance (MB)** 

Issue: 1

Revision No: 0

# **Characteristics**

Freezing Point (Id A)

Iodine Value Acid Value (Id B)

Colour max., Lovibond 51/4" cell

Water (Karl Fischer)

Assay (fatty acid composition):

Composition C18

Composition C16 + C18

Identification C Appearance

Appearance at 20°C

Acidity Nickel

Heavy Metal as Pb

Arsenic Lead Mercury

Unsaponifiable matter Residue on Ignition Organic Volatile Impurities Neutral Fat or Paraffin 54 – 56 °C

0.0 - 1.0 g l<sub>2</sub>/100g

206 – 210 mg KOH/g

5.0Y 0.5R 0.2% max 98% min 40 – 60 % 90% min

Complies with monograph

Y<sub>7</sub> or BY<sub>7</sub> White Powder

Complies with monograph

0.0 - 1.0 ppm 0.0 - 10 ppm 3 mg/kg max 1 mg/kg max 1 mg/kg max 1.5% max 0.0 - 0.1 % Passed Passed

Tests according to Ph Eur 1474. Material complies with Stearic Acid 50 Ph Eur 1474. Material complies with 2008/84/EC E570. 100% Vegetable Origin.

NB: This document nullifies and replaces all previous documents referring to this product.