upsalite®

(C101)

Technical Data Sheet

1. General information

1.1. Manufacturer/supplier

Disruptive Materials Operations AB

Kungsängsvägen 27
SE-753 23 Uppsala, Sweden

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www.disruptivematerials.com

1.2. Product description

1.2.1. Trade name

Upsalite® (C101)

1.2.2. Raw material category

Absorbent, Mattifying agent, Blurring agent, Anti-caking, Texture modifier, Rheology modifier

1.2.3. Substance identification

Product Identifier	CAS No.	INCI Name
Upsalite® C101	n/a	Magnesium Carbonate

1.2.4. Material characterization

Component	Composition	Source
Amorphous Mesoporous Magnesium Carbonate	100%	Chemical Synthesis

1.3. Shelf life and storage conditions

Upsalite® is a hygroscopic material and adsorbs moisture from the atmosphere. Prompt, airtight closing of the packaging after usage is therefore important. Shelf life is >24 months when stored in a dry environment, below 25°C (unopened original packaging).

1.4. Customs tariff number

28369911 (Magnesium carbonate)

2. Information on manufacturing

2.1. Production process

General description of production process:

The material is synthesized by pressurizing a methanol (liquid) suspension of MgO (solid) with CO2(gas) followed by extensive drying to remove organic solvent and generate a dry powder of Amorphous Mesoporous Magnesium Carbonate. The product is not irradiated.

2.2. Source and geographic origin of raw materials

Raw Material	Source	Country of Origin
Magnesium Oxide (MgO)	Produced from natural $MgCl_2$ from sea water	Israel
Carbon Dioxide (CO_2)	Biologically produced from fertilizers and other natural sources derived from vegetable oil	Germany

2.3. Impurities and contaminants

Type	Substance	Limit	Method
Heavy metals	Antimony (Sb) Arsenic (As) Lead (Pb) Cobalt (Co) Chromium (Cr) Nickel (Ni) Cadmium (Cd) Mercury (Hg)	≤ 0.5 mg/kg ≤ 0.5 mg/kg ≤ 0.5 mg/kg ≤ 3.0 mg/kg ≤ 10.0 mg/kg ≤ 5.0 mg/kg ≤ 0.1 mg/kg ≤ 0.1 mg/kg	ICP-MS
Volatile organic compound (VOC)*	Methanol	< 3%	TGA-µGC

*Methanol is a residue from the synthesis process thus, the presence in the material is non-intended and technically unavoidable.

3. Statements and compliance

3.1. Nanomaterial compliance

Upsalite® is not classified as a nanomaterial according to the definition set in Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU) determined by Tier 1 and Tier 2 (confirmatory) analytical methods, as stated in 2011/696/EU. See report 2022-036_IR.

Upsalite® is not classified as a nanomaterial according to the definition set in Article 2.1.k) in the European Parliament and of the Council of 30 November 2009 on cosmetic products (1223/2009/EU).

As Upsalite® is not a nanomaterial, the French Decree 2012-232. February 2012 on the annual declaration on substances at nanoscale in application of article R. 523-4 of the Environment code does not apply.

3.2. Natural origin index

Upsalite® has a Natural Origin Index of 0.99 and as such, are to be considered under the definition as a Derived Mineral according to the definition in ISO 16128-2 2017 (Criteria for ingredients and products).

3.3. Non-animal testing

No animal tests have been conducted or commissioned, in full compliance with the European Cosmetics Regulation (EC) N° 1223/2009, on the raw material Upsalite®. nor on any cosmetic prototype containing Upsalite, or on any other ingredients contained in finished cosmetic products or prototypes containing Upsalite, developed by Disruptive Materials.

3.4. Non-GMO compliance

Upsalite® is produced in the strictest absence of any animal derived material of any type. The item does not contain ingredients that might have been derived from GM sources. Neither proteins nor DNA are present. Consequently, the product will be PCR negative when tested.

3.5. Vegan compliance

Upsalite® is a material containing no products, bi-products or derivates with animal origin. It is therefore considered to be compliant to be used in "Vegan" products.

3.6. No CMR substances

No CMR substances of category 1A, 1B or 2 is present in Upsalite®, and thereby is in full compliance with Article 15 of the Cosmetics Regulation 1223/2009. No CMR substances have been intentionally added, neither is formed during the manufacturing process according to our knowledge of the chemistry.

3.7. No SHVC substances

No SHVC chemical substances is present in Upsalite®, and thereby is in full compliance with the Candidate List of substances of very high concern for Authorization, in accordance with Article 59(10) of the REACH Regulation 1907/2006. No SHVC chemical substances have been intentionally added, neither is formed during the manufacturing process according to our knowledge of the chemistry.

3.8. Allergens

Upsalite® does not contain any of the fragrance allergens regulated in Annex Ill of the regulation EC 1223/2009.

None of the listed fragrance allergens have been intentionally added to the raw materials or are added or formed during the manufacturing process according to our knowledge of the chemistry.

4. Certifications

4.1. COSMOS

Upsalite® (C101) is a raw material verified by ECOCERT GREEN LIFE, compliant with the COSMOS Standard and without animal origin (F363(COS)v09, Issued 02/11/2021).

5. Regional compliance

5.1. Europe

Registration Authority	Reach Registration No.	Status
European Chemicals Agency (ECHA)	01-2120819291-60-0000	Complete

5.2. United States of America

Upsalite® is a compliant raw material for use in cosmetic products in USA, as the Federal Food, Drug, and Cosmetic Act does not require cosmetic ingredients to be approved by FDA before they go on the market.

5.2.1. Proposition 65

Upsalite® is compliant with The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 et seq. Proposition 65.

5.2.2. Mineral hydrocarbons

Upsalite® does not contain any mineral hydrocarbons/white mineral oil and is compliant with FDA CFR172.886 Compliance for Mineral Hydrocarbons.

5.3. China

Trade Name	Ingredient No.	Ingredient Safety Code	Manufacturer No.	Status
Upsalite®	006582	006582-07117-1497	07117	Complete

5.4. Other countries

Currently, Upsalite® is not registered in any other country. However, many countries do not require cosmetic raw materials to be approved by any relevant authority before placing the product on the market.

If Upsalite® is planned to be used in cosmetic products intended to be sold in any other country where registration of cosmetic ingredients is required, please contact Disruptive Materials for further notice.

6. Toxicology and Ecotoxicology

Upsalite® shows no toxicity for human dermal fibroblasts cells up to a concentration of 1000 m/ml and 48 h exposure (external results*).

The viability of Reconstructed human epidermal model is> 50%, according to results obtained from In Vitro EpiDermTM Skin Irritation Test (EPI-200-SIT). Thus, Upsalite® is classified as NI (Not irritant)/not required classification (external results*).

Upsalite® is classified as "non-irritant" wr1en tested in a single use patcr1 test on 20 volunteers, applied as 100% under occlusive conditions (external results*).

A human repeated insult patch test (HRIPT) on 50 volunteers showed no dermal sensitization potential of 100% Upsalite® applied topically on the skin. None (0%) of the 50 volunteers exhibited a slightly irritant reaction, or noticed any erythema, dryness or edema neither before the first application, during the induction period nor after the challenge phase, according to the scale used for the interpretation of the results (external results*).

A comprehensive toxicological risk assessment from external toxicology expert is available upon request. See report 2021-130_IR.

* These studies were performed under GLP and GCP at OACS Ltd laboratory, an external, accredited quality assurance laboratory. See report 2018-0l0_IR.

7. Microbiological status

See report 2020-218_1R

Microorganism	Result
Aerobic bacteria	< 10 CFU*/g
Moulds	< 10 CFU*/g
Yeasts	< 10 CFU*/g
Total Aerobic Microbial Count (TAMC)	< 10 CFU*/g
Total Combined Yeasts and Moulds Count (TYMC)	< 10 CFU*/g

*Colony forming unit