



Safety Data Sheet

107 Technology Drive, Lincolnton, NC 28092 USA

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AC Melatonin Liposome SF

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Date: 10 / 20 / 2022

Version: 4

Cancels and replaces version: 3

SECTION 1. IDENTIFICATION

Product Name/Identifier	AC Melatonin Liposome SF
Product Code	61012
Recommended Use	Topical Cosmetic Use
Restrictions on Use	Refer to the detailed list of labeling/restrictions (Section 15 Regulatory Information)
Supplier/Manufacturing Site	Active Concepts, LLC
Address	107 Technology Drive Lincolnton, NC 28092, USA
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SECTION 2. HAZARD(S) IDENTIFICATION

Classification:

GHS / CLP

Basis for Classification: Based on present data no classification and labeling is required according to GHS, taking into account the national implementation (United Nations version 2011)

USA

OSHA Regulatory Status: This material is non-hazardous as defined by the American OSHA Hazard Communication Standard (29 CFR 1910.1200).

Europe

Basis for Classification: -According to present data no classification and labeling is required according to Reg. (EC) No 1272/2008.
-This product is not classified as hazardous to health or environment according to the CLP regulation.

Labeling Elements:

Pictograph: No hazard symbol expected

Hazard statements/Signal Word: Not applicable

Precautionary statements: P233: Keep container tightly closed
P281: Use personal protective equipment as required
P402: Store in a dry place
P404: Store in a closed container
P410: Protect from sunlight
P411: Store at temperatures not exceeding 32°C

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Other hazards which do not result in classification:

No particular fire or explosion hazard.

By mechanical effect: No particular hazards.

By hygroscopic effect: No particular hazards.

US NFPA 704 (National Fire Protection Association) Hazard Rating System:

Health hazard: Rating 0; Normal Material

Flammability: Rating 0, Will Not Burn

Reactivity: Rating 0, Stable

Other Hazard Information: None

Results of PBT and vPvB assessment:

-PBT: Not applicable

-vPvB: Not applicable

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS

Common Chemical Name: Water & Phospholipids & Melatonin

Generic name:

Chemical Family: Liposome

Description: Mixture: consisting of the following components. This section describes all components of the mixture

<u>Substance</u>	<u>CAS Numbers</u>	<u>EC Numbers</u>	<u>Percentage</u>
Water	7732-18-5	231-791-2	89.00%
Phospholipids	123465-35-0	N/A	5.00%
Melatonin	73-31-4	200-797-7	4.00%
Lactobacillus Ferment	68333-16-4 (or) 1686112-36-6	N/A (or) N/A	2.00%

Formula: Not applicable

SECTION 4. FIRST-AID MEASURES

General: In all cases of doubt, or when symptoms persist, seek medical attention.

Inhalation: Move to fresh air from exposure area. Get medical attention for any breathing difficulty.

Skin contact: Rinse with soap and water. Get medical advice if irritation develops.

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Eye contact: Immediately rinse with plenty of water for at least 15 minutes, while keeping the eyes wide open. Consult with a physician.

Ingestion: Consult with a physician.

Protection of first-aiders: No special protection required.

SECTION 5. FIRE-FIGHTING MEASURES

Fire and explosion hazards: Not considered to be a fire and explosion hazard

Extinguishing media:

Suitable: Water, dry chemicals, foam and carbon dioxide
Not suitable: None known

Fire fighting: Move container from fire area if it can be done without risk. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low area

Protection for fire-fighters: Boots, gloves, goggles.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Avoid contact with eyes.
Personal Protective Equipment:
-Protective goggles

Environmental precautions: Prevent entry into sewers and waterways. Do not allow material to contaminate ground water system

Methods for cleaning up:

Recovery: Pick up free liquid for recycling or disposal. Residual liquid can be absorbed on an inert material. Sweep or vacuum up any powder and place in a clearly labeled waste container, avoiding dust formation.

Cleaning/Decontamination: Wash non-recoverable remainder with water.

Disposal: For disposal of residues refer to sections 8 & 13.

SECTION 7. HANDLING AND STORAGE

Handling

Technical measures: Labeling: Keep out of the reach of children.
Measures: For industrial use, only as directed.
Safe handling advice: Wash hands after use. Avoid storage near feed or food stuff.

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Storage

Technical measures: Keep container closed.
Recommended Storage Conditions: Store in a dry place at temperatures not exceeding 32°C. Based on stability studies, the optimum storage temperature for maximization of shelf life is 23 - 25°C. However, it may be stored at temperatures between 16 and 32°C if such specific temperature control is not available. Do not freeze. Please refer to stability data for effects heat or cold may have on the specifications of the product.
Incompatible products: Avoid contact with strong oxidizers. Refer to the detailed list of incompatible materials (Section 10 Stability/Reactivity)
Packaging: Product may be packaged in normal commercial packaging.
Packaging materials: Recommended - Polypropylene & High Density Polyethylene

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Precautionary statements: Ensure adequate ventilation

Control parameters

Occupational exposure Limits:

France: Not Determined
ACGIH: Not Determined
Korea: Not Determined
UK: Not Determined

Surveillance procedures: Not Determined
Engineering measures: Not Determined

Personal Protective Equipment:

Respiratory protection: Local exhaust
Hand protection: Protective gloves made of rubber or neoprene.
Eye protection: Safety glasses.
Collective emergency equipment: Eye fountain.
Skin and Body Protection: Suitable protective clothing
Hygiene measures: Handle in accordance with good industrial hygiene and safety practice.

Measures related to the Environment: No particular measures.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Liquid liposomal dispersion
Color: Yellow to amber

Odor: Characteristic

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pH:	4.0 – 6.5
Particle Size:	< 300 nm
Heavy Metals:	< 20 ppm
Lead:	< 10 ppm
Arsenic:	< 2 ppm
Cadmium:	< 1 ppm
Microbial Content:	< 100 CFU/g; No pathogens
Yeast & Mold:	< 100 CFU/g
Gram Negative Bacteria:	0 CFU/g
Specific Gravity:	Not determined
Vapor density:	Not applicable
Boiling Point:	Not determined
Freezing Point:	Not determined
Melting point:	Not applicable
Flash point:	> 200°F
Oxidizing properties:	Non oxidizing material according to EC criteria.
Solubility:	
In water:	Dispersible
In organic solvents:	Not determined
Log P:	Not determined

SECTION 10. STABILITY AND REACTIVITY

Stability:	Stable under ordinary conditions of use and storage up to one year then re-test to full product specifications to extend shelf life
Hazardous reactions:	None known
Conditions to avoid:	No dangerous reactions known under use of normal conditions. Avoid extreme heat.
Materials to avoid:	No dangerous reaction known with common products.
Hazardous decomposition products:	None known

SECTION 11. TOXICOLOGICAL INFORMATION

Ingestion:	Not Determined
Dermal:	Non-Irritant (Dermal Irritation Model)
Ocular:	Non-Irritant (Ocular Irritation Model)
Inhalation:	Not Determined

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Acute toxicity data:	Non-Irritant, Non-Primary Sensitizer & Non-Photo Irritant
Sensitization:	Non-Primary Irritant & Non-Primary Sensitizers; Will not cause allergic contact dermatitis (In Chemico Skin Sensitization Direct Peptide Reactivity Assay & In Vitro Skin Sensitization ARE-Nrf2 Luciferase Test Method)
Repeated dose toxicity:	No known effects
Subacute to chronic toxicity:	Not Determined
Mutagenicity:	Non-Mutagenic (OECD471/ISO10993.Part 3 – Genotoxicity: Bacterial Reverse Mutation Test)

Additional Toxicological Information: This product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

Specific effects:	
Carcinogenicity:	No known effects
Mutagenicity:	No known effects
Reproductive toxicity:	No known effects
Neuro-toxicity:	No known effects

For more information: Does not present any particular risk on handling under normal conditions of good occupational hygiene practice.

This product has not been tested for the following:

- Primary cutaneous and corrosive irritation
- Acute oral toxicity

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Effects on the aquatic environment: EC₁₀ (Freshwater Alga): 137.16 mg/L - Not harmful to aquatic organisms
EC₂₀ (Freshwater Alga): 229.11 mg/L - Not harmful to aquatic organisms

Biodegradability:

Persistence: Readily Biodegradable (89.7% biodegradation after 28 days of testing)

Bioaccumulation:

Octanol / water partition coefficient: Not Determined

Mobility:

Precipitation:
Expected behavior of the product: Ultimate destination of the product: Soil & sediment.

Other Adverse Effects: None known

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SECTION 13. DISPOSAL CONSIDERATIONS

Residues from product

Prohibition: Do not allow the product to be released into the Environment.
Destruction/Disposal: Dispose of in accordance with relevant local regulations

Contaminated packaging

Decontamination/cleaning: Cleaning is not required prior to disposal.
Destruction/Disposal:

Note: Take all necessary precautions when disposing of this product according to local regulations.

SECTION 14. TRANSPORT INFORMATION

UN Number: None
UN Shipping Name: None

Transport Hazard Class: Not classified as dangerous for transport

Land (rail/road): Material is not restrictive for land transport and is not regulated by ADR/RID
Sea: Material is not restrictive for sea transport and is not regulated by IMO/IMDG
Air: Material is not restrictive for air transport and is not regulated by ICAO/IATA

Marine Pollutant: No

Transport/Additional Information: Not regulated for US DOT Transport in non-bulk containers
This material is not dangerous or hazardous

Special Precautions for User: None known

The above regulatory prescriptions are those valid on the date of publication of this sheet. However, given the possible evolution of transport regulations for hazardous materials and in the event of the MSDS in your possession dating back more than 12 months, it is advisable to check their validity with your sales office.

SECTION 15. REGULATORY INFORMATION

Labeling/Restrictions:
EC regulations: This product does not need to be labeled in accordance with EC Directives or respective national laws

Japanese regulations:
Restrictions: Hormones and it's derivatives (i.e. Melatonin) is listed on Japan's List of Substances Prohibited in Cosmetic Products

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Further regulations

United Kingdom: Handle in accordance with relevant British regulation: control of substance Hazardous to Health Regulations Environmental Hygiene Guidance: EH40
Workplace Exposure Limits (revised annually)

Korea regulations: Industrial safety and hygiene regulation: No
Hazardous material control regulation: No
Fire prevention regulation: No

Other regulations:

EINECS inventory status: Aqua: 231-791-2
Phospholipids: N/A
Melatonin: 200-797-7
Lactobacillus Ferment: N/A (or) N/A

TSCA inventory status: Exempt

AICS inventory status: Not Listed: 1686112-36-6
Listed: 7732-18-5 & 123465-35-0 & 73-31-4 & 84775-94-0

Canadian (CEPA DSL) inventory status: Not Listed: Lactobacillus Ferment (1686112-36-6)
Listed as Water (DSL) & Phospholipids (DSL) & Acetamide, N-[2-(5-methoxy-1H-indol-3-yl)ethyl]- (Revised ICL) & Radish, ext. (Revised ICL)

Japan (MITI list): Not Allowed: Melatonin
Listed: Water & Phospholipids & Lactobacillus Ferment

Korea: Water & Phospholipids & Melatonin & Lactobacillus Ferment

China inventory status: Water & Phospholipids & Melatonin & Lactobacillus Ferment

Philippines inventory status: Exempt: Phospholipids (123465-35-0)
Not Listed: Lactobacillus Ferment (68333-16-4 (or) 1686112-36-6)
Listed as Water & Acetamide, N-[2-(5-methoxy-1H-indol-3-yl)ethyl]-

Note: The regulatory information given above only indicates the principal regulations specifically applicable to the products described in this sheet. The user's attention is drawn to the possible existence of additional provision which complete these regulations. Please refer to all applicable international, national and local regulations and provisions

SECTION 16. OTHER INFORMATION

Prohibited uses: For specific uses, food industry, ask the manufacturer for more information.

Last Revision Date: 09/09/2020

Preparation Date: 10/20/2022

MSDS summary of changes - Updated Europe Basis for Classification – Section 2 (Hazards Information), Added Irritation, Acute Toxicity, Sensitization & Mutagenicity Data – Section 11 (Toxicological Information) & Added Ecotoxicity & Biodegradability Data – Section 12 (Ecological Information)

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MSDS summary of changes (Cont.) - Updated Japanese Regulations – Section 15 (Regulatory Information)
- Updated Recovery Methods for Cleaning up – Section 6 (Accidental Release Measures)

The information given is based on our knowledge of this product, at the time of publication in good faith. The attention of the user is drawn to the possible risks incurred by using the product for any other purpose other than which it was intended. This is not in any way excuse the user from knowing and applying all the regulations governing their activity. It is sole responsibility of the user to take all precautions required in handling the product. The purpose of mandatory regulation mentioned is to help the user to fulfill his obligations regarding the use of products. This information is not exhaustive, this is not exonerate the user from ensuring that legal obligations other than those mentioned, relating to the use and storage.

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