

AC Melatonin Liposome SF Certificate of Compliance

Code: 61012
INCI Name: Water & Phospholipids & Melatonin
INCI Status: Conforms
CAS #: 7732-18-5 & 123465-35-0 & 73-31-4
EINECS #: 231-791-2 & N/A & 200-797-7
China NMPA #: N/A

Below is a list of processing aids used, but not declared on the ingredient label:

INCI Name	CAS#	EINECS#	Percentage (%)	Function
Lactobacillus Ferment	68333-16-4 (or) 1686112-36-6	N/A (or) N/A	2.00%	Natural Antimicrobial

The following information on regulatory clearances is believed to be accurate and is given in good faith as a guide to a global use of our ingredients in cosmetic applications. No representation or warranty as to its competences or accuracy is made. Information is offered for use in general cosmetic applications and may vary in particular applications. Users are responsible for determining the suitability of these products for their own particular use. All regulatory decisions should be made on the advice of your regulatory group or legal counsel.

Country / Regulatory Body	Status of Product
EU (CosIng)	Compliant
USA (TSCA)	Compliant
Australia (AICS)	Compliant
Japan (METI)	<u>Restrictions:</u> See page 3 for details Contact Us
Canada (DSL)	<u>Restrictions:</u> See page 3 for details Compliant
China (IECIC)	Compliant
Brazil (ANVISA)	Compliant
Korea (KECI)	Compliant
Philippines (PICCS)	Contact Us
Mexico (COFEPRIS)	Compliant

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Attention must be paid to the use of AC Melatonin Liposome SF in the equivalent of OTC formulations (eg. quasi-drugs in Japan, or therapeutic goods in Australia). Some countries maintain restricted inventories of raw materials that can be used in those applications so more detailed guidance may be required.

AC Melatonin Liposome SF and its components and impurities are in compliance with the rules governing cosmetic products in the European Union (Directive 76/768/ECC & Regulation No. 1223/2009). The recommended use levels for AC Melatonin Liposome SF is 1.00 – 10.00%.

The Nagoya Protocol provides a scheme for the fair and equitable sharing of benefits derived from Genetic Resources. Information regarding the Nagoya Protocol and Access and Benefit Sharing (ABS) is available at <https://www.cbd.int/abs/>. The agreement focusses on wild taxa and excludes most commercially cultivated crops. For the signatories to the agreement, responsibility for Benefit Sharing falls on the entity exporting or extracting the resource from the signatory country. Active Concepts audits its suppliers to conform compliance with the Nagoya Protocol where applicable.

AC Melatonin Liposome SF is considered a non-hazardous material. All significant toxicological routes of absorption have been considered as well as the systemic effects and margin of safety (MoS) based on a no observed adverse effects level (NOAEL). Due to the restriction placed on animal testing of cosmetic raw materials, and Active Concepts, LLC's internal non-animal testing policy, this product was not tested for NOAEL.

AC Melatonin Liposome SF was tested using *in vitro* dermal and ocular irritation models. This product was found to be non-irritating in both models.

To our knowledge the above material is free of CMR (*) substances, as defined according to Regulation (EC) No 1272/2008 and Cosmetic Regulation (EC) No 1223/2009 as amended. Products supported for Personal Care applications will not be classified as CMR (*), as defined by (EC) 1272/2008 on the Classification, Labelling and Packaging of Substances and Mixtures, unless supported by a positive SCCS opinion..

(*) Carcinogenic, Mutagenic, toxic for Reproduction

Active Concepts, LLC certifies that to the best of our knowledge our product does not contain any material listed on California Proposition 65.

As of August 12, 2022, AC Melatonin Liposome SF does not contain any substances present on the so called "candidate list" provided by the European Chemicals Agency (ECHA). We further certify that this material has not been manufactured using any of the species listed in the CITES Appendices as of August 12, 2022.

AC Melatonin Liposome SF is REACH Compliant and free of the following:

- 1,4-Dioxane
- Butylphenyl methylpropional (Lilial)
- Formaldehyde or formaldehyde donors
- Glycol ethers
- Gluten
- Lactose
- Nanoparticles
- Nitrosamines
- Palm oil/palm kernel oil (or derivatives)
- Parabens
- Paraffin/petroleum products
- Phthalates
- Polyethylene glycol (PEG)
- Residual solvents
- Sulfates
- Volatile organic compounds

Raw Component Regulations

Please note that the below are global regulations for the raw materials used to manufacture AC Melatonin Liposome SF and are not for the product itself.

AC Melatonin Liposome SF contains 5.00% Phospholipids & 4.00% Melatonin. See below for a list of regulations:

Phospholipids (Lecithin):

- **USA: Safe as used in rinse-off products; but 15.00% in leave-on products. Should not be used in products where N-nitroso compounds may be formed. Insufficient data to determine safety in products where these ingredients are likely to be inhaled**

*Journal Citation: IJT 20(S1): 21-45, 2001

Melatonin:

- **Japan:** Hormones and its derivatives is listed on Japan's List of Substances Prohibited in Cosmetic Products
- **Australia:** Melatonin (INCI Name); Acetamide, N-[2-(5-methoxy-1H-indol-3-yl)ethyl]- (Chemical Name); can be manufactured or imported into Australia for commercial purposes without notification, if the Australian importer/manufacturer is currently registered. Read about record keeping obligations for importing and manufacturing chemicals under the 'listed introduction' category. This chemical may be subject to other Australian Government and State or Territory Government regulations:
 - <https://www.industrialchemicals.gov.au/chemicals/acetamide-n-2-5-methoxy-1h-indol-3-ylethyl>