

**Code:** 60184  
**INCI Name:** Caprylic/Capric Triglyceride & Phospholipids & Retinol  
**INCI Status:** Conforms  
**CAS #:** 65381-09-1 & 123465-35-0 & 68-26-8  
**EINECS #:** 265-724-3 & N/A & 200-683-7  
**China NMPA #:** 173194-02809-8048

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 <u>Labeling Requirements:</u> Contains Vitamin A – Consider your daily intake before use
USA (TSCA)	Compliant
Australia (AICS)	Compliant
Japan (METI)	Compliant
Canada (DSL)	Compliant
China (IECIC)	Compliant
Brazil (ANVISA)	Compliant
Korea (KECI)	Compliant
Philippines (PICCS)	Compliant
Mexico (COFEPRIS)	Compliant

## AC Retinol Liposome OS

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Attention must be paid to the use of AC Retinol Liposome OS 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 Retinol Liposome OS 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 Retinol Liposome OS 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 Retinol Liposome OS 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 Retinol Liposome OS 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

Retinol (also termed 'vitamin A') can be described in IU. IU is the International Unit which measures biological activity of a compound and may vary from substance to substance. 1 IU of vitamin A is typically equivalent to 0.3 µg retinol or retinol equivalents. So 2,500 IU/g is expected to equate to approximately 750 µg/g Vitamin A or 0.075%.

Developmental and reproductive toxicity: The California EPA's Proposition 65 list identifies all-trans retinoic acid as a developmental toxicant. It also identifies retinol/retinyl esters as developmental toxicants, but only when daily dosages exceed 10,000 international units. The listing notes that retinol/retinyl esters are required and essential for maintenance of normal reproductive function and that the recommended daily level during pregnancy is 8,000 international units. Furthermore, based on information provided by our suppliers, the composition, and manufacturing methods, Active Concepts, LLC, located at 107 Technology Drive, Lincolnton, NC 28092 (USA) certifies that AC Retinol Liposome OS contains less than 0.10% Butylated hydroxyanisole (BHA) and less than 0.35% Butylated hydroxytoluene (BHT).

Active Concepts, LLC certifies that AC Retinol Liposome OS does not contain any materials prohibited by Halal laws.

As of October 26, 2023, AC Retinol Liposome OS 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 October 26, 2023.

## AC Retinol Liposome OS

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AC Retinol Liposome OS is REACH Compliant and free of the following:

- 1,4-Dioxane
- Alkylphenols
- Animal by-products
- Butylphenyl methylpropional (Lilial)
- Endocrine troublemakers
- Formaldehyde or formaldehyde donors
- Glycol ethers
- Gluten
- Lactose
- Nanoparticles
- Nitrosamines
- Nonylphenols
- Palm oil/palm kernel oil (or derivatives)
- Parabens
- Paraffin/petroleum products
- Pesticide residues
- Petrochemicals
- Phenols
- 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 Retinol Liposome OS and are not for the product itself.

AC Retinol Liposome OS contains 80.00% Caprylic/Capric Triglyceride, 10.00% Phospholipids & 10.00% Retinol. See below for a list of regulations:

### Caprylic/Capric Triglyceride:

- **USA: Maximum Authorized Concentration: Safe up to 84.00%**  
\*Journal Citation: JEPT 4(4):105-20, 1980 confirmed 06/01 IJT 22(S1):1-35, 2003

### 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

### Retinol, Retinyl Palmitate & Retinyl Acetate:

- **Europe: Maximum Authorized Concentration:**
  - a) **Annex III to Regulation (EC) No 1223/2009 entry 376**
    1. In body lotions: Up to 0.05% of retinol equivalent
    2. Other leave-on and rinse-off products: Up to 0.30% of retinol equivalent

\*Conditions of use and warnings: For any cosmetic product containing Retinyl, Retinyl Acetate or Retinyl Palmitate, labeling is obligatory: "Contains Vitamin A. Consider your daily intake before use"
- **Scientific Committee on Consumer Safety (SCCS): Maximum Authorized Concentration:**
  - a) In body lotions up to the maximum concentration of 0.05% of retinol equivalent\*

\*The SCCS has estimated that exposure to Vitamin A (retinol, retinyl palmitate and retinyl acetate) via **body lotion** at the maximum concentration of 0.05% may lead to a daily systematic dose of 1,003 IU for an adult. This exposure would constitute up to 20% of the Upper Limit (UL) of 5,000 IU/day of Vitamin A. Therefore, the SCCS considers that the use of Vitamin A in **body lotions per se** is safe.
  - b) In hand/face cream, leave-on (other than body lotions) and rinse-off products up to the concentration of 0.30% of retinol equivalent\*
    - i. Via **hand cream** at the maximum concentration of 0.3% may lead to daily systemic dose of 1,661 IU for an adult. This exposure could constitute up to 33% of the UL of 5,000 IU/day of Vitamin A. Therefore, the SCCS considers that the use of Vitamin A in **hand cream products per se** is safe.
    - ii. Via **face cream** at the maximum concentration of 0.3% may lead to daily systemic dose of 1,185 IU for an adult. This exposure could constitute up to 24% of the UL of 5,000 IU/day of Vitamin A. Therefore, the SCCS considers that the use of Vitamin A in **face cream products per se** is safe.
    - iii. Via **rinse-off products** at the maximum concentration of 0.3% may lead to daily systemic dose of 408 IU for an adult. This exposure could constitute up to 8.8% of the UL of 5,000 IU/day of Vitamin A. Therefore, the SCCS considers that the use of Vitamin A in **rinse-off products per se** is safe.
- **USA: Safe up to 5.00%**  
\*Journal Citation: JACT 6(3):276-320, 1987 confirmed 06/05