

Code: 10414
INCI Name: Euterpe Oleracea Sterols & Linoleic Acid & Oleic Acid & Linolenic Acid
INCI Status: Approved
CAS #: 68990-51-2 & 60-33-3 & 112-80-1 & 463-40-1
EINECS #: 273-605-2 & 200-470-9 & 204-007-1 & 207-334-8
China NMPA #: N/A

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) | Compliant |
| Canada (DSL) | Contact Us |
| China (IECIC) | Contact Us |
| Brazil (ANVISA) | Compliant |
| Korea (KECI) | Compliant |
| Philippines (PICCS) | Compliant |
| Mexico (COFEPRIS) | Compliant |

ABS Acai Sterols EFA

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Attention must be paid to the use of ABS Acai Sterols EFA 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.

ABS Acai Sterols EFA 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 ABS Acai Sterols EFA is 0.50 – 5.00%.

ABS Acai Sterols EFA is in compliance with the standardized set of rules developed and approved by the NPA (Natural Products Association).

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.

ABS Acai Sterols EFA 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.

ABS Acai Sterols EFA 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 ABS Acai Sterols EFA is produced in compliance with the programs/regulations set by the following agencies in the State of California:

- Office of Environmental Health Hazard Assessment (OEHHA)
- California Air Resources Board (CARB)
- South Coast Air Quality Management District (SCAQMD)
- California Safe Cosmetics Act (SB 484)
- California Proposition 65

Active Concepts, LLC certifies that ABS Acai Sterols EFA does not contain any materials prohibited by Halal laws.

As of November 16, 2023, ABS Acai Sterols EFA 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 November 16, 2023.

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ABS Acai Sterols EFA is REACH Compliant and free of the following:

- 1,4-Dioxane
- Asbestos
- Butylphenyl methylpropional (Lilial)
- Formaldehyde or formaldehyde donors
- Glycol ethers
- Gluten
- Lactose
- Microplastics
- Nanoparticles
- Nitrosamines
- Palm oil/palm kernel oil (or derivatives)
- Parabens
- Paraffin/petroleum products
- Per and Polyfluoroalkyl Substances (PFAS)
- Pesticide residues
- Petrochemicals
- Phthalates
- Polyethylene glycol (PEG)
- Residual solvents
- Silicone
- Sulfates
- Talc
- Volatile organic compounds

Raw Component Regulations

Please note that the below are global regulations for the raw materials used to manufacture ABS Acai Sterols EFA and are not for the product itself.

ABS Acai Sterols EFA contains 0.50% Oleic Acid. See below for a list of regulations:

Oleic Acid:

- **USA: Safe up to 50.00%**
*Journal Citation: JACT 6(3):321-401, 1987 confirmed 06/05 IJT 25(S2), 2006