

ACB Bio-Chelate 5

Certificate of Compliance

Code: 20339
INCI Name: Water & Saccharomyces/Zinc Ferment & Saccharomyces/Copper Ferment & Saccharomyces/Magnesium Ferment & Saccharomyces/Iron Ferment & Saccharomyces/Silicon Ferment
INCI Status: Conforms
CAS #: 7732-18-5 & 8013-01-2 & 8013-01-2 & 8013-01-2 & 8013-01-2 & 8013-01-2
EINECS #: 231-791-2 & 232-387-9 & 232-387-9 & 232-387-9 & 232-387-9 & 232-387-9

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

INCI Name	CAS#	EINECS#	Percentage (%)	Function
Propylene Glycol	57-55-6	200-338-0	0.56%	Preservative
Diazolidinyl Urea	78941-02-8	878-928-2	0.30%	Preservative
Methylparaben	99-76-3	202-785-7	0.11%	Preservative
Tetrasodium EDTA	64-02-8	200-573-9	0.10%	Chelating Agent
Propylparaben	94-13-3	202-307-7	0.03%	Preservative

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 at Suggested Use Levels <u>Labeling Requirements:</u> Protect cuticles with grease or oil; Contains formaldehyde <u>Restrictions:</u> Prohibited in aerosol dispensers (sprays); Not to be used on products designed for application on the nappy area of children under 3 years of age
USA (TSCA)	Compliant
Australia (AICS)	Compliant
Japan (METI)	Contact Us
Canada (DSL)	Compliant at Suggested Use Levels <u>Restrictions:</u> Prohibited in aerosol dispensers (sprays)
China (IECIC)	Compliant at Suggested Use Levels <u>Restrictions:</u> Prohibited in aerosol dispensers (sprays)
Brazil (ANVISA)	Compliant at Suggested Use Levels <u>Labeling Requirements:</u> Protect cuticles with wax or oil; Contains formaldehyde <u>Restrictions:</u> Prohibited in aerosol dispensers (sprays)
Korea (KECI)	Compliant at Suggested Use Levels
Philippines (PICCS)	Compliant at Suggested Use Levels <u>Restrictions:</u> Prohibited in aerosol dispensers (sprays) <u>Labeling Requirements:</u> Contains formaldehyde
Mexico (COFEPRIS)	Compliant at Suggested Use Levels <u>Restrictions:</u> Prohibited in aerosol dispensers (sprays); Not for children or infants <u>Labeling Requirements:</u> Contains formaldehyde

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Attention must be paid to the use of ACB Bio-Chelate 5 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.

ACB Bio-Chelate 5 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 ACB Bio-Chelate 5 is 0.50 – 5.00%.

ACB Bio-Chelate 5 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.

ACB Bio-Chelate 5 was tested using *in vitro* dermal and ocular irritation models. This product was found to be non-irritating in both models.

As of June 18, 2012, ACB Bio-Chelate 5 does not contain any substances present on the so called "candidate list" provided by the European Chemicals Agency (ECHA).

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 ACB Bio-Chelate 5 contains Diazolidinyl Urea, which is considered a formaldehyde donor. Formaldehyde is listed on the California Proposition 65 list.

Based on information provided by our supplier, Active Concepts, LLC certifies that Propylene Glycol is free of Diethylene Glycol (DEG) and Ethylene Glycol (EG) up to the threshold limit indicated in the USP 38 monograph (0.10% maximum).

Active Concepts, LLC certifies that ACB Bio-Chelate 5 does not contain any materials prohibited by Halal laws.

ACB Bio-Chelate 5 is REACH Compliant and free of the following:

- Gluten
- Glycol ethers
- Lactose
- Nanoparticles
- Nitrosamines
- Palm oil/palm kernel oil (or derivatives)
- Paraffin
- Phthalates
- Residual solvents
- Sulfates
- Volatile organic compounds

Raw Component Regulations

Please note that the below are global regulations for the raw materials used to manufacture ACB Bio-Chelate 5 and are not for the product itself.

ACB Bio-Chelate 5 contains 10.00% Saccharomyces/Zinc Ferment, 0.56% Propylene Glycol, 0.30% Diazolidinyl Urea, 0.14% Parabens & 0.10% Tetrasodium EDTA. See below for a list of regulations:

Saccharomyces/Zinc Ferment:

- **Europe: Maximum Authorized Concentration in the finished product:** 1.00% Calculated as Zinc

Propylene Glycol:

- **USA: Safe when formulated to be non-irritating**
*Journal Citation: JACT 4(5):223-48, 1985 reopened 12/09 tentative amended report 04/10 available from CIR

Diazolidinyl Urea:

- **Europe: Maximum Authorized Concentration of 0.50%**
*Formaldehyde & Paraformaldehyde: Maximum Authorized Concentration:
a) 0.10% Oral Products
b) 0.20% Other Products
*All finished products containing formaldehyde or substances that release formaldehyde must be labeled with the warning "contains formaldehyde" where the concentration in the finished product exceeds 0.05%.
*Limitations: Prohibited in aerosols
*Conditions of use and warnings which must be printed on the label: Protect cuticles with grease or oil; Contains formaldehyde
- **USA: Safe when used up to 0.50%** (Journal Citation: JACT 9(2):229-45, 1990 confirmed 12/06)
- **Japan: Not all Formaldehyde-donor-type preservatives are permitted in Japan, those that are approved can only be used in rinse-off products, e.g. shampoos**
*Please see the detailed list of allowed formaldehyde donors in Japan prior to use
*Not to be used in leave-on or mucous membrane applications
*Requires warning: Should not be used by infants or by people who are hypersensitive to formaldehyde
- **Canada: Permitted in non-aerosols up to 0.20% as a preservative**
*Nail hardeners containing formaldehyde must be sold with nail shields, directions for use, and a caution regarding sensitization potential
- **China: Maximum Authorized Concentration of 0.50%**
*Formaldehyde and Paraformaldehyde: Maximum Authorized Concentration:
a) 0.20% (other than oral health products)
a) 0.10% (oral health products) (Calculated as free formaldehyde)
* Limitations: Use in spray-on products is prohibited
- **Mexico: Maximum Authorized Concentration of 0.50%**
*Formaldehyde & Paraformaldehyde: Maximum Authorized Concentration: 0.20% (as free HCHO)
*Limitations: Prohibited in aerosols. Not for children or infants.

Regulatory (continued)

- **Brazil: Maximum Authorized Concentration of 0.50%**
 *Limitations: Prohibited in aerosol dispensers (sprays)
 *Conditions of Use and Warnings: Contains formaldehyde (for concentrations higher than 0.50% in final product)
 *Nail Hardeners: Maximum Allowable concentration in the finished products is 5.0% calculated as formaldehyde. Should only be used as a preservative; Warnings that must be printed on the label: Protect cuticles with wax or oil. Contains formaldehyde
- **Mexico: Maximum Authorized Concentration of 0.60%**
- **ASEAN: Maximum Authorized Concentration of 0.50%**
 *Formaldehyde and Paraformaldehyde: Maximum Authorized Concentration:
 - a) 0.20% (except for products for oral hygiene)
 - b) 0.10% (products for oral hygiene) expressed as free formaldehyde
 * Limitations: Prohibited in aerosol dispensers (sprays)
 *Conditions of Use and Warnings: Contains formaldehyde (for concentrations higher than 0.50% in final product)
- **Mercosur: Maximum Authorized Concentration of 0.50%**

Parabens:

- **Europe: Maximum authorized concentration:**
4-Hydroxybenzoic acid and its Methyl- and Ethyl- esters and their salts:
 0.4% (acid) for 1 ester
 0.8% (acid) for mixtures of esters

Butyl 4-hydroxybenzoate and its salts & Propyl 4-hydroxybenzoate and its salts:
 0.14% (as acid) for the sum of the individual concentrations
 0.80% (as acid) for mixtures of substances of Methyl- and Ethyl- esters & Butyl- and Propyl- parabens, where the sum of the individual concentrations of butyl- and Propylparaben and their salts do not exceed 0.14%
 *Not to be used on products designed for application on the nappy area of children under 3 years of age
 *Conditions of Use and Warnings: For Leave-on products designed for children under 3 years of age "Do not use on the nappy area"
- **USA: Maximum authorized concentration:**
 0.4% (acid) for 1 ester and / or 0.8% (acid) for mixtures of esters
 *Journal Citation: IJT 27(S4): 1-82, 2008 JACT 3(5):147-209, 1984
- **Japan: Maximum authorized concentration:**
 1.00% (acid) for 1 ester or mixture of esters
 *All esters except Benzyl are allowed for ingestion.
- **China: Maximum authorized concentration:**
 0.4% (acid) for 1 ester and / or 0.8% (acid) for mixtures of esters
- **Brazil: Maximum authorized concentration:**
 0.4% (acid) for 1 ester and / or 0.8% (acid) for mixtures of esters

Regulatory (continued)

- **Korea: Maximum authorized concentration:**
0.4% (acid) for 1 ester and / or 0.8% (acid) for mixtures of esters
- **Mexico: Maximum authorized concentration:**
0.4% (acid) for 1 ester and / or 0.8% (acid) for mixtures of esters
- **ASEAN: Maximum authorized concentration:**
0.4% (acid) for 1 ester and / or 0.8% (acid) for mixtures of esters
- **Mercosur: Maximum authorized concentration:**
0.4% (acid) for 1 ester and / or 0.8% (acid) for mixtures of esters

Tetrasodium EDTA:

- **USA: Maximum Authorized Concentration: Less than 1.00%**
*Journal Citation: IJT 21(S2):95-142, 2002

Please refer to the product's Compositional Breakdown for a list of preservatives included