

# ACB Willow Bark Extract 20%

## Certificate of Compliance

**Code:** 20200  
**INCI Name:** Water & Salix Nigra (Willow) Bark Extract  
**INCI Status:** Approved  
**CAS #:** 7732-18-5 & 84650-64-6  
**EINECS #:** 231-791-2 & 283-522-3

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>Restrictions:</u> Not to be used in preparations for children under 3 years of age – See page 3 for details
USA (TSCA)	Compliant
Australia (AICS)	Compliant
Japan (METI)	Compliant up to 4.75%
Canada (DSL)	Compliant at Suggested Use Levels
China (IECIC)	Compliant at Suggested Use Levels <u>Restrictions:</u> Not to be used in preparations for children under 3 years of age, except for shampoos
Brazil (ANVISA)	Compliant at Suggested Use Levels <u>Restrictions:</u> Not to be used in preparations for children under 3 years of age, except for shampoos
Korea (KECI)	Compliant at Suggested Use Levels <u>Restrictions:</u> Not to be used in preparations for children under 3 years of age, except for shampoos
Philippines (PICCS)	Compliant at Suggested Use Levels <u>Restrictions:</u> Not to be used in preparations for children under 3 years of age, except for shampoos
Mexico (COFEPRIS)	Compliant at Suggested Use Levels <u>Restrictions:</u> Not to be used in preparations for children under 3 years of age, except for shampoos

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Attention must be paid to the use of ACB Willow Bark Extract 20% 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 Willow Bark Extract 20% 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). However, ACB Willow Bark Extract 20% contains natural phenolics which will test positive for salicylic acid (see also Specification). This should be borne in mind when formulating products containing ACB Willow Bark Extract 20%. The recommended use levels for ACB Willow Bark Extract 20% is 1.00 – 10.00%.

ACB Willow Bark Extract 20% is in compliance with the standardized set of rules developed and approved by NPA (Natural Products Association).

As of March 21, 2022, ACB Willow Bark Extract 20% 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 March 21, 2022.

ACB Willow Bark Extract 20% 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 Willow Bark Extract 20% was tested using *in vitro* dermal and ocular irritation models. This product was found to be non-irritating in both models.

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. As discussed, ACB Willow Bark Extract 20% contains natural phenolics which will test positive for salicylic acid. Salicylic acid (2-hydroxybenzoic acid) has been classified as a CMR substance of category 2, but it fulfills conditions laid down in Article 15(1) of Regulation (EC) No 1223/2009 and can therefore be used in cosmetic products according to the restrictions listed herein.

(\*) 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.

Active Concepts, LLC certifies that ACB Willow Bark Extract 20% does not contain any materials prohibited by Halal laws.

ACB Willow Bark Extract 20% is REACH Compliant and free of the following:

- 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 ACB Willow Bark Extract 20% and are not for the product itself.

ACB Willow Bark Extract 20% contains >18.00% Salicylates. See below for a list of regulations:

### Salicylic Acid and salts:

- **Europe: Maximum Authorized Concentration up to 3.00% when used other than a preservative, depending on the application:**
  - a) **Annex III to Regulation (EC) No 1223/2009 entry 98**
    - 1. Rinse-off hair products: Up to 3.00%
    - 2. Other products except body lotion, eye shadow, mascara, eyeliner, lipstick, roll-on deodorant: Up to 2.00%
    - 3. In body lotion, eye shadow, mascara, eyeliner, lipstick and roll on deodorant applications: Safe up to 0.5% only as preservative – Exclusions apply to oral products (i.e. toothpaste, mouthwash) and sprayable products
      - \*Limitations and requirements: Not to be used in preparations for children under 3 years of age. Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation. Not to be used in oral products. For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product.
      - \*Conditions of use and warnings which must be printed on the label: Not to be used for children under 3 years of age
  - b) **Annex V to Regulation (EC) No 1223/2009 entry 3**
    - 1. Up to 0.5% (acid) when used as a preservative
      - \*Limitations and requirements: Not to be used in products for children under 3 years of age. Not to be used in oral products. Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation. Not to be used in products for children under 3 years of age, except for shampoos.
      - \*Conditions of use and warnings which must be printed on the label: Not to be used for children under 3 years of age
- **USA: Salicylic Acid is safe when formulated to avoid irritation and to avoid increasing sun sensitivity, or when increased sun sensitivity would be expected, directions for use include the daily use of sun protection.** (\*Journal Citation: IJT 22(3):1-108)
- **Japan: Maximum Authorized Concentration:**
  - \*Salicylic Acid: 0.20 (per 100 grams) or \*Salicylic Acid Salts: 1.00 as total (per 100 grams)
- **Canada: Salicylic Acid permitted in concentrations of 2.00% or less**
- **China: Maximum Authorized Concentration of 0.50% (as acid)**
  - \*Limitations and requirements: Not to be used in products for children under age 3, except for shampoo
  - \*Warnings: Do not use for children under 3
- **Brazil: Maximum authorized concentration 0.50% (as acid):**
  - \*Limitations: Not to be used in children's products under 3 years, except for shampoos
  - \*Warnings: Not to be used for children under 3 years of age (1)
  - \*Note (1): Solely for products which might be used for children under three years of age and which remain in prolonged contact with the skin

## Regulatory (Continued)

- **ASEAN: Maximum authorized concentration 0.50% (as acid):**
  - \*Limitations: Not to be used in preparations for children under 3 years of age, except for shampoos
  - \*Warnings: Not to be used for children under 3 years of age
  - \*Note (1): Solely for products which might be used for children under three years of age and which remain in prolonged contact with the skin
- **Mexico: Maximum authorized concentration 0.50% (as acid):**
  - \*Limitations: Not to be used in preparations for children under 3 years of age
- **Mercosur: Maximum authorized concentration 0.50% (as acid):**
  - \*Limitations: Not to be used in preparations for children under 3 years of age, except for shampoos
  - \*Warnings: Not to be used for children under 3 years of age
  - \*Note (1): Solely for products which might be used for children under three years of age and which remain in prolonged contact with the skin