

Code: 10200
INCI Name: Salix Nigra (Willow) Bark Extract
INCI Status: Approved
CAS #: 84650-64-6
EINECS #: 283-522-3
China NMPA #: 002808-02809-5172

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 at Suggested Use Levels
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

ABS Willow Bark Extract

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Attention must be paid to the use of ABS Willow Bark Extract 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 Willow Bark Extract 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, ABS Willow Bark Extract contains natural phenolics which will test positive for salicylic acid (see also Specification). This should be borne in mind when formulating products containing ABS Willow Bark Extract. The recommended use levels for ABS Willow Bark Extract is 2.00 – 5.00%.

ABS Willow Bark Extract 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 Willow Bark Extract 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 Willow Bark Extract 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, ABS Willow Bark Extract 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 ABS Willow Bark Extract does not contain any materials prohibited by Halal laws.

As of February 4, 2025, ABS Willow Bark Extract does not contain any substances present on the so called "Candidate List" of Substances of Very High Concern (SVHC) 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 February 4, 2025.

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ABS Willow Bark Extract is REACH Compliant and free of the following:

- 1,4-Dioxane
- Butylated hydroxyanisole (BHA)
- Butylated hydroxytoluene (BHT)
- Butylphenyl methylpropional (Lilial)
- Camphor
- Crystalline silica
- Ethylene oxide (EO)
- Formaldehyde or formaldehyde donors
- Furocoumarines
- Glycol ethers
- Gluten
- Hydroquinone
- Irradiation
- Lactose
- Microbeads
- Microplastics
- Mycotoxin
- Nanoparticles
- Nitrosamines
- Nonylphenol Ethoxylates
- Oxybenzone
- 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
- Retinyl Palmitate
- Sulfates
- Titanium Dioxide (TiO₂)
- Volatile organic compounds

Raw Component Regulations

Please note that the below are global regulations for the raw materials used to manufacture ABS Willow Bark Extract and are not for the product itself.

ABS Willow Bark Extract contains 9.80 – 11.50% 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
- **Korea: Maximum authorized concentration 0.50% (as acid):**
 - *Limitations: Not to be used in preparations for children under 3 years of age, except for shampoos

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