

# ABS Apple AHA's Certificate of Compliance

**Code:** 10286  
**INCI Name:** Water & Propylene Glycol & Malic Acid & Pyrus Malus (Apple) Fruit Extract & Glycolic Acid & Lactic Acid & Citric Acid  
**INCI Status:** Approved  
**CAS #:** 7732-18-5 & 57-55-6 & 97-67-6 & 85251-63-4 & 79-14-1 & 50-21-5 & 77-92-9  
**EINECS #:** 231-791-2 & 200-338-0 & 202-601-2 & 286-475-7 & 201-180-5 & 200-018-0 & 201-069-1

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 at Suggested Use Levels <u>Labeling requirements:</u> The presence of Glycolic Acid must be clearly stated on cosmetic labels; Consumers should be advised that using Glycolic Acid may cause an increased sensitivity to sunburn and a sunscreen should also be used; Use of the product should be discontinued if skin irritation occurs.
Japan (METI)	Compliant
Canada (DSL)	Compliant
China (IECIC)	Compliant
Brazil (ANVISA)	Compliant
Korea (KECI)	Compliant
Philippines (PICCS)	Compliant
Mexico (COFEPRIS)	Compliant
New Zealand (ERMA)	Compliant

## ABS Apple AHA's Code: 10286

Attention must be paid to the use of ABS Apple AHA's 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 Apple AHA's and its components and impurities are in compliance with the rules governing cosmetic products in the European Union (Directive 76/768/ECC) and Cosmetics Regulation n°1223/2009. The recommended use levels for ABS Apple AHA's is 1.00 – 10.00%.

ABS Apple AHA's 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 Apple AHA's 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 to the best of our knowledge, our raw material does not contain any contaminants or bi-products known to the State of California to cause cancer or reproductive toxicity as listed under Proposition 65 State Drinking Water and Toxic Enforcement Act.

Active Concepts, LLC certifies that ABS Apple AHA's does not contain any materials prohibited by Halal laws.

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).

As of June 20, 2022, ABS Apple AHA's 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 June 20, 2022.

ABS Apple AHA's is REACH Compliant and free of the following:

- 1,4-Dioxane
- Butylphenyl methylpropional (Lilial)
- Formaldehyde, Formalin or formaldehyde donors
- Gluten
- Glycol ethers (Series E)
- Lactose
- Nanoparticles
- Nitrosamines
- Palm oil/palm kernel oil (or derivatives)
- Parabens
- Paraffin/petroleum products
- Pesticide residues
- Phthalates
- Polyethylene glycol (PEG)
- Polyfluoroalkyl substances (PFAS)
- Residual solvents
- Sulfates
- Volatile organic compounds

## Raw Component Regulations

Please note that the below are global regulations for the raw materials used to manufacture ABS Apple AHA's and are not for the product itself.

ABS Apple AHA's contains 22.00% Propylene Glycol, 20.50% Malic Acid, 7.00% Glycolic Acid & 6.00% Lactic Acid. See below for a list of regulations:

### 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

### Malic Acid:

- **USA: Safe for use as pH adjusters; Insufficient data to support safety for other uses**  
\*Journal Citation: IJT 20(S1): 47-55, 2001

### Glycolic Acid:

- **USA:** Glycolic Acid, their common salts and their simple esters, are safe for use:
  - \*In cosmetic products at concentrations  $\leq 10.00\%$ , at final formulation ( $\text{pH} \geq 3.5$ , when formulated to avoid increasing sun sensitivity or when directions for use include the daily use of sun protection)
  - \*In salon products as concentrations  $\leq 30.00\%$ , at final formulation ( $\text{pH} \geq 3.0$ , in products designed for brief, discontinuous use followed by thorough rinsing from the skin, when applied by trained professionals, and when application is accompanied by directions for the daily use of sun protection)
  - \*Journal Citation: IJT 17(S1):1-242, 1998
- **Australia: A product containing 10.00% or more glycolic acid is classed as a Hazardous Substance**
  - \*Conditions of use and warnings which must be printed on the label: Contains Glycolic Acid
  - \*Warnings: Consumers should be advised that using glycolic acid may cause increases sensitivity to sunburn and a sunscreen should also be used. Use of the product should be discontinued if skin irritation occurs
  - \*The more glycolic acid in a product the more irritation it is to the skin. Product labels must reflect the different levels of hazard according to the concentration of glycolic acid in the finished product.
  - \*Workers using cosmetics containing glycolic acid should:
    - Keep the container tightly closed and out of reach of children
    - Wear protection for their skin and avoid touching their eyes

### Lactic Acid:

- **USA:** Lactic Acid, their common salts and their simple esters, are safe for use:
  - \*In cosmetic products at concentrations  $\leq 10.00\%$ , at final formulation ( $\text{pH} \geq 3.5$ , when formulated to avoid increasing sun sensitivity or when directions for use include the daily use of sun protection)
  - \*In salon products as concentrations  $\leq 30.00\%$ , at final formulation ( $\text{pH} \geq 3.0$ , in products designed for brief, discontinuous use followed by thorough rinsing from the skin, when applied by trained professionals, and when application is accompanied by directions for the daily use of sun protection)
  - \*Journal Citation: IJT 17(S1):1-242, 1998