

ABS Orange Polyphenols PBF Certificate of Compliance

 Code:
 16734

 INCI Name:
 Water & Propylene Glycol & Citrus Aurantium Amara (Bitter Orange) Flower Extract

 INCI Status:
 Conforms

 CAS #:
 7732-18-5 & 57-55-6 & 72968-50-4

 EINECS #:
 231-791-2 & 200-338-0 & 277-143-2

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

INCI Name	CAS#	EINECS#	Percentage (%)	Function
Leuconostoc/Radish	1686112-10-6	N/A (or)	2.00%	Natural
Root Ferment Filtrate	(or) 84775-94-0	283-918-6		Antimicrobial
Tetrasodium EDTA	64-02-8	200-573-9	0.10%	Chelating Agent

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



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Attention must be paid to the use of ABS Orange Polyphenols PBF 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 Orange Polyphenols PBF 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 Orange Polyphenols PBF is 1.00 – 10.00%.

ABS Orange Polyphenols PBF 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 Orange Polyphenols PBF 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 product does not contain any material listed on California Proposition 65.

Active Concepts, LLC certifies that ABS Orange Polyphenols PBF 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).

ABS Orange Polyphenols PBF 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

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Raw Component Regulations

Please note that the below are global regulations for the raw materials used to manufacture ABS Orange Polyphenols PBF and are not for the product itself.

ABS Orange Polyphenols PBF contains 38.95% Propylene Glycol & 0.10% Tetrasodium EDTA. 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

Tetrasodium EDTA:

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