

Aevum Vita 525



Date: 11 September 2023

INCI Declaration

This product contained the following ingredients which are listed in the Inventory of Cosmetic Ingredients:

INCI Name	CAS Number	Contains (by weight)
Ammonium polyacryloyldimethyl taurate	62152-14-1	100 %

Cosmetic Safety

Aevum Vita 525 is fully compliant with the European Cosmetic Products Regulation (EC No. 1223/2009) for use as a preservative.

According to Annex V of the regulation, Aevum Vita 525 is permitted for use in all categories of cosmetics at the following maximum permitted levels:

Leave-on products:	unlimited
Rinse-off products:	unlimited

Animal Testing

This product has never been tested on animals, and no materials used in its manufacture have ever been the subject of animal testing.

Shelf Life

The shelf life of Aevum Vita 525 is 2 years from the date of manufacture.

The shelf life is the period of time during which the product retains its chemical and physical stability, and exhibits full efficacy for its intended use as a personal care preservative, providing that it is kept unopened, in its original packaging, stored out of direct sunlight and avoiding extremes of temperature.

Origin

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Aevum Vita 525 is manufactured from raw materials that are derived from the following sources (Animal / Plant / Synthetic):

RAW MATERIAL	ORIGIN
Ammonium polyacryloyldimethyl taurate	Synthetic

Calculation of Natural Origin (ISO 16128)

According to the principles of ISO 16128 (*Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products*), the product has the following Natural and Organic Indices:

Natural Index, $I_n = 0$	[includes formulation water]
Natural Origin Index, I _{no} = 0	[includes formulation water]
Organic Index, I _o = 0	
Organic Origin Index, I _{oo} = 0	

Vegan Friendly

No material of animal origin is used in the manufacture of Aevum Vita 525, and the product is manufactured in a facility that is free from animal products and derivatives. Aevum Vita 525 is therefore suitable for use in products intended for vegans.

Genetically Modified Organisms (GMO)

The above mentioned product is not derived from, and does not contain any Genetically Modified Organisms.

BSE / TSE

No material of animal origin is used in the manufacture of Aevum Vita 525, and the product is never, at any time during handling, placed in contact with any biological materials. We can therefore state that Aevum Vita 525 is free from Bovine Spongiform Encephalopathy (BSE) and Transmittable Spongiform Encephalopathy (TSE).

Allergenic Substances

According to the EU Cosmetics Regulation, (EC) 1223/2009:

"A number of substances have been identified by the SCCS as likely to cause allergic reactions and it will be necessary to restrict their use and/or impose certain conditions concerning them. In order to ensure that consumers are adequately informed, the presence of these substances should be mentioned in the list of ingredients and consumers' attention should be drawn to the presence of these ingredients."

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We confirm that Aevum Vita 525 does not contain any of the substances listed as an allergen in Annex III of Regulation (EC) 1223/2009:

Substances of Very High Concern

The product does not contain any materials listed as a Substance Of Very High Concern according to the REACH Regulations (EC No 1907/2006) as specified in either the current Candidate List or Authorisation List.

Carcinogenic, Mutagenic or Toxic (CMR)

No component of this product present at levels greater than or equal to 0.1% is identified as a known, presumed or suspected carcinogen (CMR 1A, 1B, or 2) according to Regulation (EC) 1272 /2008 (Classification Labelling and Packaging Regulation).

Microbiological Specification

The microbiological specification for the product as supplied is:

	Total Viable Count (cfu/g)
Bacteria	< 10
Yeasts and Moulds	< 10

Microplastics

Aevum Vita 525 does not contain any intentionally added synthetic polymer microparticles ("microplastics"), as defined by the European Chemicals Agency's definition:

"a particle containing solid polymer, to which additives or other substances may have been added, and where $\ge 1\%$ w/w of particles have (i) all dimensions 1 nm $\le x \le 5$ mm, or (ii) a length of 3 nm $\le x \le 15$ mm and length to diameter ratio of > 3."

Nanomaterials

Aevum Vita 525 does not contain any nanomaterials as defined in article 3 of EC regulation 1223/2009, Art. 16. No nanomaterials are used in the facility where the product is manufactured.

Irradiation

This product has not been irradiated or treated with ethylene oxide. Additionally, the vendors of any individual ingredients that make up this product certify that they do not use any irradiation or ethylene oxide treatment during the manufacturing process.

Palm Oil

The product does not contain any raw materials derived from Palm Oil or Palm Kernel Oil.

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Residual solvents are defined by both the FDA and the European Union as organic volatile chemicals used in the manufacture of a product, which may not be completely removed during the manufacturing process.

The ICH "Guidelines for Residual Solvents", and the current edition of the USP General Chapter (467), establishes 3 classes of residual solvents: Class 1 are known carcinogens or environmental hazards, Class 2 are those with irreversible toxicity, or that have significant but reversible toxicity, and Class 3 have a low toxic potential.

Based on our knowledge of the raw materials and processes used, there is no potential for residual solvents to be present in Aevum Vita 525.

Impurities

The above mentioned product complies with the European Cosmetics Regulation (EC) 1223/2009 in relation to impurity levels.

(EC) 1223/2009 – Article 17

We the undersigned confirm that the product does not contain the following substances:

- Alkyl phenols
- Antioxidants
- Bisphenol A
- Butylated hydroxytoluene (BHT) / Butylated hydroxyanisole (BHA)
- Diethanolamine (DEA)
- Ethylenediaminetetraacetic acid (EDTA)
- Formaldehyde
- Gluten
- Glycol ethers
- Latex
- Mycotoxins
- Nitrosamines
- Nonylphenols or derivatives
- Nuts, nut oil, nut derivatives or sesame seeds.
- Organohalogens
- Parabens
- Polychlorinated biphenyls (PCB)
- Polycyclic aromatic hydrocarbons (PAH)
- Polyethylene Glycol (PEG)
- Phthalates
- Plasticisers
- Preservatives
- Propylene oxide
- Soy / Soy derivatives

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• Sulphates

Heavy Metals

Aevum Vita 525 complies with the European Cosmetics Regulation (EC) 1223/2009 in relation to heavy metals content.

In accordance with Article 17 of the ECR, the product does not contain any of the below mentioned heavy metals as intentional additives. These substances may be present unavoidably as impurities, but their concentrations are below the following limits quoted by the International Cooperation on Cosmetic Regulation (ICCR) Working Group on Traces:

Impurity	Maximum Permitted Level
Lead	< 10 ppm
Arsenic	< 3 ppm
Cadmium	< 3 ppm
Mercury	< 3 ppm
Antimony	< 5 ppm
Antimony	< 5 ppm

We certify that, to the best of our knowledge, the above information is true and correct.

Antony Hudson

Technical Director ISCA UK Ltd

Date: 11 September 2023

Disclaimer: The information contained in this document is intended to be of assistance to users. We believe the information set forth above to be true and accurate as of the date of this letter, but such information is provided without any warranty, and shall establish no legal duty or responsibility on the part of Isca UK Ltd.

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