

PRODUCT REGULATORY INFORMATION

GALESLIME®

(INCI name: Snail Secretion Filtrate, Aqua, Phenethyl Alcohol, Caprylyl Glycol)

ANIMAL TESTING: This is to confirm that GALESLIME® has ever been tested on animals, we do not carry out animal experiments in any way, nor that we have performed them in the past.

BSE/TSE: This is to confirm that GALESLIME® does not contain nor come in contact with bovine extracts of the brain, bone marrow, spinal cord and eye, so it is free from B.S.E. (Bovine Spongiform Encephalopathy) and T.S.E. (Transmissible Spongiform Encephalopathy).

CMR/SVHC: This is to confirm that GALESLIME® doesn't contain any substances listed on Annex VI of Regulation (EC) No 1272/2008 or listed by the ECHA as "Substance of very high concern".

PROPOSITION 65: This is to confirm that GALESLIME® complies with the requirements of the California Proposition 65. To the best of our knowledge, it does not contain any contaminations or by-products known in the State of California to cause cancer or reproductive toxicity as listed in the California Proposition 65.

NANOMATERIAL/NANOPARTICLES: (Art. 2.1.k (Chapter I) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of November, 30 2009 on cosmetic products):

Definition: On 14 June, the new Commission Recommendation for the definition of nanomaterial (COMMISSION RECOMMENDATION of 10 June 2022 on the definition of nanomaterial (2022/C 229/01)) was published, updating the previous Recommendation 2011/696/EU (2).

The new definition is worded as follows:

Nanomaterial' means a natural, incidental or manufactured material consisting of solid particles that are present, either on their own or as identifiable constituent particles in aggregates or agglomerates, and where 50 % or more of these particles in the number-based size distribution fulfil at least one of the following conditions:

- (a) one or more external dimensions of the particle are in the size range 1 nm to 100 nm;*
- (b) the particle has an elongated shape, such as a rod, fibre or tube, where two external dimensions are smaller than 1 nm and the other dimension is larger than 100 nm;*
- (c) the particle has a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm.*

In the determination of the particle number-based size distribution, particles with at least two orthogonal external dimensions larger than 100 µm need not be considered. However, a material with a specific surface area by volume of < 6 m²/cm³ shall not be considered a nanomaterial.

2. For the purposes of point 1, the following definitions apply:

- (a) 'particle' means a minute piece of matter with defined physical boundaries; single molecules are not considered 'particles';*
- (b) 'aggregate' means a particle comprising of strongly bound or fused particles;*

(c) 'agglomerate' means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components.

3. It is recommended that the definition of the term 'nanomaterial' set out in the latest recommendation or other act providing a definition of nanomaterial for horizontal policy and legislative use adopted by the Commission or Union legislator is used when addressing materials or issues concerning products of nanotechnologies:

(a) by the Commission, when preparing legislation, policy programmes or research programmes and when implementing such legislation or programmes also with other Union institutions and agencies; C 229/4 EN Official Journal of the European Union 14.6.2022

(b) by Member States, when preparing legislation, policy programmes or research programmes and when implementing such legislation or programmes;

(c) by economic operators, when preparing and conducting their own policies and research

GALESLIME® doesn't contain Nanomaterials based on the New Cosmetic Regulation definitions.

FRANCE Décret: GALESLIME® does contain nanomaterials based on definition of the FRANCE Décret no 2012-232 du 17 février 2012 relatif à la déclaration annuelle des substances à l'état nanoparticulaire pris en application de l'article L. 523-4 du code de l'environnement

MICROPLASTICS: GALESLIME® doesn't contain Microplastic based on the following definitions:

Definition: Microplastic is intended to be solid particles in plastic, insoluble in water, of a size equal to or less than 5 millimeters, intentionally added to exfoliating and cleansing cosmetic products.

By plastic we mean "molded, extruded or physically manipulated polymers into different solid forms, which, during use and subsequent disposal, maintain the shapes defined in the intended applications".

GMO: Snails (*Helix aspersa*) cannot be subjected to genetic manipulation. Crosses between the different species are difficult, in particular due to the different sizes of the snails.

VOC: This is to confirm that GALESLIME® does not contain VOCs (VOLATILE ORGANIC COMPOUNDS).

SVHC: according to the list of candidates, article 59 (1, 10) European REACH Regulation (EC) n. 1907/2006, To the best of our knowledge, none of these materials are generated during the production of GALESLIME®.

NAGOYA: GALESLIME® manufactured in Italy, is in compliance with REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union.

ANIMAL TESTING: GALESLIME® and its component ingredients, have not been subject to animal testing for any reason by or on behalf of Gale&Cosm since the 11th of March 2013.

Origin: product GALESLIME® is made in our plant located in Tuscany, so the product is made in Italy.

Cruelty Free: GALESLIME® is manufactured in Tuscany (Italy) in a farm managed according to the principles of "biological". The production takes place in full respect of the snails. The snails are not killed and, after the extraction of the secretion, they continue their natural life cycle.

REACH Registration:

- *Snail Secretion Filtrate*, which is a naturally occurring and animal-derived substance, not chemically modified and therefore exempt from REACH registration, according to Annex V of the REACH regulation;
- *Phenethyl Alcohol**: REACH Registration Number 01-2119963921-31-XXXX;
- *Caprylyl Glycol**: REACH Registration Number 01-2119966905-22-XXXX.

Please note that in the percentages used in our products, Gale & Cosm does not exceed one ton/year.

MISCELLANEOUS: This is to confirm that GALESLIME[®] does not contain known allergens or has been in contact with nuts or pesticides. It is Petrochemical-free, Phthalate-free and does not contain residual solvents. It is not microbiologically sensitive and does not contain Aflatoxins. Ethylene Oxide, Propylene Oxide and Irradiation are not used on the product. GALESLIME[®] does not contain other substances such as enzymes, toxins and microorganisms. It does not contain residue catalytic synthesis, heavy metals, toluene, benzene, xylene, styrene, polycyclic aromatic compounds (PAHs), formaldehyde, nitrosamines, 1,4-dioxan or organohalogen compounds.

GLOBAL REGULATORY COMPLIANCE: This is to confirm that GALESLIME[®] complies with Ukraine, Switzerland, Norway, US, EU, Korea, China, Japan, Hong Kong, ASEAN, Algeria and Iran regulation criteria.


GALE & COSM SRL