

Cosmetics Regulatory Support

Imerys perlite grades used in cosmetics applications

(make-up, toiletries, skin care and hair care)

ImerCare® 20P	ImerCare® 270P-Scrub
ImerCare® 25P	ImerCare® 400P-Scrub
ImerCare® 30P	ImerCare® 700P-Scrub
ImerCare® 90P-Scrub	ImerCare® 800P-Scrub
ImerCare® 120P-Scrub	ImerCare® 800P-Scrub(S)
ImerCare® 120P-Scrub(S)	ImerCare® Perlwhite 19
ImerCare® 190P-Scrub	

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This regulatory support document provides information on the perlite grades manufactured by Imerys Perlita Barcelona and dedicated to cosmetics applications. This document will be modified as needed to reflect the most current legislation.

The information on the safe use of the product is available in the safety data sheet.

General product information

INCI name:	Perlite
Product origin:	Mineral
Geographic origin:	European Union
CAS number:	93763-70-3
Customs Code:	2530 10 00

Allergens

Perlite is a naturally occurring mineral. As such, none of the perlite grades produced by Imerys naturally contains any allergens. No allergens or allergenic substances are added during any stage of the production processes for our perlite grades.

Therefore it is reasonable to assume that these mineral products do not contain any allergens listed in :

- Annex III, reference 67 to 92 of the European Regulation (CE) n°1223/2009;
- Annex II of European Regulation (UE) N°1169/2011 on the provision of food information to consumers.

Animal testing

These perlite grades are compliant with European Cosmetics Regulation (CE) n°1223/2009 concerning tests on animals. Nevertheless, Imerys could consider the commissioning of tests on animals to external labs if needed for animal welfare applications or to fulfil regulatory commitments.

BSE (Bovine Spongiform Encephalopathy)/TSE (Transmissible Spongiform Encephalopathy)

These perlite grades are mineral products; they are not derived from animal or human origin products and have not come in contact with such products during their manufacturing processes. They should not, therefore, transmit Bovine Spongiform Encephalopathy or Transmissible Spongiform Encephalopathy.

California PROP 65 (California Safe Drinking Water and Toxic Enforcement Act Proposition 65)

Perlite is not listed, however, the above mentioned products may contain titanium dioxide (TiO₂) and/or respirable crystalline silica (airborne particles of respirable size) which have been identified by the State of California to cause cancer.

CLP

The labelling and packaging of these perlite grades are in accordance with Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures ("the CLP Regulation").



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CMR

None of these perlite grades is classified as CMR (carcinogenic, mutagenic or reprotoxic) and no substances classified as CMR are added during any stage of the production processes in accordance with Commission Regulation (EU) 2019/831.

Composition

These perlite grades are produced from naturally occurring mineral deposits. They can be considered as 100% perlite.

Conflict Minerals Law

These perlite grades come from mineral ore bodies that are not located in Angola, Burundi, Central African Republic, Congo Republic, Rwanda, Sudan, Tanzania, Uganda, or Zambia. To produce our perlite grades, Imerys does not buy tin, tungsten, tantalum or gold coming from these countries. Consequently, Imerys' European perlite products do not fall under the Conflict Minerals law.

CosIng (Chemical database of the European Union for substances used as cosmetic ingredient)

All the above mentioned ImerCare™ perlite grades are expanded perlite with CAS # 93763-70-3. They are obtained by the heating process of natural perlite (CAS# 130885-09-5). Perlite and expanded perlite only differs in their water content.

They both are identified in the CosIng database under the name perlite with CAS# 130885-09-5.

COSMOS

These cosmetics perlite grades are in conformity with the COSMOS standard related to raw material ; except ImerCare® 120P-Scrub(S), ImerCare® 800P-Scrub(S) and ImerCare® 700P-Scrub.

Crystalline silica fine fraction / Respirable crystalline silica

These grades are produced from naturally occurring mineral deposits.

As in all mineral fillers the mineralogical composition may vary, the total amount of quartz (the only form of crystalline silica in these grades) may also vary to a small extent.

Crystalline silica fine fraction is determined using the SWeRF method adopted by the European mineral industries (for more information please consult : <https://safesilica.eu/safety-and-measurement/>.)

The "crystalline silica fine fraction" value corresponds to the maximum content of crystalline silica (the worst case) able to become respirable when handling and using the product.

"Respirable crystalline silica" (expressed in mg/m³) relates to airborne dust in workplace atmospheres and is dependent on the handling conditions and use. The respirable crystalline silica value cannot, therefore, be determined in a bulk powder.

The crystalline silica fine fraction value of below 1% is the only warranty Imerys can give on the above grades. As such, these grades are not classified as hazardous under Regulation (EC) No. 1272/2008 ("the CLP Regulation").



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CTPA

There are no specific requirements for these products.

Dioxin

These perlite grades have been found to be below the maximum permitted limit of dioxin set by the European Union.

European Cosmetics Regulation 1223/2009/EC

Perlite does not appear among the prohibited substances listed in Annex II of Regulation (EC) No 1223/2009 on cosmetics products, nor is it among the substances in Annex III that can only be used with restrictions. Perlite is, therefore, permitted for use in cosmetics products.

Moreover, these cosmetics grades do not contain :

- any of the prohibited substances listed in Annex II of European Regulation (CE) n°1223/2009;
- any of the colorants listed in Annex IV;
- any of the preservatives listed in Annex V;
- any of the UV filters listed in Annex VI.

Genetically Modified Organism (GMO)

These perlite grades are mineral products and do not contain any products of plant origin. No GMOs are used during the manufacturing processes and the products have not been in contact with any GMOs during the manufacturing processes.

Halal

According to the FAO "General guidelines for use of the term Halal" (CAC/GL 24-1997), "the term halal may be used for foods which are considered lawful. Under the Islamic Law, all sources of food are lawful except the following sources, including their products and derivatives":

- 1 - Animal origin products
- 2 - Plant origin products
- 3 - Drink (including alcoholic drinks)
- 4 - Food Additives (all food additives derived from Items 1, 2 and 3).

These perlite grades are free from the above substances and their derivatives and are, therefore, eligible to be certified Halal.

Heavy metals

As naturally occurring minerals these perlite grades may inherently contain trace quantities of certain chemical elements that occur as part of the natural environment and are commonly found within mineral deposits. These generally occur as trace impurities (ppm levels) bound substitutionally within the individual mineral crystalline lattices and are, therefore, virtually non-extractable, non-bioavailable and technically unavoidable. As with all naturally occurring materials these levels fluctuate from point to point. Data on the values of chemical elements present as naturally occurring impurities in these perlite grades is available on request.



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The tables below summarize the soluble chemical elements determined by ICP-OES* after hydrochloric acid (0,07 mol/l) extraction at 23° C during 30 minutes (DIN 53770-1 method).

* Inductively Coupled Plasma-Optical Emission Spectrometry

Grade	ImerCare 20P	ImerCare 25P	ImerCare 30P	ImerCare PerlWhite 19
Element	Typical value ppm	Typical value ppm	Typical value ppm	Typical value ppm
Antimony (Sb)	< 1	< 1	< 1	<1
Arsenic (As)	1	1	2	<1
Barium (Ba)	17	12	9	33
Cadmium (Cd)	< 1	< 1	< 1	<1
Chromium (Cr)	< 1	< 1	< 1	<1
Cobalt (Co)	< 1	< 1	< 1	<1
Lead (Pb)	< 1	< 1	< 1	<1
Mercury (Hg)	< 1	< 1	< 1	<1
Nickel (Ni)	< 1	< 1	< 1	<1
Selenium (Se)	< 1	< 1	< 1	<1
Zinc (Zn)	< 1	< 1	< 1	<1

Grade	ImerCare 90P-Scrub	ImerCare 120P-Scrub	ImerCare 190P-Scrub	ImerCare 270P-Scrub	ImerCare 400P-Scrub	ImerCare 700P-Scrub	ImerCare 800P-Scrub
Element	Typical value ppm	Typical value ppm	Typical value ppm	Typical value ppm	Typical value ppm	Typical value ppm	Typical value ppm
Antimony (Sb)	< 1	< 1	< 1	< 1	<1	< 1	< 1
Arsenic (As)	1	<1	<1	<1	<1	< 1	< 1
Barium (Ba)	8	11	7	10	<1	20	20
Cadmium (Cd)	< 1	< 1	< 1	< 1	<1	< 1	< 1
Chromium (Cr)	< 1	< 1	< 1	< 1	<1	< 1	< 1
Cobalt (Co)	< 1	< 1	< 1	< 1	<1	< 1	< 1
Lead (Pb)	< 1	< 1	< 1	< 1	<1	< 1	< 1
Mercury (Hg)	< 1	< 1	< 1	< 1	<1	< 1	< 1
Nickel (Ni)	< 1	< 1	< 1	< 1	<1	< 1	< 1
Selenium (Se)	< 1	< 1	< 1	< 1	<1	< 1	< 1
Zinc (Zn)	< 1	< 1	< 1	< 1	<1	< 1	< 1

International Fragrance Association (IFRA)

Perlite is not listed as a prohibited ingredient (P), restricted ingredient (R) or a specified ingredient (S) in the Index of IFRA Standards.

International inventories

Perlite appears in the following national positive lists and chemical inventories. The list is not exhaustive and is provided to the best of our current knowledge. Australian Inventory of Chemical Substances (AICS), Canadian Domestic Substances List (DSL), Inventory of Existing Chemical Substances in China (IECSC), Korea Existing Chemicals Inventory (KECI), New Zealand Inventory of Chemicals (NZIoC), Philippine Inventory of Chemicals and Chemical Substances (PICCS), Taiwan National Existing Chemical Substance Inventory, US Code of Federal Regulations Chapter 21: Food and Drugs, and US Toxic Substances Control Act (TSCA).

Perlite is exempt from the following: Canadian Non-Domestic Substances List (NDSL), Mexico National Inventory of Chemical Substances (INSQ), Registration, Evaluation, Authorisation & restriction of Chemicals (REACH), and Turkey Inventory and Control of Chemicals (CICR).



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Irradiation

None of these perlite grades has received any type of irradiative treatment ; except ImerCare® 120P-Scrub(S) and ImerCare® 800P-Scrub(S) treated by gamma rays.

Kosher

Perlite is mineral in origin and comes from natural sources. No additive is added during the manufacturing process. These grades are therefore eligible to be certified kosher.

Labelling of cosmetics products

According to Commission Decision (EU) 2019/701 establishing a glossary of common ingredient names for use in the labelling of cosmetics products, these grades are registered under the ingredient name “Perlite” under entry number 18059.

Nanomaterials

European Cosmetics Regulation (EC) n° 1223/2009/EC defines ‘nanomaterial’ as “an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm”.

These perlite grades are not intentionally manufactured at nano-scale and do not, therefore, fall within the European Cosmetics Regulation definition of a nanomaterial.

Consequently, these perlite grades are not required to be:

- registered under the Belgian Royal Decree of 27 May 2014;
- reported to the Danish Inventory of Nanoproducts;
- declared annually to ANSES according to the French Decree No. 2012-232.

Natural and biological cosmetic ingredients and products

The above mentioned perlite grades correspond to the definition of the **ISO 16128-1:2016** Standard of a natural mineral ingredient : “natural ingredient consisting of inorganic substances, naturally occurring on Earth, having his own chemical formula and a consistent set of physical properties”

According to ISO 16128-2:2017 Standard, these grades have :

- A natural index equal to 1
- A natural origin index equal to 1
- A biological index equal to 0
- A biological origin index equal to 0

PCPC (Personal Care Products Council, formerly CTFA)

There are no specific requirements for these products.

REACH registration status

These perlite grades are exempted from registration according to Annex V.7 (naturally occurring substances not chemically modified) of Regulation (EC) n° 1907/2016 as amended.



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Residual Solvents

These perlite grades are produced from natural perlite ores. No chemical additives are used in the production processes.

No solvents are added during any stage of the production processes for our cosmetics perlite grades. Furthermore, none of perlite cosmetics grades contains or is contaminated with any residual solvents.

Shelf life

These perlite grades are chemically stable, inert and non-reactive. They can, therefore, be stored for an indefinite period in a cool, clean and dry covered area with no significant detrimental effects. These perlite grades do not have an expiry date and do not have a shelf life when stored in original containers and as instructed. However a 60 month shelf life is recommended.

Substances of Very High Concern (SVHC)

These perlite grades are naturally occurring minerals. No substances of very high concern (SVHC) or any chemicals that contain substances of very high concern as defined by the European Chemical Agency (ECHA) are used in the production processes.

Although we do not test for their presence, we do not expect these perlite products to contain any of the substances published in the ECHA Candidate list valid at the date of the document.

Undesirable substances

These grades contain no chemical additives and have not come in contact with any other chemical substances during processing.

Chemical additives or chemical substances means the regulated hazardous or undesirable substances such as the one listed in the following regulations :

- Regulation (EU) No 321/2011 (Bisphenol A);
- Commission Decision 2009/251/EC (Dimethylfumarate);
- Regulation (EC) No 1005/2009 (ozone-depleting substances);
- European Directive 2005/84/EC (phthalates);

as well as any product of the following categories:

- Any product of vegetal origin, in particular latex, gluten or aflatoxins, genetically modified organism (GMO) or genetically modified derived ingredient;
- Any pesticides, mycoplasma or molds, vegetal hormones or growth promoters;
- Endocrine disruptors;
- Preservatives or antioxidants,
- Any other chemical product.

This list is not exhaustive. **These grades exclusively contain natural minerals.**



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Vegetarian / Vegan

These grades do not contain and have not been in contact with any animal ingredients or any animal by-products ; no animal ingredients or by-products are used in the manufacturing process.
These products are therefore suitable for vegetarians and vegans.

This information is given according to our knowledge of the legislation in force at the date indicated in reference of this document.

NB: It is the sole responsibility of the producer of the finished products to ensure the final compliance of its products.