

PRODUCT DESCRIPTION

nanoXIM•CarePaste is a synthetic nano-hydroxyapatite aqueous suspension for cosmetic applications, manufactured by FLUIDINOVA, S.A.



Identification

Trade name	nanoXIM•CarePaste
SKU	504102
INCI name	Hydroxyapatite (nano)
IUPAC name	Pentacalcium hydroxide triphosphate
CAS number	12167-74-7
EC number	235-330-6
Synonyms	Hydroxyapatite (CAS No.1306-06-5)
Chemical formula	$\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$
REACH ID number	01-2119490075-38-0021
HS code	283526

PRODUCT SPECIFICATIONS

	Unit	Specifications
Hydroxyapatite identification		Conforms to structure
Solids	wt%	20,0 ± 1,0
Hydroxyapatite, $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$	wt%	15,5 ± 0,5
Potassium Chloride, KCl	wt%	4,5 ± 0,5
Water, H_2O	wt%	80,0 ± 1,0
pH @ 25°C		10,0 ± 0,5
Total heavy metals (as Pb)	ppm ≤	20
Total Aerobic Mesophilic Microorganisms (bacteria, yeast & mold)	cfu/g ≤	100

COMPANY CERTIFICATION/REGISTRATIONS

ISO 9001:2015

https://www.fluidinova.com/docs/iso_9001_certificate.pdf

REACH

All products sold by FLUIDINOVA are compliant with REACH regulatory requirements. All substances of the FLUIDINOVA portfolio have been registered under REACH or are exempt from REACH registration. To fully understand the obligations that you as our customer have under REACH, we recommend that you consult the ECHA website.

General properties

	Unit	Value
Density	g/cm ³	1,13 ± 0,02
Particle size	nm	< 100
Relative Dentin Abrasion (RDA)		< 10

Particle morphology	Nano-rods
Shelf life	3 years
Physical appearance	White aqueous suspension

USES AND APPLICATIONS

nanoXIM•CarePaste is recommended for cosmetic products. In oral care formulations is mainly used in toothpastes, mouthwashes, foams, gels and products for whitening, remineralization and sensitivity treatment.

This products can be easily incorporated in water-based formulas, simply by replacing part of the water in the formulation.

For toothpastes, typical incorporation range is 3 to 20%, with a maximum of 64.5%.

For mouthwashes, typical incorporation range is 1 to 3%, maximum.

PACKAGE

Standard packing available in 20 kg food-grade HDPE containers. Large quantities are supplied in 20 kg containers packed on pallets, preferably in multiples of 240 kg up to a maximum of 720 kg per pallet. Other options may be available upon request.

Minimum Order Quantity: 1kg

STORAGE, SAFETY AND HANDLING

To ensure the quality of the product, keep it in a closed container at room temperature in a clean and dry place. Do not freeze.

For more details about product safety and handling information, please see the product Safety Data Sheet (SDS).

Shake before use to ensure homogeneity.

PRODUCT SEALS



NATRUE Approved

STATEMENTS

Animal and vegetable derivatives	This product is a fully synthetic inorganic product, does not contain and it is not derived from any animal or vegetable source. Therefore, no animal or vegetable-based material is present in its composition.
BSE/TSE	Transmissible Spongiform Encephalopathies (TSE) and Bovine Spongiform Encephalopathy (BSE): This products is made from inorganic calcium and phosphate salts and water, in a dedicated plant. The ingredients and the sources of these ingredients are inorganic and not of animal or vegetable origin, therefore there are no additives or extracts from the brain, spinal cord, bone marrow, or eyes of any animal.
Derived mineral ingredient	This product is considered a derived mineral ingredient according to point 4 of the latest edition of ISO 16128-1. Hydroxyapatite is included in the list of derived mineral ingredients in Annex D of the latest edition of ISO 16128-1. This product is obtained through the chemical processing of inorganic substances that occur naturally in the earth and have the same chemical composition as natural mineral ingredients.
Dyes free	This product is dye free. No dyes are used at any stage of the production process.
GMO	This product is a fully synthetic inorganic product. This product is not genetically modified or not derived from a genetically modified organism (GMO).
HALAL	This product sole manufactured by FLUIDINOVA is compliant with all the HALAL requirements: - Do not contain any ingredient of animal origin; - No process aid of animal origin is used in the production process; - Do not contain any ingredient of vegetable origin; - Do not contain alcohol and alcohol has not been used in the manufacturing process; - The equipment used for the manufacturing, filling and packing is dedicated for these products and is not used for any other process related with products of animal origin or containing ingredients of animal source; - During the manufacturing, storage and handling, the product is completely fully separated from foods and alcohol; - The ingredients used to produce these products are inorganic and purified water.
Ionization	This product has not been subject to any irradiation or ionization procedure at any stage of its manufacturing or final storage.
KOSHER	This product sole manufactured by FLUIDINOVA is compliant with all the KOSHER requirements. - Do not contain any ingredient of animal origin; - No process aid of animal origin is used in the production process; - Do not contain any ingredient of vegetable origin; - Do not contain alcohol and alcohol has not been used in the manufacturing process; - The equipment used for the manufacturing, filling and packing is dedicated for these products and is not used for any other process related with products of animal origin or containing ingredients of animal source; - During the manufacturing, storage and handling, the product is completely fully separated from foods and alcohol; - The ingredients used to produce these products are inorganic and purified water.
Microplastics	FLUIDINOVA has not conducted specific tests for the presence of microplastics in our product. However, we use food-grade reagents and primary packaging materials approved for food contact in our manufacturing processes. We firmly believe that these measures greatly minimize the likelihood of microplastics being present in our product.
Nano-safety and SCCS Final Opinion approval	SCCS considers hydroxyapatite (nano) safe when used at concentrations up to 10% in toothpaste (i.e. 64.5% nanoXIM•CarePaste), and up to 0.465% in mouthwash (i.e. 3% nanoXIM•CarePaste). The SCCS safety evaluation only applies to the hydroxyapatite (nano) with the characteristics of nanoXIM•CarePaste: - composed of rod-shaped particles of which at least 95.8% (in particle number) have an aspect ratio less than 3, and the remaining 4.2% have an aspect ratio not exceeding 4.9; - the particles are not coated or surface modified. This Opinion is not applicable to hydroxyapatite (nano) composed of needle-shaped particles. The nanoXIM•CarePaste does not contains needle-shaped particles.

NATRUE	This product is approved by The International Natural and Organic Cosmetics Association (NATRUE) as a NATRUE approved raw materials, classified as 100% Nature-identical substances, being suitable for cosmetic formulations, including, but not limited, to oral care products.
Natural Origin Index (NOI)	According to the latest edition of ISO 16128-2, the Natural Origin Index (NOI) of this product is equal to 1.
Origin	This product is a fully synthetic inorganic product, produced at our site in Maia, Portugal (COO).
Parabens free	This product is a parabens free.
Palm oil	This product do not contain any palm oil source and are considered completely palm oil free. It is not used any vegetable source components or raw materials in its manufacturing process. This product is inorganic and synthetic, being manufactured, packaged and stored in a dedicated equipment and facilities.
Pesticides	This product does not contain pesticides. It is a fully synthetic inorganic product and is not derived from any animal or vegetable source.
PFAS (Per- and Polyfluoroalkyl Substances)	FLUIDINOVA has not conducted specific tests for the presence of PFAS in our product. However, we use food-grade reagents and primary packaging materials approved for food contact in our manufacturing processes. We firmly believe that these measures greatly minimize the likelihood of PFAS being present in our product.
Residual Solvents	This product is a fully synthetic inorganic product and does not contains nor it is derived from any solvent source. This product is never in contact with any solvent at any stage of its manufacturing or storage. No residual solvents are present in this product.
SLS/SLES	This product is free from Sulphate (aka Sulfate), SLS (Sodium Lauryl Sulfat), SLES (Sodium Lauryl Ether Sulfate).
Triclosan-Free	This product is free from triclosan. Triclosan is not used at any stage of our manufacturing process. From raw materials to the final product, our production exclusively involves inorganic materials.
Vegan	This product sole manufactured by FLUIDINOVA is compliant with all the VEGAN requirements. - Do not contain any ingredient of animal origin; - No process aid of animal origin is used in the production process; - Do not contain any ingredient of vegetable origin; - Do not contain alcohol and alcohol has not been used in the manufacturing process; - Do not contain known animal-derived GMOs or genes in the ingredients or finished product manufacture; - Do not involve any animal testing of ingredients or finished product; - The equipment used for the manufacturing, filling and packing is dedicated for these products and it is not used for any other processes related with products of animal or vegetable origin nor containing ingredients of animal or vegetable source; - The ingredients used to produce these products are inorganic salts and purified water.

REGULATION

Regulation (EC) No 1907/2006 - REACH

Endocrine-disrupting properties	This product does not contain any substances having endocrine-disrupting properties listed in the Candidate List published by the European Chemicals Agency (ECHA) in accordance with the procedure set out in Article 59 (10) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council.
SVHC	This product does not contain any of the REACH Substances of Very High Concern (SVHC) listed in the Candidate List published by the European Chemicals Agency (ECHA) in accordance with the procedure set out in Article 59 (10) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council.

Substances subject to authorization	This product does not contain any substances listed in Annex XIV relating to "List of substances subject to authorization" of Regulation (EC) No. 1907/2006 of the European Parliament and of the Council.
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Regulation (EC) No 1223/2009 - Cosmetic products	
Prohibited Substance	This product does not contain and is not derived from the known substances listed in Annex II of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.
Restricted Substance	This product is compliant with the restrictions outlined in reference number 372 of Annex III of Regulation (EC) No 1223/2009 of the European Parliament and of the Council regarding the use of the hydroxyapatite nanomaterial in cosmetics products. We ensure compliance with the following characteristics: - Rod-shaped particles of which at least 95.8% (in particle number) have an aspect ratio less than 3, and the remaining 4.2% have an aspect ratio not exceeding 4.9; - The particles are not coated or surface modified. We ensure compliance with the following concentrations: - Up to 10% in toothpaste (i.e. 64.5% nanoXIM•CarePaste) - Up to 0.465% in mouthwash (i.e. 3% nanoXIM•CarePaste).
Animal Non-Testing	This product complies with the animal test restrictions of the Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, in particular with the article 18 of chapter V of this regulation.

Regulation (EC) No 1272/2008 - Classification, labelling and packaging (CLP)	
CMR Substances	This product does not contain any carcinogenic, mutagenic, or toxic for reproduction (CMR) substances classified as category 1A, 1B, and 2 according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008.

Regulation (EC) No 1169/2011 - Provision of food information to consumers	
Allergens	This product does not contains and is not derived from the known allergens listed in Annex II regarding "Substances or products causing allergies or intolerances" of the Regulation (EC) No 1169/2011 of the European Parliament and of the Council of 25 October 2011. Gluten-free and Lactose-free

Proposition 65 - Safe Drinking Water and Toxic Enforcement Act	
List of chemicals known to cause cancer or reproductive toxicity	This product do not contain any of the chemicals listed on California's Safe Drinking Water & Toxic Enforcement Act of 1986, commonly known as Proposition 65 (Prop 65).

GRAS substances - Generally Recognized As Safe by the United States Food and Drug Administration (FDA)	
GRAS status	FLUIDINOVA has not submitted any products for direct FDA analysis. However, it's important to note that hydroxyapatite, the primary component of our product, is a form of calcium phosphate. Relevantly, FDA's Title 21/Chapter I/Subchapter B/Part 182/Subpart B §/182.1217 lists "Calcium phosphate" as a safe ingredient. We firmly believe that the FDA-listed "Calcium phosphate", which among others includes hydroxyapatite, reinforces the safety of our product.

Disclaimer

FLUIDINOVA monitors the information and regulations mentioned in this document. Only the changes that impact the product will be reflected in this document.

Although the information set forth herein are presented in good faith and believed to be correct as of the date hereof, the persons receiving the same will make their own determination as to its suitability for their purposes prior to use.

Additionally, it is the user's responsibility to verify, in every case, the local legislation related to the use of the product. The product specification limits are subject to change.

Please contact FLUIDINOVA for the most current data sheet.