

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

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
Particle type		rod-shaped
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 15%, 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

Absence of restricted substances: This product does not contain and it 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.

Allergen: 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 (EU) No 1169/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.

Gluten-free and Lactose-free

Animal Non-Testing: This product has not been subject to any animal testing by or on behalf of FLUIDINOVA S.A.
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.

Animal and vegetable derivatives: This product does not contain and it is not derived from any animal or vegetable source.
Therefore, any animal or vegetable based material is present in its composition.
This product is fully synthetic produced by wet chemical precipitation using purified water and inorganic chemical reactants.

BSE/TSE: 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. There are no additives or extracts of the brain, spinal cord, bone marrow, or eyes of any animal. The product does not contain, nor is it derived from any category A, B or C materials as defined in the Note for Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products (EMA/410/01 rev.3) (2011/C 73/01). Bovine Spongiform Encephalopathy (BSE) / Transmissible Spongiform Encephalopathy (TSE) should not be a concern associated with the use of this product.

CMR substances: This product does not contains 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.

Dyes free: This product is dye free. No dyes are used at any stage of the production process.

GMO: This product is not genetically modified or not derived from a genetically modified organism as defined by the EC regulations:
- Directive 2001/18/EC on the deliberate release of GMOs into the environment
- Regulation (EC) 1829/2003 on genetically modified food and feed
- Regulation (EC) 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.

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 product 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.

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.

The Final Opinion SCCS/1648/22 (https://health.ec.europa.eu/publications/hydroxyapatite-nano-0_en) and safe use conclusions will only apply to the nano-hydroxyapatite with the characteristics of nanoXIM.CarePaste product referred in the studies and manufactured only by FLUIDINOVA. For more information, visit <https://fluidinova.com/nano-safety>.

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.

Origin: This product is fully synthetic, 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 comply with Regulation 2005/396/EC on maximum level of pesticides in or on food and feed and animal origin and its amendments.

Prop. 65: 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).

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, SLES.

SVHC: This product do not contain any of the REACH Substances of Very High Concern (SVHC), according to the Candidate list published by ECHA (European Chemical Agency).

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.

MISCELLANEOUS

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.