

	Dossier technique et réglementaire <i>Technical and regulatory document</i> CIRE D'ABEILLE CERA ALBA	Octobre 2024 / <i>October 2024</i>
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INCI : **Cera Alba**
N° CAS : 8012-89-3
N°EINECS/ELINCS: 232-383-7

DESCRIPTION / DESCRIPTION:

Cire obtenue par blanchiment de cire d'abeille jaune / *Wax obtained by whitening of yellow beeswax*

CTFA NAME: *Beeswax*

Matière première conforme à la Pharmacopée Européenne en vigueur (monographie: **Cire d'abeille blanche**) /
*Raw material according to the European Pharmacopoeia in force (monograph: **white beeswax**)*

CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:

CARACTERISTIQUES	SPECIFICATIONS	METHODES / METHODS
Aspect	Pastilles ou écailles / pellets or flakes	visual
Point de goutte / <i>Dropping form</i>	61 – 66 (°C)	Ph. Eur
Indice d'acide / <i>Acid value</i>	17 – 24 mg KOH / g	Ph. Eur
Indice d'ester / <i>Ester value</i>	70 – 80 mg KOH / g	Ph. Eur
Indice de saponification / <i>Saponification value</i>	87 – 104 mg KOH / g	Ph. Eur
Ratio ester acide / <i>Ester acid ratio</i>	3.3 – 4.3	Ph. Eur

Ces éléments seront repris sur nos BA / these elements will be on our CoA

CARACTERISTIQUES A TITRE D'INFORMATION / ADDITIONAL INFORMATION:

Pratiquement insoluble dans l'eau, partiellement soluble dans l'éthanol chaud (90% V/V) et complètement soluble dans les huiles gras et essentiels / *Practically insoluble in water, partially soluble in hot ethanol (90%V/V) and completely soluble in fatty and essential oils*

Densité relative / *Relative density: about 0.960 g/ml*

ISO 16128:

Substance INCI name	Ingredient type	% mass fraction	Natural index	Natural origin index	Organic index	Organic origin index
<i>Cera Alba</i>	<i>Natural</i>	100%	1	1	0	0
Natural origin content % (the mass percentage, between 0% and 100%, of all natural ingredients and natural portions of derived natural ingredients in the product.)						100%

APPLICATIONS :

Cosmétique, Produits de soins personnels / *Cosmetic, Personal care products*

(Is an excellent consistency agent that nourishes, moisturizes and softens the skin. Due to its high compatibility, it is very easy to use in all type of formulations.)

CONDITIONNEMENT STANDARD / STANDARD PACKAGING :

Sacs 25 Kg / *25 kg bags*

En raison du comportement collant spécifique de la cire d'abeille, des agglomérats/flocons de granulés peuvent se produire / *Due to the specific sticky behaviour of Beeswax, pellets agglomerates/flakes may occur.*

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Ne pas ouvrir les sacs tissés en coupant le tissage. Ces sacs sont cousus par une ficelle. Couper les 2 bouts à gauche et à droite de l'ouverture et ensuite ouvrir les 2 rabats à la main. La ficelle reste bien sûr cousu dans le tissage

Do not open the weaved bags by cutting the weave. These bags are sewn by a string. Cut the 2 ends left and right of the opening and then open the 2 flaps by hand. The string is of course sewn into the weave

Additives	does not contain additives, preservatives or antioxidants. This product is exempted of nonylphenol, alkylphenols, phenol, nitrosamines. Doesn't contain Bisphenol A. doesn't contain PABA.					
Allergen	Does not contain any of the allergens listed in the Regulation (EC) No 1223/2009 (Annex III), as well as in the Regulation (EU) 2023/1545. Gluten free					
Animal Testing	Has not been tested on animals					
BSE - Bovine Spongiform Encephalopathy	This product is not from cattle, sheep or goat origin and no BSE derived materials or processing aids are employed in the manufacture of the product					
California Prop 65	Does not contain any substances listed in the proposition 65.					
Carcinogenic, Mutagenic and Reprotoxic (CMR)	Does not contain any substances listed in regulation 1272/2008 and amendments : Commission Regulation (CE) n° 790/2009 and n°286/2011 as well as in the Regulation 2023/1490 .					
Composition	INCI/USA	INCI/EEC	CAS N°.	EINECS / ELINCS N°	Function	%
	Beeswax	Cera Alba	8012-89-3	232-383-7	Consistency agent	100 %
Cosmetic	In conformance to the Regulation (EC) No 1223/2009 in respect to the use in Cosmetic products, this product is exempted of prohibited substances (Annex II) and restricted substances (Annex III)					
Cosmos / Ecocert	This product is Cosmos approved					
Danger	This product is not classified as dangerous in accordance with CLP and ADR					
Dioxane	<i>No data available</i>					
Ecolabel	<i>No data available</i>					
European Pharmacopeia	Conform to the European Pharmacopeia					
Food	Not for human Consumption					
Genetically Modified Organisms (GMO)	- does not contain GMO's or GMO derived components - no GMO derived materials or processing aids are employed in the manufacture of this product.					
Inventories	Europe No restriction USA No restriction Canada No restriction Japan No restriction China No restriction Korea No restriction					
Geographic origin (for plant)	Not concerned					
Glycol ether	Exempted of glycol esters					
Halal	This product has been manufactured in conformity to the following conditions: - Contains animal derived substances : wax derived from bees secretion. - Does not contain alcohol and has not been produced by using alcohol. - All the equipment, tools, dispensers and carriages employed in the production, filling and packaging have never been in contact with animal-derived products.					

Heavy Metals	Pb	<LOQ (LOQ = 0.05ppm)
	As	<LOQ
	Cd	<LOQ
	Hg	<LOQ
	Cr	<LOQ
	Ni	<LOQ
	Others	≤ < 3 ppm
	HS code	15219099
Irradiation / ionization	Has not been treated with ionizing radiation	
Kosher	<p>This product is a bees derived ingredient conforming to Kosher requirements at all stages of the production, handling, and labelling of the item, under the following conditions :</p> <ul style="list-style-type: none"> - Does not contain any alcohol and any sort of alcohol are used during the manufacturing process. - Does not contain any ingredients or derived ingredients of the banned list, including pig, hare, hyrax and camel. . - All equipment used for the manufacture of this product are not used for the manufacture of any other products. - The manufacturing process does not contain any sort of animal product and product is stored into clean and neat warehouses whereas there is no presence of animals in the surrounding area of the plant. 	
Latex	Doesn't contain latex	
Manufacturing location	France	
Microbiological data	<p>This product respects the below microbiological parameters :</p> <ul style="list-style-type: none"> • Bacteria specification < 1000 cfu/g/ml • Yeasts and molds specification < 100 cfu/g/ml • Absence of pathogen micro-organisms : <ul style="list-style-type: none"> - Absence of Pseudomonas aeruginosa - Absence of Escherichia coli - Absence of Staphylococcus aureus - Absence of Enterococcus faecium and Enterococcus faecalis - Absence of Candida albicans 	
Microplastic	Does not contain microplastics in accordance with Microplastics Regulation (EU) 2023/2055	
Nanomaterials	We hereby confirm the absence of nanomaterials in this product in accordance with the definitions according to the Cosmetics Regulation (EC) No 1223/2009, French Decree No 2012-232 and the Commission Recommendation on the definition of nanomaterial 2022/C229/01 (updating Recommendation 2011/696/EU).	
Nutritional data	<i>No data available</i>	
Origin	100% natural – animal (exudation of the abdominal glands of the honeybee – origin China)	
Pesticide	<i>No data available</i>	
PFAS	is free from PFAs (Polyfluoroalkyl and Polyfluoroalkyl Substances).	
Phthalate	Exempted of Phthalates	
Preservative	Doesn't contain preservatives	
Process	<p>Beeswax is an exudation of the abdominal glands of the honeybee. Crude Beeswax color varies from pale yellow to brownish due to the presence of pollen and honey. The crude wax is then processed through a non-chemical bleaching process to achieve a light, white color and to obtain this product.</p> <p>The crude wax is carried out in a multistage process :</p>	

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	Melted under steam heating Purified with filter press (specific) Decolorised with bleaching earth Re-purified with filter press (specific). Under high temperature, the wax is filtered on a paper filter of 5µm, to be then transformed in pellets. The product is then packed in bags of 25 kg
REACH	Compliant with the Regulation (CE regulation n°1907 / 2006) Exempted Annex V ch 7
Residual Solvents	Is solvent free
RSPO	The product doesn't contain palm derivatives – Not concerned
Shelf Life	24 months in original unopened containers
Substances of Very High Concern (SVHC)	This product doesn't contain substances identified as SVHC featuring in the "REACH candidate list" published.
Vegan	We hereby declare that this product is obtained in respect of the natural eco-system and in respect to our environmental policy. Manufacturer is in favour of sustainable and controlled sourcing, respectful of public health and the planet: "In the case of the Beeswax, we established strong partnership with our supplier of crude Beeswax and we organize regular visits to implement a common environmental charter and thereby control environmental performance through systematic monitoring and supervision of processes and products. Beeswax is a natural by-product created during honey production. The wax is secreted by honey bees as part of a natural process, and forms a significant part of the structure of a bee's hive. Essentially, bees collect nectar, produce honey and wax in the hive, and the life cycle of their colony will continue indefinitely Our charter is focus on bees protection and hives preservation by harvesting the wax in an ethical way to ensure a continuity of the bee's life cycle. Besides that, we participate in the development of the agro-system by investing in the sponsorship and protection of wild hives on the French Riviera. Veganism is a way of living which seeks to exclude, as far as is possible and practicable, all forms of exploitation of, and cruelty to, animals for food, clothing or any other purpose."
Volatiles organic compounds (VOC)	Doesn't contain VOC

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Ce document annule et remplace tous documents techniques ou réglementaires précédents / *This document cancels and replaces all technical and regulatory previous documents.*