



Dossier technique et réglementaire / *technical and regulatory document*

Novembre 2025 /
November 2025

OZOKERITE

INCI: **Ozokerite**

N° CAS: 64742-33-2(ou 8021-55-4)

N°EINECS/ELINCS: 265-134-6

DESCRIPTION / DESCRIPTION :

Ozokérite raffinée de structure microcristalline / *Refined Ozokerite microcrystalline structure*

CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:

CARACTERISTIQUES	SPECIFICATIONS	METHODES / METHODS
Couleur / <i>Color</i>	Blanche / <i>White</i>	Visuel / <i>Visual</i>
Point de fusion / <i>Melting point</i>	78 – 82°C	Lecture directe
Pénétration à 25°C / <i>Penetration at 25°C</i>	9 – 13°C	NFT 60-123
Viscosité à 100°C / <i>Viscosity at 100°C</i>	8 – 12 mm ² /s	ISO 3104

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

CARACTERISTIQUES A TITRE D'INFORMATION / ADDITIONAL INFORMATION :

Insoluble dans l'eau / *Insoluble in water*

Ne respecte pas les exigences du Colipa 14 du fait d'une viscosité à 100°C non-garantie ≥ 11 cSt / *doesn't comply to the colipa regulation because of viscosity 100°C not guaranty ≥ 11 cSt*

Vegan product

ISO 16128 :

Natural Index = 0

Natural Origine Index = 0

Organic Index = 0

Organic Origine Index = 0

APPLICATIONS :

Cosmétologie, Pharmacie / *Cosmetology, Pharmacy*

CONDITIONNEMENT STANDARD / STANDARD PACKAGING :

Pain de 1,25kg logés en carton de 25 kg / *Bread of 1,25kg housed in cardboard of 25 kg*

Additives	BHT is present due to manufacturing ingredient
Allergen	This product doesn't contain allergens (1169/2011, 1223/2009 & 2023/1545)
Animal Testing	Ozokerite MD has not been tested on animals
BSE - Bovine Spongiform Encephalopathy	No risk of BSE
California Prop 65	This product (CAS: 64742-33-2) is not listed
Carcinogenic, Mutagenic and Reprotoxic (CMR)	This product doesn't contain CMR (1272/2008)
Composition	100% Ozokerite
Cosmetic	This product can be used in cosmetic
Cosmos / Ecocert	Not accepted by cosmos standards
Danger	This product is not classified as dangerous in accordance with CLP and not applicable to ADR



Dioxane	<i>No data available</i>	
Ecolabel	<i>No data available</i>	
European Pharmacopeia	The ingredients for this mixture are complying to current European pharmacopoeia	
Food	<i>No data available</i>	
Genetically Modified Organisms (GMO)	Not expected	
Inventories	Cas 64742-33-2 is listed in USA TSCA, New Zealand NZIoC,	Korea KECL, Australia AIC, Canada NDSL
Geographic origin (for plant)	Not concerned	
Glycol ether	This product doesn't contain glycol ether	
Halal	Not certified	
Heavy Metals	Metals catalysis content < 1ppm	
HS code	<i>No data available</i>	
Irradiation / ionization	This product did not undergo any ionization step	
Kosher	Not certified	
Latex	This product doesn't contain latex	
Manufacturing location	France	
Microbiological data	Not expected due to water absence	
Microplastic	Not expected (2023/2055)	
Nanomaterials	This product doesn't contain nanomaterial (2011/696 & 1223/2009)	
Nitrosamine	Not expected	
Nutritional data	<i>No data available</i>	
Origin	100% mineral	
PAH/PFAS	PFAS are not expected	
Pesticide	This product doesn't contain pesticide	
Phthalate	This product doesn't contain phthalates	
Preservative	<i>No data available</i>	
Process	Mixture of microcrystalline wax and paraffin	
REACH	This product is exempted from registration REACH (< 1 Ton)	
Residual Solvents	This product doesn't contain residual solvents (note CPMP/ICH/283/95)	
RSPO	Doesn't contain palm derivative – not concerned	
Shelf Life	3 years	
Substances of Very High Concern (SVHC)	This product doesn't contain SVHC	
Volatiles organic compounds (VOC)	VOC content < 3% (2010/75 & 2004/42)	

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