

## Dossier technique et réglementaire / Technical and regulatory document

## **KAOLIN LIGHT BP**

Juillet 2019 / July 2019

INCI: **Kaolin** N° CAS: 1332-58-7

N°EINECS/ELINCS: 310-194-1

#### **DESCRIPTION / DESCRIPTION:**

Ce produit est du silicate naturel d'aluminium raffiné qui contient un agent dispersant approprié / This product is refined natural aluminum silicate which contains a suitable dispersing agent.

Produit conforme à la Pharmacopée Anglaise / Product conforms to the British Pharmacopoeia

#### **CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:**

CARACTERISTIQUES	SPECIFICATIONS	METHODES / METHODS
Arsenic / Arsenic	≤ 2 ppm	ВР
Métaux lourds / Heavy metals	≤ 20 ppm	ВР
Chlorure / Chloride	≤ 330 ppm	ВР
Matière soluble / Soluble matter	≤ 10 mg	ВР
Grosses particules / Coarse particles	≤ 25 mg	ВР
Fines particules / Fine particles	≥ 70 wt %	ВР
Perte à la dessication / Loss on drying	≤ 1.5 wt %	ВР
Perte au feu / Loss on ignition	≤ 15 wt %	ВР

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

Ces caractéristiques sont conformes aux précédentes spécifications datées de Fevrier 2014 / These features are in accordance with previous specifications dated on February 2014

#### CARACTERISTIQUES A TITRE D'INFORMATION / ADDITIONAL INFORMATION:

Point de fusion, méthode A1 de l'EU /  $Melting\ point$ ,  $EU\ A1\ method$ : > 450°C Densité relative /  $Relative\ Density$ : 2.6

#### **APPLICATIONS:**

Additif fonctionnel / Functional additive

#### **CONDITIONNEMENT STANDARD / STANDARD PACKAGING:**

Sac de 25 kg / 25kg bag

Matière première non classifiée comme substance dangereuse / Raw material not classified as dangerous substance

Additives	This product is a naturally occurring mineral, as such this product doesn't naturally contain aflatoxins, bisphenol A, diethylene glycol (DEG), PVC (polyvinylchloride), PAHs (polycyclic aromatic hydrocarbons) melamine, nitrosamines, formaldehyde and none of these substances are added during any stage of the production process. No routine presence testing is performed
Allergen	This product is a naturally occurring mineral. As such, this product doesn't naturally contain any allergens. No allergens or allergenic substances are added during any stage of the production process. With respect to the cosmetics, this product doesn't naturally contain any detectable quantity of the allergens listed in European Council



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	Directive 76/768/EEC and subsequent amendments or regulation (EC) No 1223/2003,
	which replaced it.
	This product doesn't naturally contain gluten and no gluten is added during any stage
	of the production process. No routine presence testing is performed
Animal Testing	This product has not been tested or retested on animals for use in a cosmetic or household product.
BSE - Bovine	This product doesn't contain BSE. The production of this product doesn't use
Spongiform	ingredients from animal parts or their derivatives. This product doesn't come into
Encephalopathy	contact with animal products or derivatives during the manufacturing process. No
	routine presence testing is performed
California Prop 65	Kaolin products are not listed in the Californian Safe Drinking Water and Toxic
	Enforcement Act of 1986 "Proposition 65" Listing. With the exception of trace amount
	of the naturally occurring impurities titanium (as dioxide/TiO <sub>2</sub> ), crystalline silica
	(SiO <sub>2</sub> /quartz), arsenic, cadmium, chromium, lead, mercury, and nickel, no listed
	materials are naturally present in this product. No listed materials are added during
	any stage of the production process and none of the materials used during the
	production of this product contains or is contaminated with listed materials
Carcinogenic,	No data available
Mutagenic and	
Reprotoxic (CMR)	
Composition	This product is produced from naturally occurring mineral deposits. In accordance with
•	the requirements of the current British Pharmacopoeia Monograph for Light Kaolin BP,
	in addition to kaolin, this product contains ≤ 2 % or pure (i.e., food grade), tetrasodium
	pyrophosphate ("TSPP")
Cosmetic	This product doesn't 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
Cosmos / Ecocert	
Danger	This product is not classified as dangerous in accordance with CLP and ADR
Dioxane	Samples of this product grades have been found to be below the maximum permitted
	limit of dioxin set by the European Union. Periodic testing is conducted to ensure that
	the product continue to meet these limits
Ecolabel	No data available
European	This product is compliant with British Pharmacopoeia
Pharmacopeia	
Food	This product is conform to food contact as FDA 21CFR186 or directive 2002/72/CE
<b>Genetically Modified</b>	This product is not a living organism and so has no genes to manipulate. As such, this
Organisms (GMO)	product doesn't naturally contain any GMOs. No GMOs are added during any stage of
	the production process. No routine presence testing is performed
Inventories	Compliant with China IECSC and IECIC, USA TSCA, New Zealand NZIoC, Japan ENCS,
	ISHL and MITI, Korea KECI and KECL, Philippines PICCS, Australia AICS, Canada DSL,
	Swiss Ordinance 817.023.21, Taiwan TCSI
Geographic origin	Australia
Glycol ether	This product doesn't naturally contain any glycol ethers. No glycol ethers are added
	during any stage of the production process. No routine presence testing is performed.
Halal	This product is not halal certified but it is in accordance with the Halal requirements
Heavy Metals	This product complies with the limits specified in the British Pharmacopoeia (max 20
	ppm)
HS code	25070020
Irradiation / ionization	This product doesn't receive any type of irradiation treatment during its production or
	storage
Kosher	This product is not kosher certified, but it is in accordance with the kosher
	requirements
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Latex	This product doesn't naturally contain any latex. No latex is added during any stage of
	the production process of this product. No routine presence testing is performed
Manufacturing location	Australia
Microbiological data	No data available
Nanomaterials	This product is not intentionally manufactured to be a nanomaterial. No nanomaterials
	are added during any stage of the production process of this product. None of the
	materials used during the production contains or is contaminated with any
	nanomaterials. According to the internal assessment and in the absence of any
	available harmonized methods of Commission Recommendation 2011/696/EU and
	Cosmetics regulation (EC) No1223/2009, this product doesn't fall under the definition
	of a nanomaterial
Nutritional data	No data available
Origin	100% mineral
Pesticide	This product doesn't naturally contain any pesticides. No pesticides are added during
	any stage of the production process. No routine presence testing is performed
Phthalate	This product doesn't naturally contain any phthalates. No phthalates are added during
	any stage of the production process. No routine presence testing is performed
Preservative	This product doesn't naturally contain any parabens. No parabens are added during
	any stage of the production process. No routine presence testing is performed
Process	The natural kaolin are drawn from separate open cut mine sites, blended and then
	refined to desired particle sizes using wet processing techniques such as
	hydrocyclones, centrifuges and setting tanks to achieve the correct final product
	specifications
REACH	This product is exempted by annex V as "substances which occur in nature and which
	are not chemically modified"
Residual Solvents	This product doesn't naturally contain any residuals solvents. No residuals solvents are
	added during any stage of the production process. No routine presence testing is
	performed. This product meets the requirements of USP <467> RESIDUAL SOLVENTS
RSPO	This product doesn't naturally contain any palm oil or palm oil derivatives – Not
	concerned
Shelf Life	2 years
<b>Substances of Very High</b>	This product doesn't naturally contain any SVHC (as defined in article 57 of regulation
Concern (SVHC)	(EC) no. 1907/2006 ("the Reach regulation")) above the maximum permitted values.
	No SVHCs are added during any stage of the production processes.
Volatiles organic	This product doesn't naturally contain any VOCs or SVOVs. No VOCs or SVOVs are
compounds (VOC)	added during any stage of the production process. No routine presence testing is
	performed

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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.