



CERTIFICATE OF ANALYSIS

BP Light Kaolin (BPLK)

A sample of the above mentioned product has been tested in the manner defined by the specification of the 2021 British Pharmacopoeia, and has been found satisfactory.

Best Before Date April 2025

Batch No: **4466510**

Description:

A light, white powder free from gritty particles; odourless or almost odourless; unctuous. It contains a suitable dispersing agent.

Solubility:

Practically insoluble in water and in mineral acids.

Identification:

A native hydrated aluminium silicate.

Identification Tests A, B and C: Product conforms with requirements of 2021 British Pharmacopoeia.

Results:

	<u>Results Batch 21/7</u>	<u>Test Limits: Max.</u>
<u>Loss on Drying</u>	0.33%	1.5%
<u>Loss on Ignition</u>	11.86%	15.0%
<u>Identification Test A</u>	Passes Test	
<u>Identification Test B</u>	Passes Test	
<u>Identification Test C</u>	Passes Test	
<u>Coarse Particles</u>	1.8 mg	25mg
<u>Fine Particles</u>	77.31%	70% minimum
<u>Chloride</u>	Passes Test	330ppm
<u>Soluble Matter</u>	9.0 mg	10mg
<u>Arsenic</u>	<2 ppm	2ppm
<u>Heavy Metals*</u>	Passes Test	20ppm
<u>+ 53 micron residue**</u>	16	250ppm

*tested by 2013 B.P. monograph

** Imerys Method ATM 03



Date: 14 February 2019

Issue 8

BP LIGHT KAOLIN REGULATORY SUPPORT PACKAGE

This regulatory support package includes information on manufacturing and applicable regulatory information for the BP Light Kaolin. This support package is modified as needed to reflect the most current information so users are encouraged to check for updates.

Section 1 - General Product Information

Product: BP Light Kaolin

Chemical Names: Kaolin, Aluminium silicate

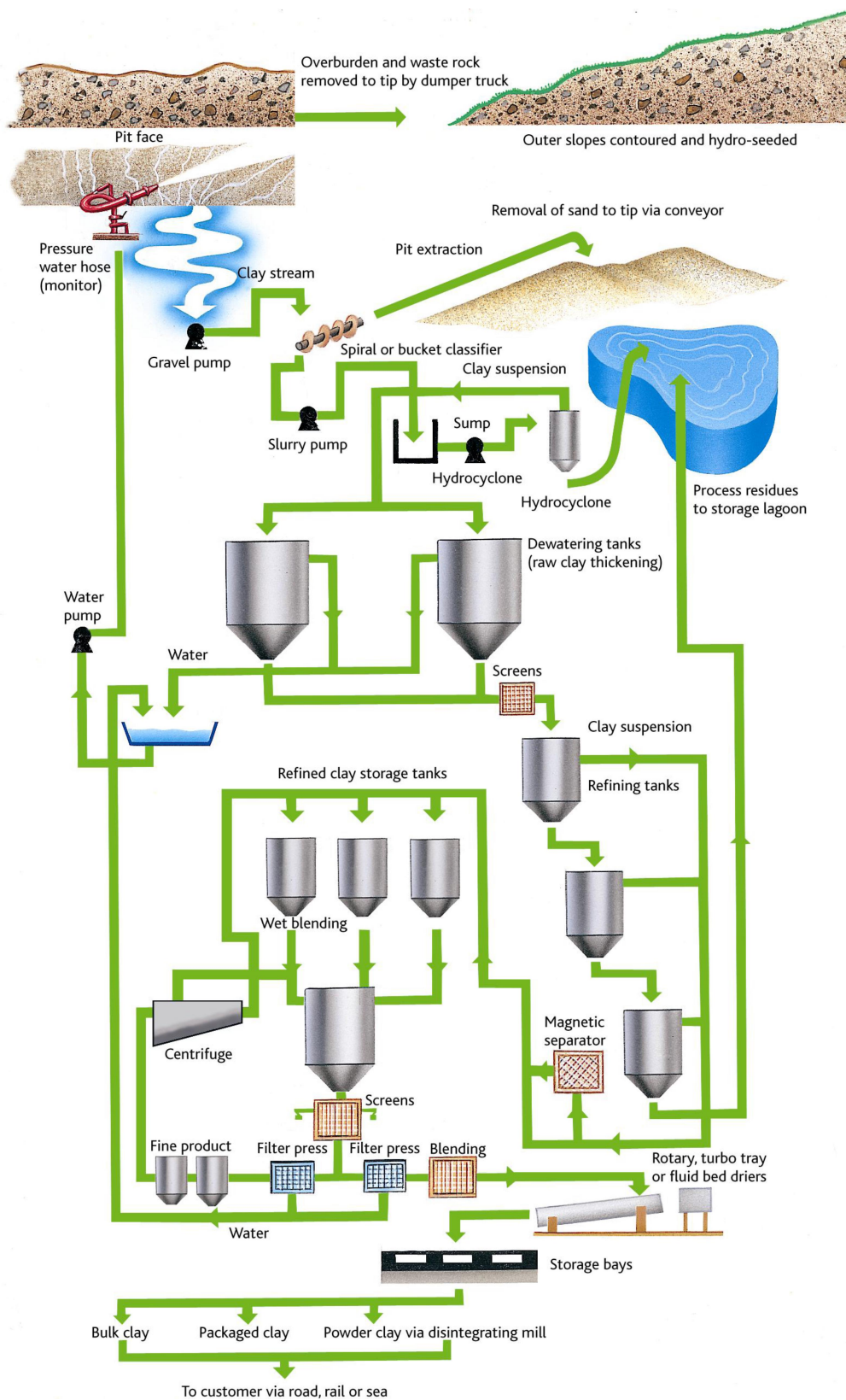
Plant: European Milling Centre (Cornwall, UK)

Section 2 - Manufacturing Information

Brief Description of Manufacture (from the Industrial Minerals Association Kaolin Factsheet (www.ima-eu.org))

“Kaolin is a white, soft, plastic clay mainly composed of fine-grained plate-like particles. Kaolin is formed when the anhydrous aluminium silicates which are found in feldspar rich rocks, like granite, are altered by weathering or hydrothermal processes. The process which converted the hard granite into the soft matrix found in kaolin pits is known as "kaolinisation". The quartz and mica of the granite remain relatively unchanged whilst the feldspar is transformed into kaolinite. Smectite may also form in small quantities in some deposits. The refining and processing of the fine fraction of the kaolinised granite yields predominantly kaolinite with minor amounts of mica, feldspar, traces of quartz and, depending on the origin, organic substances and/or heavy minerals. Kaolin is quarried from open-cast pits using either excavators or high-pressure hoses. The required grades are initially selected at the pit face and further selection and refining occurs throughout its production. It passes through a series of refining and grinding processes to achieve the required particle size. Further modifications may be made to the product by bleaching, magnetizing and classification.”

The following diagram is a schematic generic flow chart for the production of kaolin





Section 3 - Physical/Chemical Information

CAS Number: 1332-58-7

EC (EINECS) No: 310-194-1

Section 4 - Compliance Information

Aflatoxins: Kaolin is a naturally occurring mineral. As such, BP Light Kaolin does not naturally contain any aflatoxins. No aflatoxins are added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with aflatoxins. No routine presence testing is performed since the presence of aflatoxins in BP Light Kaolin is not considered a reasonable possibility.

Allergens: Kaolin is a naturally occurring mineral. As such, BP Light Kaolin does not naturally contain any allergens. No allergens or allergenic substances are added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with known allergens. No routine presence testing is performed since the presence of allergens in BP Light Kaolin is not considered a reasonable possibility. Our understanding of allergens includes: animal fats, barley, beef, celery, cereals containing gluten, cocoa, coconut, corn, crustaceans, duck, egg, enzymes, fish, fruit, gelatin, gluten, lactose, lamb, latex, lupin, maize, milk, molluscs, mustard, MSG, nuts, nut oils, oats, offal, peanuts, phenylalanine, poppy seeds, pork, poultry, rye, sesame seeds, other seeds, seed oil, soya, sugar, sulphites, tree nuts, vegetables, wheat, yeast, yellow #5, vanillin (or the extracts or derivatives of any of the prior). With respect to cosmetics, BP Light Kaolin does not naturally contain any detectable quantity of the allergens listed in European Council Directive 76/768/EEC and subsequent amendments or Regulation (EC) No 1223/2009, which replaced it.

Animal Testing: To the best of our current knowledge, BP Light Kaolin has not been tested or retested on animals for use in a cosmetic or household product. Nevertheless, Imerys Minerals Limited could consider the commissioning of tests on animals to external labs if needed to fulfil regulatory commitments or for animal welfare applications.

Asbestos: Microscopic examination of kaolin grades produced by Imerys Minerals Limited has revealed no determinable amount of mineral fibre present. These findings are supported by independent examinations by Arbejdstilsynet (National Institute of Occupational Health, Denmark) on a wide range of Imerys Minerals Limited's products. The results obtained showed no fibrous material in any of the examined samples that could be suspected of being asbestos/tremolite.



Bisphenol A (BPA): Kaolin is a naturally occurring mineral. As such, BP Light Kaolin does not naturally contain any Bisphenol A. No Bisphenol A is added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with Bisphenol A. No routine presence testing is performed since the presence of Bisphenol A in BP Light Kaolin is not considered a reasonable possibility.

BSE/TSE: Kaolin is a naturally occurring mineral. As such, BP Light Kaolin does not contain any BSE (bovine spongiform encephalopathy) or TSE (transmissible spongiform encephalopathy) contamination. The production of BP Light Kaolin does not utilise ingredients from animal parts or their derivatives. Furthermore, to the best of our current knowledge, BP Light Kaolin does not come into contact with animal products or derivatives during the manufacturing process. No routine presence testing is performed since the presence of BSE/TSE contamination in BP Light Kaolin is not considered a reasonable possibility.

California Proposition 65: Kaolin products are not listed in the California Safe Drinking Water and Toxic Enforcement Act of 1986 "Proposition 65" Listing. With the exception of trace amounts of the naturally occurring impurities titanium (as dioxide/TiO₂), crystalline silica (SiO₂/quartz), arsenic, cadmium, chromium, lead, mercury, and nickel, no listed materials are naturally present in BP Light Kaolin. No listed materials are added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with listed materials.

CLP: The labelling and packaging of BP Light Kaolin is in accordance with Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures ("the CLP Regulation").

CMR: Kaolin is a naturally occurring mineral. As such, BP Light Kaolin does not naturally contain any substances classified as CMR (carcinogenic, mutagenic or reprotoxic). No substances classified as CMR are added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with any substances classified as CMR. No routine presence testing is performed since the presence of substances classified as CMR in BP Light Kaolin is not considered a reasonable possibility.

Composition: BP Light Kaolin is produced in the UK from naturally occurring mineral deposits. In accordance with the requirements of the current British Pharmacopoeia Monograph for BP Light Kaolin, in addition to kaolin, the product contains ≤ 2 % of pure (i.e., food grade) tetrasodium pyrophosphate ("TSPP").

CONEG: The US Coalition of North-Eastern Governors' (CONEG) Model Toxics in Packaging Legislation specifies that the sum of concentration levels for lead, cadmium,



mercury, and hexavalent chromium present in packaging or packaging materials must not exceed 100 ppm by weight. BP Light Kaolin naturally contains less than 100 ppm by weight of the sum of concentration levels for lead, cadmium, mercury, and hexavalent chromium. In addition, no lead, cadmium, mercury or hexavalent chromium is added during any stage of the production process for BP Light Kaolin. BP Light Kaolin therefore complies with the CONEG requirements.

Conflict Minerals: In July 2010 President Obama of the USA signed into law H.R. 4173 - "Dodd-Frank Wall Street Reform and Consumer Protection Act". Among other things, this law imposes requirements relating to "Conflict Minerals". Specifically, Section 1502 imposes Securities & Exchange Commission (SEC) reporting requirements upon manufacturers if their products contain metals derived from minerals defined as "Conflict Minerals". These minerals include columbite-tantalite (coltan, niobium, tantalum), cassiterite (tin), gold, wolframite, or their derivatives or any other mineral or its derivatives determined by the US Secretary of State to be financing conflict in the Democratic Republic of the Congo or an adjoining country. BP Light Kaolin can in no way be considered as a mineral from which these metals can be obtained. Furthermore, all the kaolin processed by Imerys Minerals Limited is sourced from Imerys' own deposits and refined in our own facilities.

Cosmetics: Kaolin does not 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.

CTPA: The CTPA (Cosmetic Toiletry and Perfumery Association) requires that cosmetic ingredients comply with the EU cosmetics Directives. European Council Directive 76/768/EEC and subsequent amendments were repealed when Regulation (EC) No 1223/2009 came into force on 11 July 2013. The Annexes to the new Regulation list the substances that are prohibited (Annex II) and restricted (Annex III) for use in cosmetic products. Kaolin does not appear among the prohibited substances listed in Annex II, nor is it among the substances in Annex III that can only be used with restrictions. BP Light Kaolin does not contain preservatives, including those listed in Annex V.

Customs Code: 2507 00 20

Diethylene Glycol (DEG): Kaolin is a naturally occurring mineral. As such, BP Light Kaolin does not naturally contain any DEG. No DEG is added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with DEG. No routine presence testing is performed since the presence of DEG in BP Light Kaolin is not considered a reasonable possibility.

Dioxin: Samples of the kaolin grades produced by Imerys Minerals Limited have been found to be below the maximum permitted limit of dioxin set by the European Union. Periodic testing is conducted to ensure that our products continue to meet these limits.



EN71 & Directive 2009/48/EC: The EN71 Standard is based on Directive 2009/48/EC on the safety of toys. The scope of both the EN71 Standard and Directive 2009/48/EC is finished articles. Raw materials therefore fall outside the scope of both the Standard and the Directive. Part 3 of the EN71 Standard for finished articles concerns "Specifications for the migration of certain elements". The permitted limits specified in Annex II Section III. 13 of Directive 2009/48/EC are for the migration of substances from the finished articles. Migration testing, therefore, has to be carried out only on the finished articles, not on the raw materials. We do not have any data for the migration properties of chemical elements from BP Light Kaolin. Neither the Standard nor the Directive gives limits for the content of specified chemical elements in the raw materials.

EuPIA: BP Light Kaolin complies with the "EuPIA Exclusion Policy for Printing Inks and Related Products".

Flammability/Dust Explosion: Kaolin is a naturally occurring mineral. BP Light Kaolin is non-inflammable, possesses little chemical reactivity, and is non-hazardous. Additionally, the material possesses no special explosion or fire protection requirements. To the best of our current knowledge BP Light Kaolin does not exhibit any explosive properties. As such, values for maximum pressure rise (Kst) and maximum explosion pressure (Pmax), minimum explosion concentration (MEC), minimum spark ignition energy (MIE), and minimum dust cloud ignition temperature (Tc) are not available and cannot be measured in any meaningful way. However, during handling, particularly when air conveying, the product may exhibit charge accumulation properties. This phenomenon does not alter the classification of kaolin as a non-reactive material. It is advised that all customers assess their own operations in accordance with the EU Explosive Atmosphere Directives (ATEX Directives) for any potentially hazardous scenarios.

Food Contact:

- FDA: The United States Code of Federal Regulations lists kaolin as a substance affirmed as Generally Recognised As Safe (GRAS) under the FDA in accordance with 21 CFR 186. As such, no limitation is placed on the use of kaolin in an indirect food contact application other than current good manufacturing practice.
- Kaolin is described by European Commission Scientific Committee on Food (SCF) Synoptic Document No.7 as inert materials and appears on SCF List 3 without any specified Acceptable Daily Intake (ADI).
- Kaolin is permitted for use without restrictions in food contact applications under Bundesinstitut für Risikobewertung (BfR) recommendation XXXVI (of 1st September 2017) Section A.II, XXXVI/1 Section I.B.2 and XXXVI/2 Section I.B.2. Furthermore kaolin appears under Bundesinstitut für Risikobewertung (BfR) recommendations Section LII (of 1st September 2017) Fillers for Commodities Made of Plastic and may be used without restrictions.



- Regulation (EC) No 1935/2004 ("the framework Regulation") states that materials and articles:- "under normal or foreseeable conditions of use, do not transfer their constituents to food in quantities which could: (a) endanger human health; or (b) bring about an unacceptable change in the composition of the food; or (c) bring about a deterioration in the organoleptic characteristics thereof." BP Light Kaolin complies with these requirements.
- European Regulation (EU) no. 10/2011 of 14 January 2011 repealed European Commission Directive 2002/72/EC and its amendments. Regulation (EU) no. 10/2011 and subsequent amendments provide a list of additives that may be used in the manufacture of plastic materials and articles for food contact applications. Kaolin continues to be authorised for use as a starting substance in the manufacture of plastic materials and articles intended to come into contact with foodstuffs with no restrictions.
- "Kaolin", FCA No. 0779, CAS No. 1332-58-7, appears in the National Standard of the People's Republic of China GB9685-2016 ("*National Food Safety Standard/ Standards for the Uses of Additives in Food Contact Materials and Articles*") and is authorised for use in plastic (PP, PE, PS, PVC, PA, PC, ABS, AS, PET, UP), coating, ink, adhesive, and paper food contact materials and articles with no restrictions.

Formaldehyde: Kaolin is a naturally occurring mineral. As such, BP Light Kaolin does not naturally contain any formaldehyde. No formaldehyde is added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with formaldehyde. No routine presence testing is performed since the presence of formaldehyde in BP Light Kaolin is not considered a reasonable possibility.

Fragrance: Kaolin is a naturally occurring mineral. As such, BP Light Kaolin does not naturally contain any fragrances. No fragrances are used during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with any fragrances. No routine presence testing is performed since the presence of fragrances in BP Light Kaolin is not considered a reasonable possibility.

Genetically Modified Organisms (GMO): Kaolin is a naturally occurring mineral. Kaolin is not a living organism and so has no genes to manipulate. As such, BP Light Kaolin does not naturally contain any GMOs. No GMOs are added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with any GMOs. No routine presence testing is performed since the presence of GMOs in BP Light Kaolin is not considered a reasonable possibility.



Global Automotive Declarable Substance List (GADSL): Kaolin is a naturally occurring mineral. As such, BP Light Kaolin does not naturally contain any materials or substances in the Global Automotive Declarable Substance List (GADSL) of prohibited and declarable substances in the automotive industry above the maximum permitted values. No material or substance in the Global Automotive Declarable Substance List is added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with any material or substance in the Global Automotive Declarable Substance List. No routine presence testing is performed since the presence in BP Light Kaolin of materials and substances in the Global Automotive Declarable Substance List above the maximum permitted values is not considered a reasonable possibility.

Gluten: Kaolin is a naturally occurring mineral. As such, BP Light Kaolin does not naturally contain any gluten. No gluten is added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with gluten. No routine presence testing is performed since the presence of gluten in BP Light Kaolin is not considered a reasonable possibility.

Glycol Ethers: Kaolin is a naturally occurring mineral. As such, BP Light Kaolin does not naturally contain any glycol ethers. No glycol ethers are added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with glycol ethers. No routine presence testing is performed since the presence of glycol ethers in BP Light Kaolin is not considered a reasonable possibility.

HACCP (Hazard Analysis of Critical Control Points): BP Light Kaolin is not classed as either a food ingredient or a food additive. Its production site does not, therefore, have a HACCP plan in place.

Halal: Kaolin is mineral in origin and comes from natural sources. BP Light Kaolin does not naturally contain any alcohol, drug or drug derivatives, food or product of animal origin and/or animal derivatives or fats. No alcohol, drug or drug derivatives, food or product of animal origin and/or animal derivatives or fats is added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with alcohol, drug or drug derivatives, food or product of animal origin and/or animal derivatives or fats. Loss on Ignition (LOI) testing confirms the absence of organic residues. None of the equipment used to produce BP Light Kaolin is used for the manufacture of alcohol, drug or drug derivatives, food or product of animal origin and/or animal derivatives or fats. None of the storage areas or containers used for the storage of BP Light Kaolin is used to store alcohol, drug or drug derivatives, food or product of animal origin and/or animal derivatives or fats. Based on this, the production of



BP Light Kaolin is in accordance with the compliance of Halal requirements as defined by the Halal Food Authority, UK. This voluntary declaration does not constitute a certificate granted by a religious competent authority, nor is it intended as such.

Heavy Metals: BP Light Kaolin complies with the heavy metals limits specified in the British Pharmacopoeia 2013 Monograph for BP Light Kaolin.

IFRA (International Fragrance Association): Kaolin is not listed as a prohibited ingredient (P), restricted ingredient (R) or a specified ingredient (S) in the Index of IFRA Standards.

INCI (International Nomenclature Cosmetic Ingredient) Name: Kaolin.

International Registrations:

- Kaolin appears in the following national positive lists and chemical inventories. The list is not exhaustive and is provided to the best of our current knowledge. Australian Inventory of Chemical Substances (AICS), Canadian Domestic Substances List (DSL), Chinese States Environmental Protection Administration (SEPA), Inventory of Existing Chemical Substances in China (IECSC), Inventory of Existing Cosmetic Ingredients in China (IECIC), Japanese Ministry of International Trade and Industry (MITI) Existing and New Chemical Substances (ENCS) and Industrial Safety and Health Law (ISHL), Korea Existing Chemicals Inventory (KECI), Korea Existing Chemicals List (KECL), New Zealand Inventory of Chemicals (NZIoC), Philippine Inventory of Chemicals and Chemical Substances (PICCS), Swiss Ordinance 817.023.21, Taiwan National Existing Chemical Substance Inventory, US Code of Federal Regulations Chapter 21: Food and Drugs, and US Toxic Substances Control Act (TSCA).
- Kaolin is exempt from the following; Canadian Non-Domestic Substances List (NDSL), Korea Registration and Evaluation of Chemical Substances (K-REACH), Korea Toxic Chemicals Control Law (TCCL), Malaysia Environmentally Hazardous Substances Notification & Registration Scheme (ENSNR), Mexico National Inventory of Chemical Substances (INSQ), New Zealand Toxic Substances Regulations Consolidated Schedules List, New Zealand Hazardous Substances and New Organisms (HSNO), Registration, Evaluation, Authorisation & restriction of Chemicals (REACH), Swiss Chemicals Ordinance 813.11, and Turkey Inventory and Control of Chemicals (CICR).

Irradiation: BP Light Kaolin does not receive any type of irradiative treatment during its production or storage at Imerys' facilities.

ISO: Certificates of registration to ISO 9001 and ISO 14001 standards can be requested via your usual Imerys Commercial or Sales Support contacts.

Kosher: Kaolin is mineral in origin and comes from natural sources. BP Light Kaolin does not naturally contain any alcohol or alcohol derivatives, material of animal origin or



animal derivatives. No alcohol, alcohol derivatives, material of animal origin or animal derivatives are added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with alcohol, alcohol derivatives, material of animal origin or animal derivatives. Loss on Ignition (LOI) testing confirms the absence of organic residues. None of the equipment used to produce BP Light Kaolin is used for the manufacture of alcohol, alcohol derivatives, material of animal origin or animal derivatives. None of the storage areas or containers used for the storage of BP Light Kaolin is used to store alcohol, alcohol derivatives, material of animal origin or animal derivatives. Based on this, all the ingredients and processes used in the manufacture and supply of BP Light Kaolin meet the requirements of Kosher certification. This voluntary declaration does not constitute a certificate granted by a religious competent authority, nor is it intended as such.

Latex: Kaolin is a naturally occurring mineral. As such, BP Light Kaolin does not naturally contain any latex. No latex is added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with latex. No routine presence testing is performed since the presence of latex in BP Light Kaolin is not considered a reasonable possibility.

Melamine: Kaolin is a naturally occurring mineral. As such, BP Light Kaolin does not naturally contain any melamine. No melamine is added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with melamine. No routine presence testing is performed since the presence of melamine in BP Light Kaolin is not considered a reasonable possibility.

Nano:

- BP Light Kaolin is not intentionally manufactured to be a nanomaterial. No nanomaterials are added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with any nanomaterials.
- Belgian Royal Decree of 27th May 2014: BP Light Kaolin is not intentionally manufactured to be a nanomaterial but at the fine end of the particle size distribution there may be a small proportion of particles that are $< 0.1 \mu\text{m}$, which may be considered as within the nano range. However, in accordance with the official Guidance Document to the Belgian Royal Decree of 27th May 2014 concerning the placing on the market of substances produced in nanoparticulate state, as the possible nanoparticulate state of BP Light Kaolin is a by-product of human activity and not the result of intentional manufacture, BP Light Kaolin is not required to be registered under the Belgian Royal Decree of 27 May 2014.



- Commission Recommendation 2011/696/EU: In October 2011 the EU Commission recommended a definition for “nanomaterial”. The Recommendation to Member States, Agencies and Industry aims at covering “nanomaterial” in a wide range of applications and is not yet legally binding. Due to its very broad scope the definition will be tailored over the coming years according to the area to which it will apply for regulatory purposes. In essence, the Commission’s Recommendation states that:- “Nanomaterial” means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm. The Commission has yet to define and recommend a standardised measurement to correctly quantify the number of particles in this size range. According to our internal assessment and in the absence of any available harmonised methods, BP Light Kaolin does not fall under the definition of a nanomaterial.
- Cosmetics: Regulation (EC) No 1223/2009 on cosmetic products defines a nanomaterial as “an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions or an internal surface, on the scale of 1 to 100nm”. With respect to BP Light Kaolin, at the fine end of the particle size distribution there may be a small proportion of particles that are < 0.1 µm, which may be considered as within the nano range. However, these particles are naturally present as part of the whole distribution and are not added intentionally. BP Light Kaolin does not, therefore, fall within the Regulation (EC) No 1223/2009 definition of a nanomaterial.
- Danish Inventory of Nanoproducs: Statutory Order no. 644 of 13 June 2014 established an inventory of mixtures and products that contain or release nanomaterials. The definition used for a “nanomaterial” in Statutory Order no. 644 follows the definition recommended in Commission Recommendation 2011/696/EU. BP Light Kaolin is not intentionally manufactured to be a nanomaterial but at the fine end of the particle size distribution there may be a small proportion of particles that are < 0.1 µm, which may be considered as within the nano range. However, BP Light Kaolin is exempt from REACH registration under Annex V of Regulation (EC) 1907/2006 (“the REACH Regulation”) (“substances which occur in nature and which are not chemically modified”) and it has not been intentionally produced at nanoscale. For both of these reasons BP Light Kaolin is not required to be reported to the Inventory of Nanoproducs.
- French Decree No. 2012-232: A “substance with nanoparticle status” is defined as a substance that is intentionally produced at nanometric scale, containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for a minimum proportion of particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm” and “a substance at nanoscale intentionally added in a mixture from which it is likely to be extracted or released under normal or reasonably foreseeable conditions of use”. BP Light Kaolin is not



intentionally manufactured to be a nanomaterial. No nanomaterials are added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with any nanomaterials. BP Light Kaolin does not, therefore, fall within the definitions in the French Decree No. 2012-232 of a substance with nanoparticle status.

- KEMI (Swedish Chemicals Agency): BP Light Kaolin is not intentionally manufactured to be a nanomaterial. Furthermore, no nanomaterials or materials containing nanomaterials are used during any stage of the production process for BP Light Kaolin. BP Light Kaolin is not, therefore, required to be reported to the Products Register.

Nitrosamines: Kaolin is a naturally occurring mineral. As such, BP Light Kaolin does not naturally contain any nitrosamines. No nitrosamines are used during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with any nitrosamines. No routine presence testing is performed since the presence of nitrosamines in BP Light Kaolin is not considered a reasonable possibility.

Organic: BP Light Kaolin is sourced from naturally occurring mineral deposits. BP Light Kaolin does not contain genetically modified organisms or sewage sludge nor does it undergo irradiation. The production process does not utilise solvents or volatile organics as raw materials. Many aspects of “organic” certification are debated by various agencies. It is, therefore, for each user and distributor of the product to determine how regulations relate to their individual application.

Origin: BP Light Kaolin is produced in the UK from naturally occurring kaolin mineral deposits.

Ozone Depleting Substances: Kaolin is a naturally occurring mineral. As such, BP Light Kaolin does not naturally contain any ozone depleting substances. No ozone depleting substances are added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with ozone depleting substances. No routine presence testing is performed since the presence of ozone depleting substances in BP Light Kaolin is not considered a reasonable possibility.

Packaging: BP Light Kaolin is packaged in paper bags that comply with EU Directive 94/62/EC, Regulation (EC) No 1935/2004, and with the guidelines promulgated by CONEG.

PAHs (Polycyclic Aromatic Hydrocarbons): Kaolin is a naturally occurring mineral. As such, BP Light Kaolin does not naturally contain any PAHs. No PAHs are used during



any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with any PAHs. No routine presence testing is performed since the presence of PAHs in BP Light Kaolin is not considered a reasonable possibility.

Palm Oil: Kaolin is a naturally occurring mineral. As such, BP Light Kaolin does not naturally contain any palm oil or palm oil derivatives. No palm oil or palm oil derivatives are added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with palm oil or palm oil derivatives. No routine presence testing is performed since the presence of palm oil and palm oil derivatives in BP Light Kaolin is not considered a reasonable possibility.

Parabens: Kaolin is a naturally occurring mineral. As such, BP Light Kaolin does not naturally contain any parabens. No parabens are added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with parabens. No routine presence testing is performed since the presence of parabens in BP Light Kaolin is not considered a reasonable possibility.

PCPC (Personal Care Products Council, formerly CTFA): Kaolin is listed as an approved substance.

Persistent Organic Pollutants (POPs): Kaolin is a naturally occurring mineral. As such, BP Light Kaolin does not naturally contain any POPs. No POPs are added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with POPs. No routine presence testing is performed since the presence of POPs in BP Light Kaolin is not considered a reasonable possibility.

Pesticides: Kaolin is a naturally occurring mineral. As such, BP Light Kaolin does not naturally contain any pesticides. No pesticides are added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with pesticides. No routine presence testing is performed since the presence of pesticides in BP Light Kaolin is not considered a reasonable possibility.

Phthalates: Kaolin is a naturally occurring mineral. As such, BP Light Kaolin does not naturally contain any phthalates. No phthalates are added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with phthalates. No routine presence testing is performed since the presence of phthalates in BP Light Kaolin is not considered a reasonable possibility.



PVC (polyvinylchloride): Kaolin is a naturally occurring mineral. As such, BP Light Kaolin does not naturally contain any PVC. No PVC is added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with PVC. No routine presence testing is performed since the presence of PVC in BP Light Kaolin is not considered a reasonable possibility.

REACH: Annex V of Regulation (EC) 1907/2006 ("the REACH Regulation") explicitly exempts from registration and evaluation "minerals which occur in nature, if they are not chemically modified". This is because such a registration is deemed inappropriate or unnecessary for these substances and their exemption from these requirements does not prejudice the objectives of the Regulation. Kaolin falls under this exemption and is, therefore, not registered.

Residual Solvents: Kaolin is a naturally occurring mineral. As such, BP Light Kaolin does not naturally contain any residual solvents. No residual solvents are added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with any residual solvents. No routine presence testing is performed since the presence of residual solvents in BP Light Kaolin is not considered a reasonable possibility. BP Light Kaolin meets the requirements of USP <467> Residual Solvents.

RoHS: BP Light Kaolin does not contain any detectable quantities of the dangerous substances included in European Directive 2002/95/EC (the RoHS directive) or subsequent amendments. Furthermore, none of the materials listed in this Directive is used during any stage of the production process for BP Light Kaolin. The scope of Directive 2011/65/EU (RoHS II) is "electrical and electronic equipment". Therefore, strictly speaking, raw materials fall outside the scope of the Directive. Nevertheless, we can confirm that BP Light Kaolin does not naturally contain any of the restricted substances listed in Annex II of Directive 2011/65/EU and subsequent amendments above the maximum permitted values. None of the restricted substances listed in Annex II of Directive 2011/65/EU and subsequent amendments is added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with any of the restricted substances listed in Annex II of Directive 2011/65/EU and subsequent amendments.

Shelf Life: BP Light Kaolin is chemically stable, inert and non-reactive, and is chemically compatible with other substances. Furthermore, BP Light Kaolin is non-flammable and non-biodegradable. BP Light Kaolin can be stored for up to 2 years in a cool, clean and dry covered area with no significant detrimental effects.

Storage Conditions: The specification properties of BP Light Kaolin do not change with extended storage under the proper conditions. The proper method of storage is



important to maintain the continued integrity of the product. We therefore recommend the following storage practices:

- Storage facility is clean, dry, sanitary, well ventilated and able to minimise entrance of dust, dirt, insects, birds, rodents and other animals.
- Sources of odour are controlled to prevent contamination. These sources include, but are not limited to, chemicals, insecticides, engine exhaust, cleaning products, fuel, sewage and refuse.
- Handle the product carefully to prevent rips, tears, marks and damage to the integrity of the packaging.
- Rotate product so that the oldest material on hand is used before newer material. Like all finely divided mineral powders, these products can agglomerate over time. These agglomerates are soft and are usually re-dispersed with normal handling but they might cause problems in unattended volumetric feeding equipment. It is primarily for this reason that we recommend the rotation of stocks.

SVHCs (Substances of Very High Concern): As a naturally occurring mineral kaolin may inherently contain trace quantities of certain chemical elements that occur as part of the natural environment and are commonly found within mineral deposits. These generally occur as trace impurities (ppm levels) bound interstitially and substitutionally within the individual mineral crystalline lattices and are, therefore, virtually non-extractable. As with all naturally occurring materials these levels fluctuate from point to point. However, BP Light Kaolin does not naturally contain any SVHCs (as defined in Article 57 of Regulation (EC) no. 1907/2006 ("the REACH Regulation")) above the maximum permitted values. No SVHCs are added during any stage of the production process for BP Light Kaolin. Furthermore, BP Light Kaolin does not naturally contain any of the substances listed by ECHA as candidates for inclusion as SVHCs in Annexes to Regulation (EC) no. 1907/2006 above the maximum permitted values.

Vegetarian/Vegan: As a naturally occurring mineral kaolin does not naturally contain any material of animal origin. No material of animal origin is added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated with material of animal origin. No routine presence testing is performed since the presence of material of animal origin in BP Light Kaolin is not considered a reasonable possibility.

VOCs/SVOCs (Volatile Organic Compounds/Semi Volatile Organic Compounds): Kaolin is a naturally occurring mineral. As such, BP Light Kaolin does not naturally contain any VOCs or SVOCs. No VOCs or SVOCs are added during any stage of the production process for BP Light Kaolin. Furthermore, to the best of our current knowledge, none of the materials used during the production of BP Light Kaolin contains or is contaminated



with VOCs or SVOCs. No routine presence testing is performed since the presence of VOCs and SVOCs in BP Light Kaolin is not considered a reasonable possibility.

WGK (Wassergefährdungsklasse): As a naturally occurring mineral kaolin is classified as non-hazardous to waters ("nicht wassergefärdend"/"nwg") within the Administrative Regulation on the Classification of Substances Hazardous to Waters into Water Hazard Classes (Verwaltungsvorschrift wassergefährdende Stoffe - VwVwS).



SAFETY DATA SHEET

BP Light Kaolin

According to Regulation (EC) No 1907/2006, Annex II, as amended by Regulation (EU) No 453/2010

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name	BP Light Kaolin
Substance Name	Kaolin
Chemical name	Hydrated aluminium silicate
Synonyms; trade names	China clay
CAS number	1332-58-7
EC number	310-194-1
Molecular Weight	Unspecified for this UVCB substance

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses	A functional additive
Uses advised against	No specific uses advised against are identified.

1.3. Details of the supplier of the safety data sheet

Supplier	Madar Corporation limited 19 - 20 Sandleheath Industrial Estate Fordingbridge SP6 1PA Tel. +44(0)1425 655 555 technical@madarcorporation.co.uk
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1.4. Emergency telephone number

Emergency telephone

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (EC 1272/2008)

Physical hazards	Not Classified
Health hazards	Not Classified
Environmental hazards	Not Classified

Human health This product does not meet the criteria for classification as hazardous as defined in the Regulation EC 1272/2008. It is recommended that due regard be taken of the specified constituents in deriving an Occupational Exposure Standard for the workplace.

Environmental The product is not expected to be hazardous to the environment
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BP Light Kaolin

Physicochemical This product should be handled with care to avoid dust generation.

2.2. Label elements

EC number 310-194-1

Hazard statements NC Not Classified

2.3. Other hazards

This substance is not classified as PBT or vPvB according to current EU criteria.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

KAOLIN			> 99%
CAS number: 1332-58-7	EC number: 310-194-1		
Classification Not Classified			
Diphosphoric acid, tetrasodium salt			<0.3%
CAS number: 7722-88-5	EC number: 231-767-1	REACH registration number: 01-2119489794-17-XXXX	
Classification Acute Tox. 4 - H302 Eye Dam. 1 - H318			

The full text for all hazard statements is displayed in Section 16.

Composition comments This product contains less than 1% quartz (fine fraction) Quartz: CAS-No.: 14808-60-7 EC No.: 238-878-4.

Ingredient notes Kaolin is a UVCB substance sub-type 4. Kaolin - Exempted from REACH Registration in accordance with Annex V.7.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information No acute and delayed symptoms and effects are observed. Consult a physician for all exposures except for minor instances.

Inhalation Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing. Get medical attention if any discomfort continues.

Ingestion No special treatment required. Rinse mouth thoroughly with water. Get medical attention if any discomfort continues.

Skin contact No special first aid measures necessary.

Eye contact Do not rub eye. Rinse with copious quantities of water and seek medical attention if irritation persists.

4.2. Most important symptoms and effects, both acute and delayed

General information The severity of the symptoms described will vary dependent on the concentration and the length of exposure.

4.3. Indication of any immediate medical attention and special treatment needed

BP Light Kaolin

Notes for the doctor No specific recommendations.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media The product is non-combustible. No specific extinguishing media is needed. Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media No restriction on the extinguishing media to be used.

5.2. Special hazards arising from the substance or mixture

Specific hazards Non combustible. No hazardous thermal decomposition.

5.3. Advice for firefighters

Protective actions during firefighting No specific fire-fighting protection is required. Use an extinguishing agent suitable for the surrounding fire. Product on floor when wetted will become slippery and may present a hazard; wear anti-slip boots.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid airborne dust generation, wear personal protective equipment in compliance with national legislation.

6.2. Environmental precautions

Environmental precautions Do not discharge into drains or watercourses or onto the ground.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up Avoid dry sweeping and use water spraying or vacuum cleaning systems to prevent airborne dust generation. Alternatively shovel into bags.

6.4. Reference to other sections

Reference to other sections For personal protection, see Section 8. For waste disposal, see Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Usage precautions Avoid airborne dust generation. Provide appropriate exhaust ventilation at places where airborne dust is generated. In case of insufficient ventilation, wear suitable respiratory protective equipment. Handle packaged products carefully to prevent accidental bursting. If you require advice on safe handling techniques, please contact your supplier. Do not eat, drink and smoke in work areas; wash hands after use; remove contaminated clothing and protective equipment before entering eating areas. For personal protection, see Section 8.

Advice on general occupational hygiene Keep dust levels to a minimum. Minimize dust generation. General occupational hygiene measures are required. These include good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices). Shower and change clothes at end of work shift. Change work clothing daily before leaving workplace.

7.2. Conditions for safe storage, including any incompatibilities

Storage precautions Store in a dry covered area. Minimise airborne dust generation and prevent wind dispersal during loading and unloading. Keep containers closed and store packaged products so as to prevent accidental bursting.

7.3. Specific end use(s)

Usage description

If you require advice on specific uses, please contact your supplier.
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BP Light Kaolin

SECTION 8: Exposure Controls/personal protection

8.1. Control parameters

Occupational exposure limits

KAOLIN

Long-term exposure limit (8-hour TWA): WEL 2 mg/m³ respirable dust

Inorganic dust

Long-term exposure limit (8-hour TWA): WEL 4 mg/m³ respirable dust

Quartz

Long-term exposure limit (8-hour TWA): WEL 0,1 mg/m³ respirable dust

Diphosphoric acid, tetrasodium salt

Long-term exposure limit (8-hour TWA): WEL 5 mg/m³

WEL = Workplace Exposure Limit

Ingredient comments

Maintain personal exposure below occupational exposure limits for dust (inhalable and respirable) as dictated in the national legislation.

Diphosphoric acid, tetrasodium salt (CAS: 7722-88-5)

DNEL

Industry - Inhalation; Long term systemic effects: 2.79 mg/m³
Consumer - Inhalation; Long term systemic effects: 0.68 mg/m³

PNEC

STP; 50 mg/l
Fresh water; 0.05 mg/l
Marine water; 0.005 mg/l
Intermittent release; 0.5 mg/l

8.2. Exposure controls

Appropriate engineering controls

Minimise airborne dust generation. Use process enclosures, local exhaust ventilation or other engineering controls to keep airborne levels below specified exposure limits. If user operations generate dust, fumes or mist, use ventilation to keep exposure to airborne particles below the exposure limit. Apply organisational measures, e.g. by isolating personnel from dusty areas. Remove and wash soiled clothing. Observe any occupational exposure limits for the product or ingredients. ..

Eye/face protection

Eyewear complying with an approved standard should be worn if a risk assessment indicates eye contact is possible. The following protection should be worn: Chemical splash goggles or face shield. Contact lenses should not be worn when working with this product.

Hand protection

Appropriate protection (e.g. gloves, barrier cream) is recommended for workers who suffer from dermatitis or sensitive skin. Wash hands at the end of each work session. It is recommended that gloves are made of the following material: Polyvinyl chloride (PVC). Neoprene. Rubber (natural, latex).

Other skin and body protection

For skin, normal work clothes are appropriate.

Hygiene measures

When using do not eat, drink or smoke. Wash at the end of each work shift and before eating, smoking and using the toilet. Use appropriate skin cream to prevent drying of skin.

BP Light Kaolin

Respiratory protection	Local ventilation to control airborne dust levels below occupational exposure limits is recommended. In case of exposure, where engineering controls are insufficient, the use of Respiratory Protective Equipment (RPE) is recommended. A risk assessment process must be followed to ensure adequate protection from the airborne dust. The type of RPE must suit the work situation and the specific requirements of the wearer. Other environmental conditions should also be considered. The minimum "Assigned Protection Factor" (APF) required will depend on the measured or predicted occupational exposure levels divided by the OEL detailed in section 8.1. Filters specified as FFP2 and P2 have an APF of 10. Correctly fitted, these would reduce the exposure to the wearer down to one tenth of the working atmosphere. Depending on the assessment of the exposure, a lesser or higher efficiency of filter may be required. The manufacturer's instructions and regulatory guidance regarding duration of use and correct fitting should be followed. The wearer of the selected RPE should receive training before use.
Environmental exposure controls	All ventilation systems should be filtered before discharge to atmosphere. Avoid releasing into the environment. Contain the spillage.

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Appearance	Powder
Colour	White/off-white.
Odour	Almost odourless.
pH	7-9 @ 10 % Slurry
Melting point	> 450 °C EU Method A1
Initial boiling point and range	not applicable (Solid with a melting point > 450°C)
Flash point	not applicable (Solid with a melting point > 450°C)
Evaporation rate	not applicable (Solid with a melting point > 450°C)
Flammability (solid, gas)	Non flammable EU Method A1
Upper/lower flammability or explosive limits	Non explosive (void of any chemical structures commonly associated with explosive properties)
Vapour pressure	not applicable (Solid with a melting point > 450°C)
Vapour density	not applicable (Solid with a melting point > 450°C)
Relative density	2.6
Bulk density	0.5 - 0.8 g/cm ³
Solubility(ies)	Kaolin <1 mg/litre @ 20 °C EU Method A6 Diphosphoric acid, tetrasodium salt ~ 50 g/litre @ 20 °C
Partition coefficient	Not applicable (inorganic substance)
Auto-ignition temperature	No relative self-ignition temperature below 400 °C EU method A16
Decomposition Temperature	Not applicable (Solid with a melting point > 450°C)
Viscosity	Not applicable (Solid with a melting point > 450°C)
Explosive properties	There are no chemical groups present in the product that are associated with explosive properties.
Oxidising properties	There are no chemical groups present in the product that are associated with oxidising properties.

BP Light Kaolin

9.2. Other information

Other information No information required.

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity There are no known reactivity hazards associated with this product.

10.2. Chemical stability

Stability Stable at normal ambient temperatures and when used as recommended.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions There are no known reactivity hazards associated with this product.

10.4. Conditions to avoid

Conditions to avoid No particular incompatibility.

10.5. Incompatible materials

Materials to avoid No particular incompatibility.

10.6. Hazardous decomposition products

Hazardous decomposition products Does not decompose when used and stored as recommended.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Inhalation Dust in high concentrations may irritate the respiratory system.

Ingestion No harmful effects expected from quantities likely to be ingested by accident.

Skin contact Prolonged contact may cause dryness of the skin.

Eye contact Particles in the eyes may cause irritation and smarting.

Toxicological information on ingredients.

KAOLIN

Acute toxicity - oral

Notes (oral LD₅₀) LD₅₀ >2000 mg/kg, Oral, Rat OECD 420

Acute toxicity - dermal

Notes (dermal LD₅₀) LD₅₀ >2000 mg/kg, Dermal, Rat OECD 402

Acute toxicity - inhalation

Notes (inhalation LC₅₀) LC₅₀ >5.07 mg/l, Inhalation, Rat OECD 436

Skin corrosion/irritation

Skin corrosion/irritation Kaolin is not irritating to skin (OECD 404, rabbit).

Serious eye damage/irritation

Serious eye damage/irritation Kaolin is not irritating to eye (OECD 405, rabbit).

Respiratory sensitisation

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BP Light Kaolin

Respiratory sensitisation	Mouse: Not sensitising. OECD 429
<u>Skin sensitisation</u>	
Skin sensitisation	Local Lymph Node Assay (LLNA) - Mouse: Not sensitising. OECD 429
<u>Germ cell mutagenicity</u>	
Genotoxicity - in vitro	No specific test data are available.
Genotoxicity - in vivo	No specific test data are available.
<u>Carcinogenicity</u>	
Carcinogenicity	In studies where kaolin has been administered via intratracheal installation, kaolin behaves as a poorly soluble particulate of low toxicity with inflammatory responses of lung tissue. Epidemiological studies covering a large number of workers did not reveal an explicit association between kaolin exposure and tumour formation. In summary, no concern on carcinogenicity is triggered by animal studies or by epidemiological findings
<u>Reproductive toxicity</u>	
Reproductive toxicity - fertility	No specific test data are available.
<u>Specific target organ toxicity - single exposure</u>	
STOT - single exposure	No organ toxicity observed in acute tests.
<u>Specific target organ toxicity - repeated exposure</u>	
STOT - repeated exposure	Based on the results from animal studies (mainly via intratracheal administration) it seems that the severity of effects seen in the lungs may be related to the level of crystalline silica (fine fraction) present in the material as an accessory mineral. Epidemiological studies show that exposure to high levels of kaolin dust may lead to pneumoconiosis. Results indicate that the effects from kaolin exposure are typical of those seen with poorly soluble particles under conditions of lung overload i.e. the lungs clearance capacity has been exceeded. It is likely that the severity of any effects are related to the level of crystalline silica (fine fraction) present in the material as an accessory mineral.
<u>Aspiration hazard</u>	
Aspiration hazard	No specific test data are available.

Diphosphoric acid, tetrasodium salt

<u>Acute toxicity - oral</u>	
Acute toxicity oral (LD₅₀ mg/kg)	1,624.0
Species	Rat
ATE oral (mg/kg)	1,624.0

SECTION 12: Ecological Information

Ecotoxicity	The product components are not classified as environmentally hazardous. However, large or frequent spills may have hazardous effects on the environment.
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12.1. Toxicity

Ecological information on ingredients.

BP Light Kaolin

KAOLIN

Acute aquatic toxicity

Acute toxicity - fish LC₅₀, 96 hours: >1000 mg/l, Oncorhynchus mykiss (Rainbow trout)
OECD 203

Acute toxicity - aquatic invertebrates EC₅₀, 48 hours: >1000 mg/l, Daphnia magna
OECD 202

Acute toxicity - aquatic plants EC₅₀, 72 hours: >1000 mg/l, Freshwater algae
OECD 201

Acute toxicity - microorganisms No specific test data are available.

Chronic aquatic toxicity

Chronic toxicity - fish early life stage No specific test data are available.

Chronic toxicity - aquatic invertebrates No specific test data are available.

Toxicity to soil No specific test data are available.

Toxicity to terrestrial plants No specific test data are available.

12.2. Persistence and degradability

Persistence and degradability The product is not biodegradable.

Ecological information on ingredients.

KAOLIN

Persistence and degradability The substance is inorganic and therefore will not undergo abiotic degradation.

Biodegradation The substance is inorganic and therefore will not undergo biodegradation.

12.3. Bioaccumulative potential

Bioaccumulative potential The product does not contain any substances expected to be bioaccumulating.

Partition coefficient Not applicable (inorganic substance)

Ecological information on ingredients.

KAOLIN

Bioaccumulative potential Not relevant for inorganic substances.

Partition coefficient Not applicable (inorganic substance)

Diphosphoric acid, tetrasodium salt

Partition coefficient Pow: ~ -2

12.4. Mobility in soil

Ecological information on ingredients.

KAOLIN

BP Light Kaolin

Mobility Kaolin is almost insoluble and thus presents a low mobility in most soils.

Diphosphoric acid, tetrasodium salt

Mobility The product is soluble in water.

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment This substance is not classified as PBT or vPvB according to current EU criteria.

Ecological information on ingredients.

KAOLIN

Results of PBT and vPvB assessment This substance is not classified as PBT or vPvB according to current EU criteria.

12.6. Other adverse effects

Other adverse effects None known.

Ecological information on ingredients.

KAOLIN

Other adverse effects None known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

General information This mineral can be disposed of as a non toxic/inactive material in approved landfill sites in accordance with local regulations. Dust formation from residues in packaging should be avoided and suitable worker protection assured. Store used packaging in enclosed receptacles. The re-use of packaging is not recommended. Recycling and disposal of packaging should be carried out by an authorised waste management company. Comply with local regulations for disposal

Disposal methods Where possible, recycling is preferable to disposal. Can be disposed of in compliance with local regulations.

SECTION 14: Transport information

General The material is not classified as a dangerous substance and no restrictions apply for land/sea/air transportation (IMDG, IATA, ADR/RID). Avoid generation and spreading of dust.

14.1. UN number

Kaolin is not classified as hazardous for transport and does not have a UN Number

14.2. UN proper shipping name

No information required.

14.3. Transport hazard class(es)

ADR, IMDG, ICAO/IATA, RID : All not classified

14.4. Packing group

No information required.

14.5. Environmental hazards

BP Light Kaolin

Environmentally hazardous substance/marine pollutant

No.

14.6. Special precautions for user

Avoid any release of dust during transportation, by using air-tight tanks for powders and covered trucks for other dry forms.

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Transport in bulk according to No information required.

Annex II of MARPOL 73/78
and the IBC Code

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations EH40/2005 Workplace exposure limits.
Health and Safety at Work etc. Act 1974 (as amended).
The Control of Substances Hazardous to Health Regulations 2002 (SI 2002 No. 2677) (as amended).

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

Abbreviations and acronyms used in the safety data sheet

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS: Chemical Abstracts Service.
EC: European Commission
EC₅₀: 50% of maximal Effective Concentration.
FFP: Filtering Face Piece
IMDG: International Maritime Dangerous Goods.
IATA: International Air Transport Association.
LC₅₀: Lethal Concentration to 50 % of a test population.
OECD: Organisation for Economic Co-operation and Development
OEL: Occupational Exposure Limit
PBT: Persistent, Bioaccumulative and Toxic substance.
vPvB: Very Persistent and Very Bioaccumulative.
REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006.
RID: European Agreement concerning the International Carriage of Dangerous Goods by Rail.
SDS: Safety Data Sheet
TWA: Time Weighted Average
UVCB: Unknown Variable Composition or Biological

BP Light Kaolin

General information

Workers must be informed of the presence of crystalline silica and trained in the proper use and handling of this product as required under applicable regulations. A multi-sectoral social dialogue agreement on Workers Health Protection through the Good Handling and Use of Crystalline Silica and Products Containing it was signed on 25 April 2006. This autonomous agreement, which receives the European Commission's financial support, is based on a Good Practices Guide. The requirements of the Agreement came into force on 25 October 2006. The Agreement was published in the Official Journal of the European Union (2006/C 279/02). The text of the Agreement and its annexes, including the Good Practices Guide, are available from <http://www.nepsi.eu> and provide useful information and guidance for the handling of products containing crystalline silica (fine fraction). Literature references are available on request from EUROSIL, the European Association of Industrial Silica Producers. Prolonged and/or massive exposure to respirable crystalline silica-containing dust may cause silicosis, a nodular pulmonary fibrosis caused by deposition in the lungs of fine respirable particles of crystalline silica. In 1997, IARC (the International Agency for Research on Cancer) concluded that crystalline silica inhaled from occupational sources can cause lung cancer in humans. However it pointed out that not all industrial circumstances, nor all crystalline silica types, were to be incriminated. (IARC Monographs on the evaluation of the carcinogenic risks of chemicals to humans, Silica, silicates dust and organic fibres, 1997, Vol. 68, IARC, Lyon, France.) In 2009, in the Monographs 100 series, IARC confirmed its classification of Silica Dust, Crystalline, in the form of Quartz and Cristobalite (IARC Monographs, Volume 100C, 2012). In June 2003, SCOEL (the EU Scientific Committee on Occupational Exposure Limits) concluded that the main effect in humans of the inhalation of respirable crystalline silica dust is silicosis. "There is sufficient information to conclude that the relative risk of lung cancer is increased in persons with silicosis (and, apparently, not in employees without silicosis exposed to silica dust in quarries and in the ceramic industry). Therefore preventing the onset of silicosis will also reduce the cancer risk..." (SCOEL SUM Doc 94-final, June 2003). So there is a body of evidence supporting the fact that increased cancer risk would be limited to people already suffering from silicosis. Worker protection against silicosis should be assured by respecting the existing regulatory occupational exposure limits and implementing additional risk management measures where required. Health & Safety Executive: Detailed reviews of the scientific evidence on the health effects of crystalline silica have been published by HSE (Health and Safety Executive, UK) in the Hazard Assessment Documents EH75/4 (2002) and EH75/5 (2003). The HSE points out on its website that "Workers exposed to fine dust containing quartz are at risk of developing a chronic and possibly severely disabling lung disease known as "silicosis"." In addition to silicosis, there is now evidence that heavy and prolonged workplace exposure to dust containing crystalline silica can lead to an increased risk of lung cancer. The evidence suggests that an increased risk of lung cancer is likely to occur only in those workers who have developed silicosis.

Revision comments

Most of the 16 SECTIONS have been updated and formatted according to the revised ECHA Guidance on the compilation of safety data sheets (version 3.0 of August 2015). Therefore, this SDS has been completely redrafted and replaces the former SDS supplied.

Revision date

02/02/2018

Revision

4

SDS number

12680

Hazard statements in full

H302 Harmful if swallowed.
H318 Causes serious eye damage.

This safety data sheet (SDS) is based on the legal provisions of the REACH Regulation (EC 1907/2006; article 31 and Annex II), as amended. Its contents are intended as a guide to the appropriate precautionary handling of the material. It is the responsibility of recipients of this SDS to ensure that the information contained therein is properly read and understood by all people who may use, handle, dispose or in any way come in contact with the product. Information and instructions provided in this SDS are based on the current state of scientific and technical knowledge at the date of issue indicated. It should not be construed as any guarantee of technical performance, suitability for particular applications, and does not establish a legally valid contractual relationship. This version of the SDS supersedes all previous versions.

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BP Light Kaolin is a natural hydrated aluminium silicate, free from most of its impurities, dried and milled to a fine powder. It contains a suitable dispersing agent. The product complies with the latest British Pharmacopoeia monograph. It is also tested for residues retained on a 53 micron sieve in order to control and identify the trace proportion of material inevitably included during the manufacturing process.

It is a light, white powder, free from gritty particles, odourless and unctuous to the touch. Product can be supplied in 20kg paper sacks. Pallet & shrink-wrapping are available.

An irradiation service is available through a third party, which irradiates to a specified dose.

No guarantee of sterility can be provided.

TEST LIMITS are:

Loss on Drying (max. %)	1.5
Loss on Ignition (max. %)	15.0
Soluble Matter (mg. max.)	10
Coarse Particles (mg. max.)	25
Fine Particles (min. %)	70
Chloride (max. ppm)	330
Arsenic (max. ppm)	2
Heavy Metals* (max. ppm)	20

ADDITIONAL TEST

+ 53µm (ppm max.)	250
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CAS No. 1332-58-7

EC No. 310-194-1

* Tested by 2013 B.P. monograph



FM 14752

STORAGE: As a general guide, 1000kg of kaolin will occupy 1.7cu metres (powder in sacks)

***Notice:** Although the data listed are typical, they are not production specifications. The supplier provides the data in good faith, however it makes no warranty or representation of any kind, express or implied, regarding the information given or product described including any warranty of suitability for a particular purpose.*

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