



Manufacturing Process &
Risk Assessment Specifications

GLOBAL MANUFACTURING FLOW CHART
French Pink Clay Ultra Ventilated





Manufacturing Process & Risk Assessment Specifications

DETAILING OUR MANUFACTURING PROCESS

- 1 • Our clay deposit is located next to our Supplier's production site.
- 2 • The Supplier mechanically extracts the clay.
- 3 • Dumper trucks are loaded on the deposit and the product is delivered on the production site.
- 4 • Once delivered, the clay is sorted out.
- 6 • The clay undergoes a crushing process that intends not to brake the grain.
- 7 • The clay is dried in a rotary oven.
- 8 • Grains are sorted out according to their size thanks to an air induction system.
- 9 • The clay is first stored in silos.
- 10 • Depending on customers' needs and demands, the clay is stocked in paper bags or big bags.
- 11 • The clay is stored in an closed environment.
- 12 • The clay is dispatched in the warehouse.
- 13 • The clay is delivered to the customer on time.



SAFETY DATA SHEET

In compliance with appendix II of Regulation (EC) n°1907/2006 (REACH), Regulation (EC) n° 1272/2008, and Regulation (EC) n°453/2010.

1 IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

1.1 PRODUCT

Product code: French Pink Ultra Ventilated Clay
Chemical name: Clay mainly composed montmorillonite, illite and kaolin

INCI : *Montmorillonite* *Illite* *Kaolin*
CAS #: 1318-93-0 12173-60-3 1332-58-7

1.2 SUPPLIER

Naturally Balmy Ltd, 8 Benson
 Road, Nuffield Industrial Estate,
 Poole BH17 0GB

Tel: 01202 567046 | Email:
 sales@naturallybalmy.co.uk



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1.1 RELEVANT AND UNRECOMMENDED USAGES

Usages *: Cosmetics, pharmaceuticals and clay therapy.
Relevant usages : Industrial, professional & personal.
Unrecommended usages: None.

**This list isn't exhaustive*

1.2 EMERGENCY TELEPHONE NUMBER

European emergency number : 112



2. HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCE AND LABEL ELEMENTS

Product name	Classification in compliance with the directive 67/548/CEE	Classification in compliance with the Regulation (CE) n°1272/2018 (CPL)	Additional data
Pink clay	Unclassified	Unclassified	No

2.2 MAIN SYMPTOMS

An excessive production of dust may cause slight irritation of the eyes and respiratory tract. No delayed effect has been recorded.

COMPONENTS DESCRIPTION

Note: The substance described below is neither a mixture nor a multi-constituent substance (result of a manufacturing process). It is composed of:

Product name	REACH registration #*	Mass percentage
Red clay	Exempt	30%
White-pinkish clay	Exempt	70%

***REACH registration#:** the substance is exempted in a compliance with appendix V, chapter 7 of Regulation (EU) n°453/2010 instead of Regulation (CE) n° 1907/2006 (REACH) – (the substance that can be found in nature / chemically non-modified substance).



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FIRST AID MEASURES

General information: Have product container, label elements and Safety Data Sheet at hand if medical advice is needed.

After inhalation: The person should be taken outside into the open air, away from dust. Get medical attention if symptoms occur.

After skin contact: If symptoms occur, rinse cautiously with water for several minutes. Get medical attention if symptoms persist.

After eye contact: Rinse cautiously with water for several minutes. Get medical attention if symptoms persist.

After ingestion: Get medical attention if symptoms persist. Do not induce vomiting without medical attention.

FIREFIGHTING MEASURES



The product is non-inflammable and non-explosive. No specific firefighting measures is required. No unsuitable extinguishing materials. Not a dangerous substance.

SPILL MEASURES

Hoover the spilled product (to avoid raising dust).

Avoid moistening the product (wet clay can be slippery).

Deal with the recovered product as indicated in section 12.

Keep in sealed containers.

Individual measures: in case of dust formation, wear an anti-dust mask type FFP3.

Environmental measures : environmental information section 10.

HANDLING AND STORAGE

7.1 HANDLING



Reduce as much as possible dust formation and use adequate ventilation system. If the ventilation system of the premises is not sufficient, wear a respiratory gear type FFP3. Avoid eye contact. The product can be slippery when wet. The product is non-inflammable. Minimize environmental release, using filters for ventilation systems for example.



Advice on general occupational hygiene: Wash your hands after every use. Remove soiled clothes and protective equipment before getting into a catering area.

7.2 STORAGE

Keep the product in its closed container in a dry and well-ventilated place. Keep the container closed to avoid dust formation.

7.3 SPECIFIC FINAL USE

If you need more details for uses mentioned in section 1.3, contact your supplier.

If you need advice for specific uses of the product, contact your supplier.

EXPOSURE CONTROL

8.1 CONTROL PARAMETERS

Components	Exposure Limits	Type of value	Source	Biological limit values	Exposure limits in air	DNEL/PNEC Values
Pink clay	0.1 mg/m ³	VME – 8h	Decree n° 2012-746, May 9th, 2012	N/A	N/A	No available data

For occupational limit values applicable in other countries, please refer to local Regulations.

Recommended follow-up procedures

In order to monitor individual and environmental exposures, the recommended methods are described below:

- A decree issued on December 15th 2009 related to technical controls of occupational limit values at work and to certification standards of control agencies.
- Circular DGT N°2010-03 issued on April 13th 2010 related to chemical risk control measures at work

These standards are applied in France. If you are located in another European country or outside the EU, refer to the competent authorities.



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8.2 APPROPRIATE TECHNICAL CONTROLS

Avoid producing dust airborne.

Opt for collective protective equipment in order to avoid creating dust: use closed processes, a well-adapted exhaust ventilation or any other process that can keep airborne concentrations below the specified exposure limits. Organizational measures can be taken such as isolating staff from dust areas for examples.

8.3 INDIVIDUAL PROTECTION MEASURES



Wearing of gloves is advisable.



Wear a FFP3 protection in case of dust.



Wear glasses in case of dust.

PHYSICO-CHEMICAL PROPERTIES

Features	Data	Methods
Physical state	Solid	
Appearance	Powder	
Colour	Pink	
Odour	None	
Odour threshold	N/A	
pH	7,5 - 9	Measure carried out in compliance with method: NF EN ISO 787-9 T31-235 and pH-measure.
Melting point	N/A	
Freezing point	N/A	
Initial boiling point	N/A	
Flash point	N/A	
Evaporation rate	N/A	
Inflammability	N/A	
Upper/ lower or explosive limits	N/A	
Vapour pressure	N/A	
Vapour density	N/A	
Relative density	From 0.4 to 0.6	Measure carried out in compliance with the bulk density method: NF T 73-405 (March 1982) or a method from the international norm OCDE 109 (bulk density)
Solubility in water	Insoluble	
Partition coefficient n-octanol/water	Insoluble	
Auto-ignition temperature	N/A	
Decomposition temperature	N/A	
Viscosity	N/A	
Explosive properties	N/A	
Oxidising properties	N/A	

REACTIVITY AND STABILITY

Features	Data
Reactivity	Product stable and inert
Chemical stability	Product stable
Dangerous reactions	N/A
Avoiding conditions	N/A
Incompatible	N/A
Products with dangerous decomposition	N/A



SAFETY DATA SHEET

In compliance with appendix II of Regulation (EC) n°1907/2006 (REACH), Regulation (EC) n° 1272/2008, and Regulation (EC) n°453/2010.

TOXICOLOGICAL INFORMATION :

These tests were carried out before the restriction date on animal testing (03/11/2009) Regulation (CE) N°1223/2009).

TESTS	OCDE N°	Results	Species	Duration of the study	Classification
Acute oral toxicity study					
Acute dermal toxicity					
Acute inhalation toxicity study					
Acute dermal irritation study					
Acute eye irritation study					
Skin sensitisation study					
In vitro mammalian chromosome aberration test			No specific data.		
Reverse mutation bacterial test			Natural product.		
Reproduction toxicity					
Gem cell mutagenicity					
Specific target organ toxicity-single exposure					
Specific target organ toxicity- repeated exposure					
Aspiration toxicity hazard					

12. ECOLOGICAL INFORMATION

12.1 TOXICITY

These tests were carried out before the restriction date on animal testing (03/11/2009) Regulation (CE) N°1223/2009).

TESTS	OCDE N°	Results	Species	Environment	Duration of the study	Classification
Acute aquatic toxicity test						
Algal growth inhibition test						
Acute immobilisation test			No specific data.			
Oral acute toxicity test (side effects)			Natural product.			
Dermal acute toxicity test (side effects)						

12.2 PERSISTENCE AND DEGRADATION

Stable and non-biodegradable product (inorganic product).

12.3 BIOACCUMULATIVE PERSISTENCE

Non applicable (inorganic product).

12.4 MOBILITY IN SOIL

No specific data

12.5 RESULTS OF PBT AND vPvB

Do not meet the criteria for classification as PBT and/or vPvB found in the list of Appendix XIII of Regulation N°1907/2006 (inorganic product).

12.6 OTHER ADVERSE EFFECTS

None has been reported.



SAFETY DATA SHEET

In compliance with appendix II of Regulation (EC) n°1907/2006 (REACH), Regulation (EC) n° 1272/2008, and Regulation (EC) n°453/2010.

13. WASTE TREATMENT METHOD

Substance treatment: Waste must be discharged in compliance with local, national regulations and with applicable European standards and guidelines. Waste can be landfilled in compliance with local regulations. Do not dispose of waste into the drains.

Container treatment: Empty the container. Remove and sort out the product.

UN #	UN proper shipping name	Transport hazard group	Packing group	Environmental hazards	Special precautions for user	Transport in bulk according to appendix II of MARPOL 73/78 and the IBC code
Not listed	No data	Not classified	Not concerned	N/A	See section 7.1	Not concerned

14. REGULATORY INFORMATION

14.1 EU REGULATION

The substance is exempt in compliance with appendix V, chapter 7, of the Regulation (CE) n° 1907/2006 (REACH) – (substance that can be found in nature / chemically non-modified substance). The substance is not labeled in compliance with Regulation (CE) N° 1272/2008 and EU.

14.2 NATIONAL DIRECTIVES - FRANCE

No additional information.

14.3 CHEMICAL SECURITY ASSESSMENT

No assessment.

15. OTHER INFORMATION

15.1 VERSION

Reason for updating the earlier version: update by converting in table form (parts: 2.2.; 3; 8.1.; 14), by adding pictograms (parts: 8.3; 7; 5; 1.4.) and also by implementing abbreviations tab with meanings (part: 16.2.).

15.2 MEANINGS OF ABBREVIATIONS AND ACRONYMS

CAS	Chemical Abstrate Service
CE	Substances sold in the European market
INCI	Internationnal Nomenclature of Cosmetic Ingredients
REACH	Registration, Evaluation, Autorisation and restriction of Chemicals
DNEL	Derived No-effect Level
CE50	Effective concentration 50 %
CL50	Lethal concentration 50 %
DL50	Lethal dose 50 %
NOEC	No-Observed Effect Concentration
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effet Concentration
SDS	Safety data sheet
vPvB	Very Persistent Substance Very Bioaccumulative



SAFETY DATA SHEET

In compliance with appendix II of Regulation (EC) n°1907/2006 (REACH), Regulation (EC) n° 1272/2008, and Regulation (EC) n°453/2010.

16.3 BIBLIOGRAPHIC REFERENCES

<http://echa.europa.eu/>

Manufacturer disclaimer

The information given within this SDS is correct to the best of our knowledge, information and belief at the date of its revision and publication. However, the manufacturer makes no representation, warranty or guarantee as to its accuracy, reliability or completeness, nor assumes any liability. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For these and other reasons, we assume no responsibility for any loss, damage or expense caused by or in any way with the handling, storage, use or disposal. This SDS was written for this product only and should be used only for this product. If the product is used as a component of another product, the information may not be applicable.



DECLARATION

To meet specifications of the cosmetic regulation

French Pink Clay - Ultra Ventilated

We certify that the above product is:

- C.M.R free,
- Gluten free,
- Allergen free,
- Bisphenol free,
- Lactose free,
- Ethanol and Methanol free,
- Palm oil free,
- Latex free,
- Phthalate free,
- Waste solvents free,
- Phenoxyethanol free,
- BSE (bovine spongiform encephalopathy) free
- TSE (Transmissible Spongiform Encephalopathies) free
- GMO free,
- Not tested on the animals,
- Don't contain nano-materials, [according to the regulations: 1223/2009 and the French decree 2012-232](#)
- Didn't undergo any irradiation or chemical treatment.
- Crystalline Silica Free,
- Suitable for Vegans

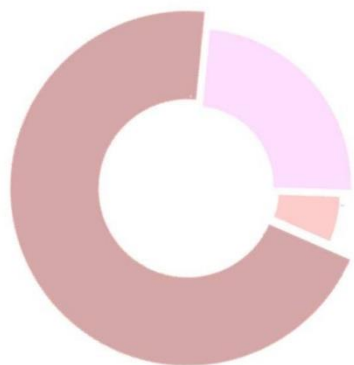
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TECHNICAL DATA SHEET

COSMETIC INGREDIENT

In compliance with Regulation (EC) n° 1223/2009



INGREDIENT INFORMATIONS

Trade name : Pink clay
 Composition : 100% natural mineral product
 Origin of the ingredient : France
 HSCode : 2508400000

Description of the manufacturing process:

The pink clay undergoes a mechanical treatment, without any chemical process. It is crushed and dried at 350 °C during 20 mins. Powder grains are then sorted thanks to an innovative and sophisticated process a selection by induction.

<p>● INCI* : Illite 24% ± 3 N° CAS : 12173-60-3</p>	<p>● INCI* : Kaolin 6% ± 2 N° CAS : 1332-58-7</p>	<p>● INCI* : Montmorillonite 70% ± 5 N° CAS : 1318-93-0</p>
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* The INCI composition above includes a portion of non-clay minerals.

INGREDIENT SPECIFICATIONS

PHYSICO-CHEMICAL ANALYSIS

Aspect	Pink powder
Odor	None
Humidity (Humidimeter METTLER TOLEDO)	< 8%
pH (Method : NF EN ISO 787-9 & T31-235)	Between 7.5 and 9
Grain size (Granulometer Mastersizer 2000 Malvern)	90 % < 80 µm and 100 % < 150 µm

MICROBIOLOGICAL ANALYSIS

Ingredient available in category 1 or 2 (According to the ISO 17 516).

	Specifications Category 1	Specifications Category 2
Total aerobic mesophilic microorganisms (Aerobic mesophilic bacteria DGAT (NF EN ISO 21149) and Yeasts and molds DMLT (NF EN ISO 16212))	< 100 CFU/g ^a	< 1 000 CFU/g ^b
Pseudomonas Aeruginosa (NF EN ISO 21148 and 22717)	NONE	NONE
Staphylococcus Aureus (NF EN ISO 21148 and 22718)	NONE	NONE
Candida Albican(NF EN ISO 21148 and 18416)	NONE	NONE
Escherichia Coli (NF EN ISO 21148 and 21150)	NONE	NONE

Due to the inherent variability of the enumeration method and according to the USP chap 61 or EP chap 2.6.12, results are out of specs if:
^a > 200 CFU/g ^b > 2 000 CFU/g

Quotes are by default in category 2. Category 1 (100% natural heat treatment) is available on request and will be clearly identified on the quote.

REGULATORY INFORMATION

Natural cosmetic ingredient in accordance with the ISO 16128-1 / 2016 standards: "Natural ingredient derived from an inorganic substance, naturally occurring in nature, having its own chemical formula and a coherent set of physical properties. "

EUROPEAN COSMETIC REGULATION 1223/2009 OF NOVEMBER 30th, 2009

The French Pink Clay is not included in the list of banned substances, ref: Annex II Regulation 1223/2009 – Cosmetics products - of the European Parliament and Council, November 30th, 2009. This product can be used in the manufacturing of cosmetics products.

COSMOS/ECOCERT

The manufacturer of our French Pink Clay is COSMOS and ECOCERT certified as a cosmetic ingredient authorized in the manufacturing of natural and organic cosmetics. www.cosmos-standard-rm.org/.

IRRADIATION

The French Pink Clay does not undergo any irradiation treatment during its manufacturing process.

REACH

This reference is exempted- Annex V, Chapter 7 of the European Regulation 1907/2006 (REACH) - (substance present in nature / substance not chemically modified). No chemical substance, PBT substance (bio accumulative and toxic substances) or any vPvB substances (very persistent and very bio accumulative substance of concern) are in contact with the product during the manufacturing process.

CMR

French Pink Clay is not classified as CMR (carcinogenic, mutagenic and reprotoxic substances) and no CMR substances are in contact or added during the manufacturing process.

SOLVENT

The French Pink Clay is from natural origin. No chemical and no solvent are in contact or added during the manufacturing process. It therefore doesn't contain solvent residues.

ALLERGENS

The French Pink Clay naturally doesn't contain allergens, and no substances are in contact or added during the manufacturing process. It does not contain any allergenic substances listed in Annex III of Regulation 1223/2009 - Cosmetics products - of the European Parliament and of Council of November 30th, 2009.

GMO

The French Pink Clay is a natural mineral and doesn't contain substances of plant origin. No GMO substances are in contact or added during the manufacturing process.

ESB/TSE

The French Pink Clay is a natural mineral and doesn't contain animal or human substances, it is not in contact with this type of substances during the manufacturing process. It can not therefore cause transmissible spongiform encephalopathy (ESB / TSE).

SVHC

The French Pink Clay is a 100% natural mineral. No preoccupating or really preoccupating substances (SVHC) and no preoccupating or really preoccupating chemicals substances defined by the European chemicals agency are used during the manufacturing process.

ANIMAL TESTING

No animal testing has been carried out since 2009, in accordance with Regulation 1223/2009 of the European Parliament and Council of November 30th, 2009 on cosmetic products.

VEGETARIAN / VEGAN

No ingredients from animal origin are in contact or added in the manufacturing process.

HALAL

General guidelines of the FAO (Food and Agriculture Organization of the United Nations) for the use of "Halal" N ° CAC / GL 24-1997 are excluding following products:

- * Product of animal origin
- * Product of vegetable origin
- * Alcoholic and / or intoxicating and dangerous drinks
- * Food additives obtained from what is listed in points 1., 2. and 3.

The French Pink Clay naturally does not contain any prohibited substances listed above. No substances are in contact or added during the manufacturing process, so this reference may be eligible to the Halal certification.

KOSHER

The French Pink Clay is a 100% natural mineral. No additives have been added during the manufacturing process, this mineral can be eligible to get the Kosher certification.

NANOMATERIALS

Regulation 1223/2009 of the European Parliament and of Council November 30th, 2009 on cosmetic products defines 'nanomaterials' as: 'insoluble, bio-persistent and intentionally produced with one or more external dimensions at the level of 1 to 100nm'. The French Pink Clay is not intentionally produced at the nanoparticle scale and therefore complies with Regulation 1223/2009 of the European Parliament and of Council November 30th, 2009 on cosmetic products. And so, French Pink Clay does not need to be annually declared to the ANSES (decree 2012-232 of 17th, 2012).

CALIFORNIA PROPOSITION 65

Not listed.

NATURALITY INDEX

"A natural ingredient is made from organic substances naturally in Earth having its own chemicals formula and its own physical properties". According to the ISO 16128, clays' characteristics are as following:

- * Natural index = 1
- * Natural origin index = 1
- * Biological index = 0
- * Biological origin index = 0

DIOXIN AND PCB

Results are near zero.

HEAVY METALS

The CosPINK™ is a mineral naturally present in nature, therefore it can contain traces of heavy metals (ppm), tolerated by the European regulation because technically unavoidable. Internal method, sample's mineralization with nitric acid at 5% (EN 15510) measurement carried out by using ICP-OES spectrometry (9820 SHIMAZU).

Antimony Sb < 0.5 ppm	Arsenic As < 10 ppm	Cadmium Cd < 0.5 ppm	Cobalt Co < 5 ppm
Tin Sn < 0.5 ppm	Mercury Hg < 0.05 ppm	Nickel Ni < 15 ppm	Lead Pb < 10 ppm

TOXICOLOGICAL AND ECOLOGICAL INFORMATION

For this section, please refer to SDS012.

EXPIRATION, PACKAGING, STORAGE

Microbiological expiry date depends on the category:

Category 1 : 3 months after leaving our warehouse

Category 2 : 18 months after leaving our warehouse

After this period of time, this parameter must be rechecked.

This product is packed in paperbag.

Store in a dry, well-ventilated and free from any microbiological contamination place.