

# Certificate of Analysis

> Product data:

**Product name:** French Green Clay Ultra Ventilated

Product reference: CLAYFRENGREE
Batch number: 4368906
Best Before End: August 2022

# > Analysis of the batch :

	Results	Specifications	Method					
Physico-chemical analysis								
Aspect	CONFORM	Beige-green powder	Visual check (compared with a sample test).					
Odour	CONFORM	None	Smell check (compared with a sample test).					
Humidity	3,41%	< 8%	Test performed with an Halogen Moisture Analyser METTLER TOLEDO.					
pH	8,96	8 - 9	NF EN ISO 787-9 T31-235					
Grain sizes	CONFORM	90%<20μm and 100%<40μm	Test performed with a Mastersizer 2000 (MALVERN) particle size analyzer.					
	Guaran	teed heavy metals						
Lead (Pb)	CONFORM	< 20 ppm						
Arsenic (As)	CONFORM	< 15 ppm	Mineralization according to EN15510. Internal method spectrometry A.A. IN 020 20					
Cadmium (Cd)	CONFORM	< 0,2 ppm	(Perkin Elmer PinAAcle 900T).					
Mercury (Hg)	CONFORM	< 0,05 ppm						
		microbiological quality						
Ingredient classified in categ	ory 2 (according to the notice of	the scientific committee of the	e EU cosmetics products dated 09/23/1998)					
DGAT	CONFORM	< 1000 CFU/g - [CAT 2]	NF EN ISO 21149					
DMLT	CONFORM	< 100 CFU/g - [CAT 2]	NF EN ISO 16 212					
Pseudomonas aeruginosa	CONFORM	NONE	NF EN ISO 21148 and 22717					
Staphylococcus aureus	CONFORM	NONE	NF EN ISO 21148 and 22718					
Candida albicans	CONFORM	NONE	NF EN ISO 21148 and 18416					

# 

☑ The batch meets specifications. Product is released.

 $\ \square$  The batch doesn't meet specifications. But the product is released with the agreement of the customer.

The Quality Service



# Manufacturing Process & Risk Assessment Specifications

# **GLOBAL MANUFACTURING FLOW CHART French Green Clay Ultra Ventilated**

1	• DEPOSIT
2	MINING PROCESS
3	TRANSPORTING RAW MATERIAL
4	SORTING OUT & STOCKING RAW MATERIAL
6	CRUSHING PROCESS
<b>X</b>	DRYING PROCESS
8	SORTING OUT GRAINS VIA AIR INDUCTION SYSTEM
9	• STORING IN SILOS
10	FILLING UP BIG BAGS OR PAPER BAGS
11	STORING THE CLAY
12	DISPATCHING THE CLAY
13	DELIVERING CUSTOMERS



# 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.
Y	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.

SDS number: 001 Revision date: 26/12/2017 Supersedes: 28/12/2015

Version 10.0



# SAFETY DATA SHEET

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

# 1. Identification of the substance and the company:

#### 1.1 Product identifier

Product name: Green Ultra Ventilated French Clay

Product code: CLAYFRENGREE

Clay mainly composed of illite, kaolin and montmorillonite.

Synonyms: None.

CAS: 12173-60-3 (Illite), 1332-58-7 (kaolin), 1318-93-0 (Montmorillonite).

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

#### 1.2 Relevant identified uses of the substance and uses advised against

Use of the substance (this list is not exhaustive): Ingredient for the cosmetic, pharmaceutical industries and clay therapy.

Relevant identified uses: Industrial, professional and individual uses.

Uses advised against: None.

#### 1.3 Details of the supplier of the safety data sheet

Identification of the company: MADAR Corporation Limited

19-20 Sandleheath Industrial Estate, Fordingbridge, Hampshire, SP6 1PA Tel. + 44 (0)1425 655555 | E-mail: sales@madarcorporation.co.uk

Approved Sellers: Cosmetic Butters, Mystic Moments, New Directions, World of Moulds

#### 1.4 Emergency telephone number

European emergency number: 112

# 2. Hazards identification:

#### 2.1 Classification of the substance

2.1.1 Classification according to the Regulation (CE) N° 1272/2008 (CLP)

The substance is not classified as hazardous according to Regulation (CE) 1272/2008.

#### 2.1.2 Classification according to the directive 67/548/CEE

The substance is not classified as hazardous according to the EU directive N°67/548/CEE.

2.1.3 Additional, national or regional information

None.

#### 2.2 Label elements

#### 2.2.1 Classification according to the Regulation (CE) N°1272/2008 (CLP)

Not applicable. The substance is not classified as hazardous according to Regulation (CE) 1272/2008.

### 2.2.2 Classification according to the directive 67/548/CEE

Not applicable. The substance is not classified as hazardous according to the EU directive N°67/548/CEE.

### 2.3 Other hazards

The components do not meet the criteria for classification as PBT and/or vPvB found in the list of the appendix XIII of Regulation N° 1907/2006. This product is not classified as hazardous. It doesn't represent a risk to health or the environment under current legislation. Dust airborne may be possible. Its quantity may be more or less important according to the grain size of the product.

#### 3. Composition/information on ingredients:

#### 3.1 Substances

<u>Note:</u> The substance described below is neither a mixture nor a multi-constituent substance (result of a manufacturing process). It is composed of natural clay.

CAS	REACH Registration number	Product name	Classification in compliance with the directive 67/548/CEE	Classification in compliance with the Regulation (CE) N° 1272/2008	Mass percentage
See 1.1	Exempt (see 1.1)	Green Ultra Ventilated French Clay	Unclassified	Unclassified	100%

#### 3.2 Mixture

Not applicable.



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

#### 4. First aid measures:

#### 4.1 Description of 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 is symptoms persist. Do not induce vomiting without medical attention.

Self-protection of the first aider: No specific care.

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

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

4.3 Indication of immediate medical attention and specific treatment needed

None. See above 4.1.

#### 5. Firefighting measures:

#### 5.1 Extinguishing materials

This product is non-inflammable and non-explosive. No specific firefighting measure is required. No unsuitable extinguishing materials.

#### 5.2 Special hazards arising from substance

None.

#### **5.3 Advice for firefighters**

No specific care is recommended.

#### 6. Accidental release measures:

#### 6.1 Personal precautions, protective equipment and emergency procedures

#### **To non-firefighters and firefighters** (Applicable if important and slightly important release)

Avoid dust formation. Avoid inhaling dust. In case of dust formation, wear an anti-dust mask - type FFP3.

#### **6.2 Environmental precautions**

No specific precaution. See environmental information section 12.

#### 6.3 Methods and materials for containment and cleaning up

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 13. Keep in sealed containers.

#### **6.4 Reference to other sections**

See sections 8 and 13 for other information.

#### 7. Handling and storage:

#### 7.1 Precautions for safe handling

#### 7.1.1 Technical measures:

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, no specific firefighting measure is recommended. Minimize environmental release, using filters for ventilation systems for example.

#### 7.1.2 Advice on general occupational hygiene

Dot not eat, drink, and smoke in working areas. Wash your hands after every use. Remove soiled clothes and protective equipment before getting into a catering area.

#### 7.2 Conditions for safe storage, including any compatibilities

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

#### 7.3 Specific final use

If you need more details for uses mentioned in section 1.2, contact your supplier. If you need advice for specific uses of the product, contact your supplier.

#### 8. Exposure control and personal protection:

#### 8.1 Control parameters

#### 8.1.1 Occupational exposure limits:

Argile verte du Velay / Velay green clay is considered as dust with no specific effect.



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

Components	Exposul	re limits	Type of value	Source
Green Ultra	10 mg/m3 (inhalable	5 mg/m3 (alveolar	VME -8h	French Ministry of Labour - Circular
Ventilated French	fraction)	fraction)		issued by the French Ministry of Labour
Clay				on May 09 <sup>th</sup> 1985.

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

#### 8.1.2 Biological limit values

Non applicable.

#### 8.1.3 Recommended follow-up procedures

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

- A decree issued on December 15<sup>th</sup> 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.

#### 8.1.4 Professional exposure limits and/ or biological limit values of air contaminants

Non applicable.

#### 8.1.5 DNEL/PNEC values

No available DNEL or PNEC values: 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 / not chemically modified substance), and was therefore not assessed further with chemical security.

#### 8.2 Exposure controls

#### **8.2.1** 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 dusty areas for example.

#### 8.2.2 Individual protection measures, such as personal protective equipment

- <u>A Face and eye protection</u>: Wear safety glasses if airborne dust generation.
- B Skin protection: Wearing gloves is advised.
- <u>C Respiratory protection</u>: Wear a respiratory equipment type FFP3 if airborne dust is generated.
- D-Thermal dangers: Non applicable.

#### 8.2.3 Environmental measures

In case of accidental spillage, refer to section 6.

In case of abnormal use of the product, follow the following instructions: Remove the product or the rinsing water in compliance with local and national rules.

#### 9. Physico-chemical properties:

#### 9.1 Information on main physical and chemical properties

Features	Data	Methods
Physical state	Solid	
Appearance	Powder	
Colour	Beige / green	
Odour	Odourless	
Odour threshold	Non applicable	
рН	Between 8 and 9.5	Measure carried out in compliance with method: NF EN ISO 787-9 T31-235 and pH-measure.
Melting point	Non applicable	
Freezing point	Non applicable	
Boiling point	Non applicable	
Flash point	Non applicable	
Evaporation rate	Non applicable	
Features	Data	Methods
Inflammability	Non inflammable	
Upper/lower flammability or explosive limits	Non applicable	



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

Vapour pressure	Non applicable	
Vapour density	Non applicable	
Relative density	From 0.4 to 0.95 according to grain size	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	Non applicable	
Auto-ignition temperature	Non applicable	
Decomposition temperature	No data available	
Viscosity	Non applicable	
Explosive properties	Non explosive	
Oxidising properties	Non oxidising	

# 9.2 Other information

None.

# 10. Stability and reactivity:

10.1 Reactivity

The product is stable and inert.

10.2 Chemical stability

The product is stable.

10.3 Possibility of hazardous reactions

None identified.

10.4 Conditions to be avoided

None identified.

10.5 Incompatible materials

No incompatible materials identified.

10.6 Hazardous decomposition product

No hazardous decomposition product identified.

# 11. Toxicological information:

11.1 Information on toxicological effects

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

TESTS	OCDE N°	Results	Species	Duration of the study	Classification
Acute oral toxicity study	423	LD <sub>50</sub> =5000mg/kg	Rat	3 hours	Category 5 or
					unclassified => non
					toxic
Acute dermal toxicity	402	LD <sub>50</sub> >2000mg/kg	Rat	14 days of study.	Category 5 => non
study					toxic
Acute inhalation toxicity	403	LD <sub>50</sub> between 2000 and 5000	Rat	Exposure: 4 hours	Category 5 or
study		mg/kg and		during 14 observation	unclassified =>non
		LC <sub>50</sub> =3,856mg/L		days	toxic
Acute dermal irritation	404	Not irritating	Rabbit	72 hours after	Unclassified => Non
study				releasing the	irritating
				substance	
Acute eye irritation	405	Not irritating	Rabbit	72 hours after	Unclassified => Non
study				instillation	irritating
Skin sensitisation study	406	Negative	Guinea pig	48 hours after	Negative
				releasing the	
				substance.	
In vitro mammalian	473	Do not provoke mammalian	In vitro test	21 hours of exposure	Do not provoke
chromosome aberration		chromosome aberrations.			mammalian
test					chromosome
					aberrations.



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

TESTS	OCDE N°	Results	Species	Duration of the study	Classification	
Reverse mutation	471	-	Salmonella	48 hours	Negative	
bacterial test			typhimurium			
			train			
Reproduction toxicity	Is not classi	fied as hazardous. (No specific data)				
	Natural pro	duct.				
Gem cell mutagenicity	Is not classi	fied as hazardous. (No specific data)				
	Natural pro	duct.				
Specific target organ	Is not classi	fied as hazardous. (No specific data)				
toxicity – single	Natural pro	duct.				
exposure						
Specific target organ	Is not classi	fied as hazardous. (No specific data)				
toxicity – repeated	Natural product.					
exposure						
Aspiration toxicity	Is not classified as hazardous. (No specific data).					
hazard	Natural product.					

# 12. Ecological information:

#### 12.1 Toxicity

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

TESTS	OCDE N°	Results	Species	Medium	Testing time	Classification
Acute aquatic toxicity test		NOEC > 100mg/L	Brachidanio rerio	Aquatic	96 hours	Safe for the
	203	LC <sub>50</sub> > 100mg/L		environment		environment.
Algal growth inhibition	201	NOEC>100mg/L	Desmodesmus	Aquatic	72 hours	Safe for the
test			subspicatus	environment		environment.
Acute immobilisation test	202	EC <sub>50</sub> >100 mg/L	Daphnia magna	Aquatic	48 hours	Safe for the
				environment		environment.
Oral acute toxicity test	213	LC <sub>50</sub> >	Apis mellifera mellifera	-	48 hours	Safe for the
(side effects)		100μg/subject	L. (Hymenoptera:			environment.
Danisal assita tasiisita taat	21.4	16.5	apidae) Apis mellifera mellifera		40 h a	Cafa fautha
Dermal acute toxicity test (side effects)	214	LC <sub>50</sub> > 100μg/subject	L. (Hymenoptera: apidae)	-	48 hours	Safe for the environment.

# 12.2 Persistance and degradability

Stable and non-biodegradable product (inorganic product).

### 12.3 Bioaccumulative persistance

Non applicable (inorganic product).

# 12.4 Mobility in soil

No specific data.

#### 12.5 Results of PBT and vPvB assessments

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.

#### 13. Disposal considerations:

# 13.1 Waste treatment method

<u>Substance treatment</u>: 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.

# 14. Transport information:

14.1 UN number: Not listed.

14.2 UN proper shipping name: No data available.

14.3 Transport hazard group: Unclassified.



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

14.4 Packing group: Not concerned.

14.5 Environmental hazards: None.

**14.6 Special precautions for user:** See section 7.1.1. Follow the same instructions as when handling the product.

14.7 Transport in bulk according to appendix II of MARPOL 73/78 and the IBC code: Not concerned.

# 15. Regulatory information:

15.1 Safety, health and environmental Regulations / legislations specific for the substance or mixture

#### 15.1.1. EU Regulations

The substance is exempt in compliance with Appendix V, chapter 7, of 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 UE Regulation.

#### 15.1.2. National directives - France

No additional information.

#### 15.2 Chemical security assessment

Green Ultra Ventilated French Clay is exempt from REACH registration. No chemical security assessment was carried out for this substance.

#### 16. Other information:

16.1 Version

#### Version number: 9

Reason for updating the earlier version: spelling and grammar mistakes. This version supersedes all previous versions.

#### 16.2 Meanings of abbreviations and acronyms

DNEL =	Derived No-Effect Level
EC <sub>50</sub> =	Effective Concentration 50 %
LC <sub>50</sub> =	Lethal Concentration 50 %
DC <sub>50</sub> =	Lethal Dose 50 %
NOEC =	No-Observed Effect Concentration
PBT =	Persistent Bioaccumulative Toxic
PNEC =	Predicted No-Effect Concentration
SDS =	Safety Data Sheet
vPvB =	Very Persistent Substance Very Bioaccumulative

# 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 Green 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,** <u>according to the regulations: 1223/2009 and the French decree</u> 2012-232
- Didn't undergo any irradiation or chemical treatment.
- Crystalline Silica Free,
- Suitable for Vegans



# **COSMETIC INGREDIENT - TECHNICAL DATA SHEET**

In compliance with CE Regulation n°1223/2009

Updated: 26/12/2017

version 16

#### **INFORMATION ON THE INGREDIENT**

**Trade name:** Green Ultra Ventilated French Clay

Product reference: CLAYFRENGREE

**Composition:** 100% natural mineral product

Origin of the ingredient: France

# Description of the manufacturing process:

*This Green 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.

#### FEATURES OF THE INGREDIENT

INCI\*: Illite:  $75\% \pm 10$  Kaolin:  $19\% \pm 5$  Montmorillonite:  $6\% \pm 3$ 

CAS N°: 12173-60-3 1332-58-7 1318-93-0

\*The INCl composition above, includes a portion of non-clay minerals.

Mineralogy: This clay is very pure: more than 80 % of clay

This clay doesn't contain quartz

Impurities: Monitoring controls carried out by a laboratory providing COFRAC results

■ Traces of heavy metals naturally occur in clays

They are permitted by CE regulation because they are technically unavoidable

Mineralization according to EN15510

Internal method spectrometry A.A. IN 020 20 (Perkin Elmer PinAAcle 900T)

Levels of dioxins and PCBs controlled are near zero

#### SPECIFICATIONS OF THE INGREDIENT

Physico-chemical analysis							
Humidity (humidimeter METTLER TOLEDO) < 8 % Aspect Beige-green p							
pH (method NF EN ISO 787-9 T31-235)	8 – 9	Odour	None				
Grain sizes (granulometer Mastersizer 2000 Malvern)	Ultra: 90%<20	Dμm / 100%<40μm and Superfi	ne : 90%<77µm / 100%<100µm				
Microbiological analysis							
Ingredient classified in category 1 or 2 (account	rding to the notice of	the scientific committee of the EU cosn	netic products of 09/23/1998)				
		Specifications category 2	Specifications category 1				
Mesophilic aerobic bacteria DGAT (NF EN ISO 21149)		< 1000 CFU/g	< 100 CFU/g				
Yeasts and molds DMLT (NF EN ISO 16212)	< 100 CFU/g	< 10 CFU/g					
Pseudomonas aeruginosa, Staphylococcus aureus	NONE	NONE					
albicans (NF EN ISO 21148, 18416, 21150, 22718, 22717)							

If not specified, please note that our price offers are automatically CAT 2 clays. Cotations for CAT 1\* clays are available upon request (no irradiation) and should be mentioned in the price offer. \*Our thermal treatment is 100% natural.

#### REGULATORY INFORMATION

Product not concerned by REACH

C.M.R. substances: None Allergenic substances: None

Nanomaterials: None E.S.B., G.M.O, C.O.V.: Not applicable to minerals

Ingredient not tested on animals

# TOXICOLOGICAL AND ECOLOGICAL INFORMATION

For this section, please refer to the MSDS

#### PRESERVATION, PACKAGING, STORAGE

Preservation: 1 year after opening

Microbiology: 12-month guarantee after picking for category 2, 6-month guarantee after picking for category 1

This ingredient is sold in bags and/or big bags

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