

FICHA DE SEGURIDAD/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: Yellow French Clay / Arcilla Amarilla Francesa
Product code: 1171
Chemical name: Clay mainly composed of illite. None.
Synonyms: 106958-53-6 (Illite).
CAS:
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 the 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 cosmetics, 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:

La Despensa del Jabón - San Ignacio Auzunea Etxetaldea, 1 048200 Durango. España.
 Tel: 944 657 841/ Fax: 941 899 765 - www.ladispensadeljabon.com / tienda@ladispensadeljabon.com
 Teléfono de urgencias: Instituto Nacional de Toxicología. Madrid. Tel: 91 562 04 20

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 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. The quantity may be more or less important according to the grain size of the product.

3. Composition/information on ingredients:

3.1 Substances

Note: 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	Pourcentage by mass
See 1.1	Exempt (see 1.1)	Yellow - Ultra Ventilated French Clay	Unclassified	Unclassified	100%

3.2 Mixture

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.

Not applicable.

4. First aid measures:

4.1 Description of first aid measures

First-aid measures general: Have product container, label elements and Safety Data Sheet at hand if medical advice is needed.

First-aid measures after inhalation: The person should be taken outside into the open air, away from dust. Get medical attention if symptoms occur.

First-aid measures after skin contact: If symptoms occur, rinse cautiously with water for several minutes. Get medical attention if symptoms persist.

First-aid measures after eye contact: Rinse cautiously with water for several minutes. Get medical attention if symptoms persist.

First-aid measures after ingestion: Get medical attention if 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 and specific treatment needed

None. See above 4.1.

5. Firefighting measures:

5.1 Extinguishing media

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

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

Do 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:

Yellow - Ultra Ventilated French Clay - is considered as dust with no specific effect.

SAFETY DATA SHEET

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Components	Exposure limits		Type of value	Source
Yellow - Ultra Ventilated French Clay	10 mg/m ³ (inhalable fraction)	5 mg/m ³ (alveolar fraction)	VME -8h	French Ministry of Labour - Circular issued by the French Ministry of Labour on May 09 th 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 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.

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 the nature /not chemically modified substance), and was therefore not assessed further with chemical controls.

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

A – Face and eye protection: Wear safety glasses if airborne dust generation.

B – Skin protection: Wearing gloves is advised.

C - Respiratory protection: Wear a respiratory equipment type FFP3 if airborne dust generation.

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	Yellow	
Odour	Odourless	
Odour threshold	Non applicable	
pH	Between 8 and 9.5	Measure carried out in compliance with the 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	

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.

Vapour pressure	Non applicable	
Vapour density	Non applicable	
Relative density	From 0.4 to 0.6 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 ₅₀ =5000mg/kg	Rat	3 hours	Category 5 or unclassified => non toxic
Acute dermal toxicity study	402	LD ₅₀ >2000mg/kg	Rat	14 days of study.	Category 5 => non toxic
Acute inhalation toxicity study	403	LD ₅₀ between 2000 and 5000 mg/kg and LC ₅₀ =3,856mg/L	Rat	Exposure: 4 hours during 14 observation days	Category 5 or unclassified =>non toxic
Acute dermal irritation study	404	Not irritating	Rabbit	72 hours after releasing the substance	Unclassified => Non irritating
Acute eye irritation study	405	Not irritating	Rabbit	72 hours after instillation	Unclassified => Non irritating
Skin sensitisation study	406	Negative	Guinea pig	48 hours after releasing the substance	Negative
In vitro mammalian chromosome aberration test	473	Do not provoke mammalian chromosome aberrations.	In vitro test	21 hours of exposure	Do not provoke mammalian chromosome aberrations.

SAFETY DATA SHEET

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TESTS	OCDE N°	Results	Species	Duration of the study	Classification
Reverse mutation bacterial test	471	-	Salmonella typhimurium train	48 hours	Negative
Reproduction toxicity	Is not classified as hazardous. (No specific data). Natural product.				
Gem cell mutagenicity	Is not classified as hazardous. (No specific data). Natural product.				
Specific target organ toxicity – single exposure	Is not classified as hazardous. (No specific data). Natural product.				
Specific target organ toxicity – repeated exposure	Is not classified as hazardous. (No specific data). Natural product.				
Aspiration toxicity hazard	Is not classified as hazardous. (No specific data). 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	Medimu	Testing time	Classification
Acute aquatic toxicity test	203	NOEC > 100mg/L ,LC ₅₀ > 100mg/L	Brachidanio rerio	Aquatic environment	96 hours	Safe for the environment.
Test d'inhibition de la croissance pour les algues	201	NOEC>100mg/L	Desmodesmus subspicatus	Aquatic environment	72 hours	Safe for the environment.
Acute immobilisation test	202	EC ₅₀ >100 mg/L	Daphnia magna	Aquatic environment	48 hours	Safe for the environment.
Oral acute toxicity test (side effects)	213	LC ₅₀ > 100µg/subject	Apis mellifera mellifera L. (Hymenoptera: apidae)	-	48 hours	Safe for the environment.
Dermal acute toxicity test (side effects)	214	LC ₅₀ > 100µg/subject	Apis mellifera mellifera L. (Hymenoptera: apidae)	-	48 hours	Safe for the environment.

12.2 Persistence and degradability

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 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

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.

14. Transport information:

14.1 UN number: Not listed.

14.2 UN proper shipping name: No data available.

SAFETY DATA SHEET

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14.3 Transport hazard group: Unclassified.

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 of 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 the nature / chemically non-modified substance). The substance is not labeled in compliance with Regulation (CE) N° 1272/2008 and UE regulations.

15.1.2. National directives – France

No additional information.

15.2 Chemical security assessment

Yellow - 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: 7

Reason for updating the earlier version: Was updated in compliance with Appendix II of Regulation (CE) n°1907/2006 (REACH), Regulation (CE) n° 1272/2008, and Regulation (CE) n°453/2010. This version supersedes all previous versions.

16.2 Meanings of abbreviations and acronyms

DNEL =	Derived No-Effect Level
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/>

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