

SURGICAL



SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 2015/830)

SECTION 1 : IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name : SURGICAL

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

Surgical plaster is a formulated hemihydrate plaster. This product is used in dentistry for the production of study models where a good white colour is required. It can be mixed with dental stone plaster for the production of model bases. It can also be used in health care applications during the production of limb supports and hearing aids.

1.3. Details of the supplier of the safety data sheet

Registered company name : Saint-Gobain Formula.

Address : Bowbridge Lane - Nottinghamshire.NG 24 3BX.Newark.United Kingdom.

Telephone : +44 (0) 1636 670200. Fax : +44 (0) 1636 670229.

info@saintgobainformula.com

http://www.saintgobainformula.com

Information contact : msds-formula@saint-gobain.com

1.4. Emergency telephone number : +33 (0)1 45 42 59 59.

Association/Organisation : INRS / ORFILA http://www.centres-antipoison.net.

SECTION 2 : HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

In compliance with EC regulation No. 1272/2008 and its amendments.

This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.

This mixture does not present a health hazard with the exception of possible occupational exposure thresholds (see paragraphs 3 and 8).

This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.

2.2. Label elements

In compliance with EC regulation No. 1272/2008 and its amendments.

No labelling requirements for this mixture.

2.3. Other hazards

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC) $\geq 0.1\%$ published by the European Chemicals Agency (ECHA) under article 57 of REACH: <http://echa.europa.eu/fr/candidate-list-table>

The mixture satisfies neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

Composition :

Identification	(EC) 1272/2008	Note	%
INDEX: PLATRE 1 CAS: 7778-18-9 EC: 231-900-3 REACH: 1-2119444918-26 CALCIUM SULPHATE		[1]	50 \leq x % < 100

Information on ingredients :

[1] Substance for which maximum workplace exposure limits are available.

SECTION 4 : FIRST AID MEASURES

As a general rule, in case of doubt or if symptoms persist, always call a doctor.

NEVER induce swallowing by an unconscious person.

4.1. Description of first aid measures

In the event of splashes or contact with eyes :

Wash thoroughly with fresh, clean water for 15 minutes holding the eyelids open.

If there is any redness, pain or visual impairment, consult an ophthalmologist.

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In the event of splashes or contact with skin :

Watch out for any remaining product between skin and clothing, watches, shoes, etc.

In the event of swallowing :

Seek medical attention, showing the label.

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

No specific symptoms or effects have been reported.

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

None

SECTION 5 : FIREFIGHTING MEASURES

Non-flammable.

5.1. Extinguishing media

Suitable methods of extinction

Any means suitable for extinguishing surrounding fire.

Unsuitable methods of extinction

None.

5.2. Special hazards arising from the substance or mixture

None.

5.3. Advice for firefighters

Special protective equipment for fire-fighters: None.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed under headings 7 and 8.

For first aid worker

First aid workers will be equipped with suitable personal protective equipment (See section 8).

6.2. Environmental precautions

Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up

Retrieve the product by mechanical means (sweeping/vacuuming) : do not generate dust.

6.4. Reference to other sections

No data available.

SECTION 7 : HANDLING AND STORAGE

Requirements relating to storage premises apply to all facilities where the mixture is handled.

7.1. Precautions for safe handling

Always wash hands after handling.

Fire prevention :

Prevent access by unauthorised personnel.

Recommended equipment and procedures :

For personal protection, see section 8.

Observe precautions stated on label and also industrial safety regulations.

Prohibited equipment and procedures :

No smoking, eating or drinking in areas where the mixture is used.

7.2. Conditions for safe storage, including any incompatibilities

No data available.

Storage

Store dry

Packaging

Always keep in packaging made of an identical material to the original.

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7.3. Specific end use(s)

No data available.

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Occupational exposure limits :

- ACGIH TLV (American Conference of Governmental Industrial Hygienists, Threshold Limit Values, 2010) :

CAS TWA :	STEL :	Ceiling :	Definition :	Criteria :	
7778-18-9	10 mg/m3	-	-	-	I

- Belgium (Order of 19/05/2009, 2010) :

CAS TWA :	STEL :	Ceiling :	Definition :	Criteria :	
7778-18-9	10 mg/m3	-	-	-	-

- France (INRS - ED984 :2008) :

CAS VME-ppm :	VME-mg/m3 :	VLE-ppm :	VLE-mg/m3 :	Notes :	TMP No :
7778-18-9	-	10	-	-	-

Derived no effect level (DNEL) or derived minimum effect level (DMEL):

CALCIUM SULPHATE (CAS: 7778-18-9)

Final use:

Exposure method:
Potential health effects:
DNEL :

Inhalation.
Short term systemic effects.
5082 mg of substance/m3

Workers.

Exposure method:
Potential health effects:
DNEL :

Inhalation.
Long term systemic effects.
21.17 mg of substance/m3

Final use:

Exposure method:
Potential health effects:
DNEL :

Ingestion.
Short term systemic effects.
11.4 mg/kg body weight/day

Man exposed via the environment.

Exposure method:
Potential health effects:
DNEL :

Ingestion.
Long term systemic effects.
1.52 mg/kg body weight/day

Exposure method:
Potential health effects:
DNEL :

Inhalation.
Short term systemic effects.
3811 mg of substance/m3

Exposure method:
Potential health effects:
DNEL :

Inhalation.
Long term systemic effects.
5.29 mg of substance/m3

Predicted no effect concentration (PNEC):

CALCIUM SULPHATE (CAS: 7778-18-9)

Environmental compartment:
PNEC :

Waste water treatment plant.
100 mg/l

8.2. Exposure controls

Personal protection measures, such as personal protective equipment

Pictogram(s) indicating the obligation of wearing personal protective equipment (PPE) :



Use personal protective equipment that is clean and has been properly maintained.

Store personal protective equipment in a clean place, away from the work area.

Never eat, drink or smoke during use. Remove and wash contaminated clothing before re-using. Ensure that there is adequate ventilation, especially in confined areas.

- Eye / face protection

Avoid contact with eyes.

Before handling powders or dust emission, wear mask goggles in accordance with standard EN166.

- Hand protection

Wear suitable protective gloves in the event of prolonged or repeated skin contact.

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Recommended properties :

- Impervious gloves in accordance with standard EN374

- Body protection

Work clothing worn by personnel shall be laundered regularly.

After contact with the product, all parts of the body that have been soiled must be washed.

- Respiratory protection

Avoid breathing dust.

Type of FFP mask :

Wear a disposable half-mask dust filter in accordance with standard EN149.

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information :

Physical state : Powder or dust.

Important health, safety and environmental information

pH : Not relevant.

Boiling point/boiling range : Not relevant.

Flash point interval : Not relevant.

Vapour pressure (50°C) : Not relevant.

Density : Not stated.

Water solubility : Soluble.

Melting point/melting range : Not relevant.

Self-ignition temperature : Not relevant.

Decomposition point/decomposition range : Not relevant.

9.2. Other information

Decomposition into CaSO₄ and H₂O about 700°C (973K).

Decomposition into CaO and SO₃ about 1000°C (1273K).

SECTION 10 : STABILITY AND REACTIVITY

10.1. Reactivity

No data available.

10.2. Chemical stability

This mixture is stable under the recommended handling and storage conditions in section 7.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Avoid :

- formation of dusts

10.5. Incompatible materials

None.

10.6. Hazardous decomposition products

No dangerous products of decomposition.

SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

No data available.

11.1.1. Substances

Acute toxicity :

CALCIUM SULPHATE (CAS: 7778-18-9)

Oral route :

LD₅₀ > 1581 mg/kg

Species : Rat

OECD Guideline 420 (Acute Oral Toxicity Fixed Dose Method)

Inhalation route :

LC₅₀ > 2.61 mg/l

Species : Rat

OECD Guideline 403 (Acute Inhalation Toxicity)

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Skin corrosion/skin irritation :

CALCIUM SULPHATE (CAS: 7778-18-9)
Corrosivity :

No observed effect.
Species : Rabbit
OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

Species : Rabbit
OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

Serious damage to eyes/eye irritation :

CALCIUM SULPHATE (CAS: 7778-18-9)

Species : Rabbit
OECD Guideline 405 (Acute Eye Irritation / Corrosion)

Species : Rabbit
OECD Guideline 405 (Acute Eye Irritation / Corrosion)

Species : Rabbit
OECD Guideline 405 (Acute Eye Irritation / Corrosion)

Species : Rabbit
OECD Guideline 405 (Acute Eye Irritation / Corrosion)

Respiratory or skin sensitisation :

CALCIUM SULPHATE (CAS: 7778-18-9)
Local lymph node stimulation test :

Non-Sensitiser.
Species : Guinea pig
OECD Guideline 406 (Skin Sensitisation)

Guinea Pig Maximisation Test (GMPT) :

Non-sensitiser.
Species : Guinea pig
OECD Guideline 406 (Skin Sensitisation)

Buehler Test :

Non-sensitiser.
Species : Guinea pig
OECD Guideline 406 (Skin Sensitisation)

Germ cell mutagenicity :

CALCIUM SULPHATE (CAS: 7778-18-9)

No mutagenic effect.

Mutagenesis (in vivo) :

Negative.
Species : Mouse
OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test)

Mutagenesis (in vitro) :

Negative.
OECD Guideline 471 (Bacterial Reverse Mutation Assay)

Carcinogenicity :

CALCIUM SULPHATE (CAS: 7778-18-9)
Carcinogenicity Test :

Negative.

No carcinogenic effect.

Reproductive toxicant :

CALCIUM SULPHATE (CAS: 7778-18-9)
No toxic effect for reproduction
Study on development :

Species : Rat
OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)

11.1.2. Mixture

No toxicological data available for the mixture.

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SECTION 12 : ECOLOGICAL INFORMATION

12.1. Toxicity

12.1.1. Substances

CALCIUM SULPHATE (CAS: 7778-18-9)

Fish toxicity :

LC50 > 79 mg/l
Species : Others
Duration of exposure : 96 h
OECD Guideline 203 (Fish, Acute Toxicity Test)

Crustacean toxicity :

EC50 > 79 mg/l
Species : Daphnia sp.
Duration of exposure : 48 h
OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)

Algae toxicity :

ECr50 > 79 mg/l
Species : Selenastrum capricornutum
Duration of exposure : 72 h
OECD Guideline 201 (Alga, Growth Inhibition Test)

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability

Abiotic Degradation Physical- and photo-chemical elimination: The product hydrolyses quickly in the presence of water to: Calcium and Sulfate Ions The individual components are poorly eliminated from water.

12.2.1. Substances

CALCIUM SULPHATE (CAS: 7778-18-9)

Biodegradability :

no degradability data is available, the substance is considered as not degrading quickly.

12.3. Bioaccumulative potential

Based on the n-octanol/water partition coefficient significant accumulation in organisms is not expected. No indication to bioaccumulation potential. The ecological data were measured on the hydrolysed product. According to experiences this product is inert and not degradable biologically.

12.4. Mobility in soil

Water-soluble solid. Natural constituent in soils. If product enters soil, it will be mobile and may contaminate groundwater

12.5. Results of PBT and vPvB assessment

This substance does not meet the criteria for classification as PBT or vPvB.

12.6. Other adverse effects

According to the criteria of the European classification and labelling system, the substance/the product has not to be labelled as dangerous for the environment.

SECTION 13 : DISPOSAL CONSIDERATIONS

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

13.1. Waste treatment methods

Do not pour into drains or waterways.

Waste codes / waste designations according to EWC

10 12 wastes from manufacture of ceramic goods, bricks, tiles and construction products

10 12 06 discarded moulds

Waste :

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

Soiled packaging :

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

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SECTION 14 : TRANSPORT INFORMATION

Exempt from transport classification and labelling.

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2015 - IMDG 2014 - ICAO/IATA 2015).

SECTION 15 : REGULATORY INFORMATION

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

- Classification and labelling information included in section 2:

The following regulations have been used:

- EU Regulation No. 1272/2008 amended by EU Regulation No. 487/2013.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 758/2013.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 944/2013.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 605/2014.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 1297/2014.

- Container information:

No data available.

- Particular provisions :

No data available.

15.2. Chemical safety assessment

No data available.

SECTION 16 : OTHER INFORMATION

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof.

Abbreviations :

DNEL : Derived No-Effect Level

PNEC : Predicted No-Effect Concentration

ADR : European agreement concerning the international carriage of dangerous goods by Road.

IMDG : International Maritime Dangerous Goods.

IATA : International Air Transport Association.

ICAO : International Civil Aviation Organisation

RID : Regulations concerning the International carriage of Dangerous goods by rail.

PBT: Persistent, bioaccumulable and toxic.

vPvB : Very persistent, very bioaccumulable.

SVHC : Substances of very high concern.