

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 29.10.2014

Version number 1

Revision: 29.10.2014

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

· **1.1 Product identifier**

· **Trade name:** PLASTALGIN NORMAL

· **Article number / formula:** 294S

· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

· **Application of the substance / the preparation :** dental product

· **1.3 Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Septodont Healthcare India Pvt. Ltd.
C-1/2, MIDC, Taloja, Tal, Panvel, Dist Raigad
410208- Maharashtra - INDIA
Tel. : +91 (22) 27 40 19 70 / 71
Fax : +91 (22) 27 40 19 72

· **1.4 Emergency telephone number:**

France (ORFILA 24h/24) - Tel : +33 (0)1 45 42 59 59
Ireland - Tel : 00 353 1 8092568 - 00 353 1 8379964 (24h/24)
EU Tel : 112

SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**

· **Classification according to Regulation (EC) No 1272/2008 :**



STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.



Eye Irrit. 2 H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

· **Classification according to Directive 67/548/EEC or Directive 1999/45/EC :**



Xn; Harmful

R48/20: Harmful: danger of serious damage to health by prolonged exposure through inhalation.

· **Information concerning particular hazards for human and environment:**

The product has to be labelled in the latest valid version according to the calculation procedure of the "General Classification guideline for preparations of the EU".

· **Classification system:**

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

· **2.2 Label elements**

· **Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the CLP regulation.

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· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Warning

· **Hazard-determining components of labelling:**

Kieselguhr, soda ash flux-calcined
dipotassium hexafluorotitanate

· **Hazard statements**

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H373 May cause damage to organs through prolonged or repeated exposure.

· **Precautionary statements**

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P264 Wash hands thoroughly after handling.

P305+P351+P338 **IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P314 Get medical advice/attention if you feel unwell.

P302+P352 **IF ON SKIN:** Wash with plenty of water.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**

· **Description:** Mixture: consisting of the following components.

· **Dangerous components:**

| | | |
|--------------------------------------|--|---------|
| CAS: 68855-54-9 EINECS: 272-489-0 | Kieselguhr, soda ash flux-calcined ☒ Xn R48/20 ☒ STOT RE 2, H373 | 50-100% |
| CAS: 57-55-6 EINECS: 200-338-0 | propane-1,2-diol | 2,5-10% |
| CAS: 16919-27-0 EINECS: 240-969-9 | dipotassium hexafluorotitanate ☒ Xn R22; ☒ Xi R41; ☒ Xi R43 ☒ Eye Dam. 1, H318; ☒ Acute Tox. 4, H302; ☒ Skin Sens. 1, H317 | ≤1% |

· **Additional information:** For the wording of the listed risk phrases, refer to section 16.

SECTION 4: First aid measures

· **4.1 Description of first aid measures**

· **After excessive inhalation:** Supply fresh air; consult a doctor in case of complaints.

· **After skin contact:** Generally the product does not irritate the skin.

· **After eye contact:** Rinse opened eye for several minutes under running water.

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- **After swallowing:** If symptoms persist consult a doctor.
- **4.2 Most important symptoms and effects, both acute and delayed :**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed :**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture :** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures :** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to item 13.
- **6.4 Reference to other sections :**
See Section 7 for information on safe handling.
See Section 8 for information on personal protective equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling :** No special precautions are necessary if used correctly.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **7.3 Specific end use(s) :** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see section 7.
- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any significant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:**
As a basis for the production of this document, the most current valid lists were used.

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- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from food, beverages and petfood.
Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
- **Gloves material :**
The selection of suitable gloves does not only depend on the material, but also on further marks of quality which may vary from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked before use.
- **Eye protection:** Not required.

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

| | |
|---------|------------------------------------|
| Form: | Powder |
| Colour: | According to product specification |
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **pH-value:** Not applicable.
- **Change in condition**

| | |
|------------------------------|---------------|
| Melting point/Melting range: | Undetermined. |
| Boiling point/Boiling range: | Undetermined. |
- **Flash point:** Not applicable.
- **Flammability (solid, gaseous):** Not determined.
- **Ignition temperature:** Not applicable.
- **Decomposition temperature:** Not determined.
- **Self-igniting:** Product is not self igniting.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Explosion limits:**

| | |
|--------|-----------------|
| Lower: | Not determined. |
| Upper: | Not determined. |
- **Vapour pressure:** Not applicable.
- **Density:** Not determined.
- **Relative density :** Not determined.
- **Vapour density :** Not applicable.
- **Evaporation rate :** Not applicable.
- **Solubility in / Miscibility with water:** Insoluble.

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- **Segregation coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
 - Dynamic:** Not applicable.
 - Kinematic:** Not applicable.
- **Solvent content:**
 - VOC (EC)** 0,00 %
- **9.2 Other information :** No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity**
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions :** No dangerous reactions known.
- **10.4 Conditions to avoid :** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:**

· **LD/LC50 values relevant for classification:**

57-55-6 propane-1,2-diol

| | | |
|--------|------|----------------------|
| Oral | LD50 | 2000 mg/kg (rat) |
| Dermal | LD50 | 20800 mg/kg (rabbit) |

- **Primary irritant effect:**
- **On the skin:** No irritant effect.
- **On the eyes:** No irritant effect.
- **Sensitisation:** No sensitising effects known.
- **Additional toxicological information:**

The product shows the following hasards according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability :** No further relevant information available.
- **12.3 Bioaccumulative potential :** No further relevant information available.
- **12.4 Mobility in soil :** No further relevant information available.
- **Additional ecological information:**
- **General notes:**

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects :** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation :**



Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, IMDG, IATA** UN3288

- **14.2 UN proper shipping name**
- **ADR** 3288 TOXIC SOLID, INORGANIC, N.O.S. (Kieselguhr, soda ash flux-calcined, dipotassium hexafluorotitanate)
- **IMDG, IATA** TOXIC SOLID, INORGANIC, N.O.S. (Kieselguhr, soda ash flux-calcined, dipotassium hexafluorotitanate)

- **14.3 Transport hazard class(es)**
- **ADR**



- **Class** 6.1 (T5) Toxic substances.
- **Label** 6.1

- **IMDG, IATA**



- **Class** 6.1 Toxic substances.
- **Label** 6.1

- **14.4 Packing group**
- **ADR, IMDG, IATA** III

- **14.5 Environmental hazards:**
- **Marine pollutant:** No

- **14.6 Special precautions for user** Warning: Toxic substances.

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| | |
|---|---|
| · Danger code (Kemler): | 60 |
| · EMS Number: | F-A,S-A |
| · 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · Transport/Additional information: | |
| · ADR | |
| · Limited quantities (LQ) | 5 kg |
| · Excepted quantities (EQ) | Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g |
| · Transport category | 2 |
| · Tunnel restriction code | E |
| · IMDG | |
| · Limited quantities (LQ) | 5 kg |
| · Excepted quantities (EQ) | Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g |
| · UN "Model Regulation": | UN3288, TOXIC SOLID, INORGANIC, N.O.S. (Kieselguhr, soda ash flux-calcined, dipotassium hexafluorotitanate), 6.1, III |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**
H302 Harmful if swallowed.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H373 May cause damage to organs through prolonged or repeated exposure.
R22 Harmful if swallowed.
R41 Risk of serious damage to eyes.
R43 May cause sensitisation by skin contact.
R48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation.

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
VOC: Volatile Organic Compounds (USA, EU)

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LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Acute Tox. 4: Acute toxicity, Hazard Category 4

Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2

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