

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

Printing date 03.08.2018

Version number 1

Revision: 09.11.2016

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

- **1.1 Product identifier**
 - **Trade name:** **EXAFLEX PUTTY (base)**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**

No further relevant information available.
- **Application of the substance / the mixture** Auxillary for dental technology
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**

GC EUROPE N.V.
Interleuvenlaan 33
B-3001 Leuven
Tel. +32/(0)16/74.10.00
Fax +32/(0)16/40.26.84
msds@gc.dental
- **Further information obtainable from:** Regulatory affairs
- **1.4 Emergency telephone number:**

National poison center for United Kingdom of Great Britain and Northern Ireland:
Belfast: +44 28 90 63 2032
Birmingham: +44 121 507 4123
Edinburgh: +44 131 242 1383
Newcastle Upon Tyne: +44 191 2606182/+44 191 2606180
Penarth: +44 292 071 55 54

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**

Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.
Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**

Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements**

H412 Harmful to aquatic life with long lasting effects.
- **Precautionary statements**

P273 Avoid release to the environment.
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.

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SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures

· Description:

Only substances required to be mentioned according to Annex II of regulation 1907/2006 are listed. Information on the other substances that may be present can be obtained upon request.

· Dangerous components:

CAS: 9016-45-9	Nonylphenol, ethoxylated	5-<10%
NLP: 500-024-6	Aquatic Chronic 2, H411; Skin Irrit. 2, H315; Eye Irrit. 2, H319	

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

SECTION 4: First aid measures

· 4.1 Description of first aid measures

· **General information:** If symptoms persist consult doctor.

· After inhalation:

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist. Take affected persons into fresh air and keep quiet.

· **After skin contact:** If skin irritation continues, consult a doctor.

· After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· After swallowing:

Rinse out mouth and then drink plenty of water.

If symptoms persist consult 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 Extinguishing media

· Suitable extinguishing agents:

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Use fire extinguishing methods suitable to surrounding conditions.

· **For safety reasons unsuitable extinguishing agents:** Water with full jet

· 5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

· 5.3 Advice for firefighters

· **Protective equipment:** Wear self-contained respiratory protective device.

· Additional information

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Remove persons from danger area.

Wear protective clothing.

· 6.2 Environmental precautions:

Do not allow product to reach sewage system or any water course.

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Inform respective authorities in case of seepage into water course or sewage system.

Do not allow to penetrate the ground/soil.

In case of seepage into the ground inform responsible authorities.

· **6.3 Methods and material for containment and cleaning up:**

Absorb liquid components with liquid-binding material.

Dispose of the material collected according to regulations.

· **6.4 Reference to other sections**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection 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:** *Store only in unopened original receptacles.*

· **Information about storage in one common storage facility:** *Store away from foodstuffs.*

· **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 item 7.*

· **8.1 Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

· **Additional information:** *The lists valid during the making were used as basis.*

· **8.2 Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals.

Wash hands before breaks and at the end of work.

· **Respiratory protection:** *Suitable respiratory protective device recommended.*

· **Protection of hands:** *Protective gloves*

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies 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 prior to the application.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:** *Safety glasses*

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SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· Form:	Pasty
· Colour:	Yellow
· Odour:	Odourless
· Odour threshold:	Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· Melting point/freezing point:	Undetermined.
· Initial boiling point and boiling range:	Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gas):** Not applicable.

· **Ignition temperature:** Undetermined.

· **Decomposition temperature:** Not determined.

· **Auto-ignition temperature:** Product is not selfigniting.

· **Explosive properties:** Product does not present an explosion hazard.

· **Explosion limits:**

· Lower:	Not determined.
· Upper:	Not determined.

· **Vapour pressure:** Not determined.

· **Density:** Not determined.

· **Relative density** Not determined.

· **Vapour density** Not determined.

· **Evaporation rate** Not determined.

· **Solubility in / Miscibility with water:**

Insoluble.

· **Partition coefficient: n-octanol/water:** Not determined.

· **Viscosity:**

· **Dynamic:** Not determined.

· **Kinematic:** Not determined.

· **Solvent content:**

· **Organic solvents:** 0.0 %

· **VOC (EC)** 0.0 g/l

· **9.2 Other information** No further relevant information available.

SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.

· **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.

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- **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** Based on available data, the classification criteria are not met.
- **LD/LC50 values relevant for classification:** No further relevant information available.
- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
No further relevant information available.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

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 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
- **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 together with household garbage. Do not allow product to reach sewage system.

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

SECTION 14: Transport information

- | | |
|--|-----------------|
| · 14.1 UN-Number | |
| · ADR, ADN, IMDG, IATA | not regulated |
| · 14.2 UN proper shipping name | |
| · ADR | not regulated |
| · ADN, IMDG, IATA | not regulated |
| · 14.3 Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | not regulated |
| · 14.4 Packing group | |
| · ADR, IMDG, IATA | not regulated |
| · 14.5 Environmental hazards: | |
| · Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | not regulated |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 46b
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

- **Relevant phrases**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H411 Toxic to aquatic life with long lasting effects.
- **Classification according to Regulation (EC) No 1272/2008** Calculation method
- **Department issuing SDS:** Regulatory affairs
- **Contact:** msds@gc.dental
- **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

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*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)**LC50: Lethal concentration, 50 percent**LD50: Lethal dose, 50 percent**PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**Skin Irrit. 2: Skin corrosion/irritation – Category 2**Eye Irrit. 2: Serious eye damage/eye irritation – Category 2**Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2**Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3***• Sources**

- ECHA (<http://echa.europa.eu/>)

- EnviChem (www.echemportal.org)

• * Data compared to the previous version altered.

This version replaces all previous versions.

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