

Safety data sheet

According to 1907/2006/EC, Article 31

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Version number 6

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

1.1 Product identifier

Trade name: UnoDent Unoloy 70 Powder (FAB416)

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

No further relevant information available.

Application of the substance: Dental filling material
/the mixture

1.3 Details of the supplier of the safety data sheet

Manufacturer/supplier:	Made for UnoDent Ltd.	Tel: 01376 500582
Address:	10 Perry Way, Witham, Essex CM8 3SX, UK	Fax: 01376 500581
Information sector:	Technical Department	Tel: 01376 500582
Emergency information:	Technical Department	
Emergency e-mail:	info@undodent.com	

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

This product is not classified according to the CLP regulation.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

Hazard pictograms:	Void
Signal word:	Void
Hazard statements:	Void
Additional information:	Safety data sheet available on request.

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 characterization: Mixtures

Description:	Alloy
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<i>- Dangerous components:</i>			
<i>CAS: 7440-22-4</i> <i>EINECS: 231-131-3</i>	<i>silver</i>	<i>substance with a Community workplace exposure limit</i>	<i>50-100%</i>
<i>CAS: 7440-50-8</i> <i>EINECS: 231-159-6</i>	<i>copper</i>	<i>substance with a Community workplace exposure limit</i>	<i>10-<25%</i>

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

General information: No special measures required.

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Rinse with water.
Generally the product does not irritate the skin.

After eye contact: Mechanical effects only.
Rinse opened eye for several minutes under running water. Then consult a doctor.

After swallowing: Rinse out mouth and then drink plenty of water.

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: The product is not flammable.

5.2 Special hazards arising from the substance or mixture

No further relevant information available.

5.3 Advice for firefighters

Protective equipment: Wear self-contained respiratory protective device.

Additional information: Cool endangered receptacles with water spray.

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:

Pick up mechanically.

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

Only adequately trained personnel should handle this product.

For use in dentistry only.

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: Not required.

Further information about storage conditions: Keep container tightly sealed.
Store receptacle in a well ventilated area.

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

<i>· Ingredients with limit values that require monitoring at the workplace:</i>	
<i>7440-22-4 silver</i>	
<i>WEL ()</i>	<i>Long-term value: 0.1 mg/m³</i>
<i>7440-50-8 copper</i>	
<i>WEL ()</i>	<i>Short-term value: 2** mg/m³</i> <i>Long-term value: 0.2* 1** mg/m³</i> <i>*fume **dusts and mists (as Cu)</i>

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

8.2 Exposure controls

Personal protective equipment:

General protective and hygienic measures: Usual hygienic measures for dental practice.

Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. After use of gloves apply skin-cleaning agents and skin cosmetics.

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:

Not required.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:

Form:	Powder
Colour:	Grey
Odour:	Odourless
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.
Self-igniting:	Product is not selfigniting.
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.
Partition coefficient (n-octanol/water):	Not determined.

Viscosity

Dynamic:	Not applicable.
Kinematic:	Not applicable.

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:	Stable under normal handling and storage conditions.
Thermal decomposition/:	No decomposition if used according to specifications
conditions to be avoided.	
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:	None under normal conditions of storage and use.

Products

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity:

Primary irritant effect:

On the skin:	No irritant effect.
On the eye:	No irritating effect.
Sensitization:	No sensitizing effects known.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:	No further relevant information available.
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12.2 Persistence and degradability:	No further relevant information available.
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12.3 Bioaccumulative potential:	No further relevant information available.
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12.4 Mobility in soil:	No further relevant information available.
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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.
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SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendation:	Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
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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: Void

14.2 UN proper shipping name

ADR, ADN, IMDG, IATA: Void

14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA

Class: Void

14.4 Packing group

ADR, IMDG, IATA: Void

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 MARPOL73/78 and the IBC Code

Not applicable.

Transport/Additional information: Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

UN "Model Regulation": -

SECTION 15: Regulatory information

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

National regulations:

Other regulations, limitations and prohibitive regulations

The product is a medical device according to the Directive 93/42/EEC.

Product complies with ISO 24234 Dentistry - Mercury and alloys for dental amalgam.

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.

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
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)