Safety data sheet

According to 1907/2006/EC, Article 31

Printing date 13.03.2014 Version number 5 Revision: 10.03.2014

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

1.1 Product identifier

Trade name:	UnoDent Unoloy Capsules 44 Liquid (FAF150-152, 170-172)
CAS Number:	7439-97-6
EC number:	231-106-7
Index number:	080-001-00-0

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:	Dental filling material/Amalgam

1.3 Details of the supplier of the safety data sheet

Manufacturer:

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@unodent.com	

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

T+;	Very toxic
R26:	Very toxic by inhalation.

T;	Toxic
Repr.	Cat. 2
R61-48/23:	May cause harm to the unborn child. Toxic: danger of serious damage to health by prolonged exposure through inhalation.

N:	Dangerous for the environment
R50/53:	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

Hazard pictograms:

Signal word:	Danger
Hazard-determining components of labelling:	Mercury

Hazard statements

H330:	Fatal if inhaled.
H360D:	May damage the unborn child.
H372:	Causes damage to organs through prolonged or repeated exposure.
H410:	Very toxic to aquatic life with long lasting effects.

Precautionary statements

P201:	Obtain special instructions before use.
P281:	Use personal protective equipment as required.
P273:	Avoid release to the environment.
P304+P340 IF INHALED:	Remove person to fresh air and keep comfortable for breathing.
P310:	Immediately call a POISON CENTER/doctor.
P403+P233:	Store in a well-ventilated place. Keep container tightly closed.

Additional information

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT:	Not applicable.
vPvB:	Not applicable.

SECTION 3: Composition/information on ingredients

3.1 Chemical characterization: Substances

CAS No. Description:	7439-97-6 mercury

Identification number(s)

EC number:	231-106-7
Index number:	080-001-00-0
Description:	Alloy powder and mercury in predosed capsules.
Dangerous components:	Void
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:	Immediately remove any clothing soiled by the product.
After inhalation:	Supply fresh air. In case of unconsciousness place patient stably in side position for transportation. Seek medical treatment.
After skin contact:	Immediately wash with water and soap and rinse thoroughly.
After eye contact:	Rinse opened eye for several minutes under running water. Then consult a doctor.
After swallowing:	Rinse out mouth and then drink plenty of water. Do not induce vomiting; call for medical help immediately.

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

Antidote:	DMPS

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents:	The product is not flammable. Use fire extinguishing methods suitable to surrounding conditions.

5.2 Special hazards arising from the substance or mixture

In case of a fire very toxic mercury fumes will generate.
Fumes are heavier than air.

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

Wear protective equipment. Keep unprotected persons away.

6.2 Environmental precautions

Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up

Spillages of mercury should be removed immediately, including from places which are difficult to access. Use a plastic syringe to draw it up. Smaller quantities can be covered by sulphur powder and removed.

Avoid inhalation of vapour.
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.

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.
Ensure good ventilation/exhaustion at the workplace.
For use in dentistry only.
Information about fire & explosion protection: Keep respiratory protective device available.

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
Ingredients with limit values that require monitoring at the workplace: Not required.

· Ingredients with biological limit values:	
7439-97-6 mercury	
BMGV ()	*20 µmol/mol creatinine* *Medium: urine* *Sampling time: random* *Parameter: mercury*

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.
- Keep away from foodstuffs, beverages and feed.

- Immediately remove all soiled and contaminated clothing
- Wash hands before breaks and at the end of work.
- Store protective clothing separately.
- Do not inhale gases / fumes / aerosols.

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.

Recommended filter device for short term use: Special gas filter Hg-P3

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 cannot be calculated in advance and has therefore to be checked prior to the application.

Natural rubber: NR
Nitrile rubber: NBR
Butyl rubber: BR
Fluorocarbon rubber (Viton)

Penetration time of glove material: The exact break through time has to be found out by the manufacturer of the protective gloves & has to be observed.

Eye protection: Tightly sealed goggles

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance

Form:	Fluid
Colour:	Silver grey
Odour:	Odourless
Odour threshold:	Not determined.
pH-value:	Not applicable.

Change in condition

Melting point/Melting range:	-38.86 °C
Boiling point/Boiling range:	356 °C

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 at 20 °C:	0.00163 hPa
Density at 20 °C:	13.54 g/cm³
Relative density:	Not determined.
Vapour density:	Not applicable.
Evaporation rate:	Not determined.
Solubility in / Miscibility with: water	Insoluble.
Partition coefficient: (n-octanol/water)	Not determined.

Viscosity

Dynamic:	Not determined.
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/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	None under normal conditions of storage and use.
Additional information:	Avoid contact with ammoniac, amines, metals & strong acids.

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:	Mercury may have a sensitizing effect on the skin and lungs, or act as a nephrotoxin or neurotoxin.
Additional toxicological information:	Alloy powder and mercury are predosed in closed capsules, therefore the danger of exposition to mercury vapours are low. Avoid exposure of mercury to pregnant person.
CMR effects (carcinogenity,: mutagenicity & toxicity for reproduction)	Repr. 1B

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.

Ecotoxical effects

Remark:	Very toxic for fish

Additional ecological information

General notes:

- Water hazard class 3 (German Regulation) (Assessment by list): extremely hazardous for water
- Do not allow product to reach ground water, water course or sewage system, even in small quantities.
- Danger to drinking water if even extremely small quantities leak into the ground.
- Also poisonous for fish and plankton in water bodies.
- Very toxic for aquatic organisms

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

European waste catalogue

18 01 10* Amalgam waste from dental care

Uncleaned packaging

Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

14.1 UN-Number

ADR, IMDG, IATA: UN2809

14.2 UN proper shipping name

ADR: 2809 MERCURY, ENVIRONMENTALLY HAZARDOUS

IMDG, IATA: MERCURY

14.3 Transport hazard class(es)

ADR:

Class: 8 (CT1) Corrosive substances.

Label: 8+6.1

IMDG, IATA:

Class: 8 Corrosive substances.

Label: 8+6.1

14.4 Packing group

ADR, IMDG, IATA: III

14.5 Environmental hazards

Marine pollutant: No

Special marking (ADR): Symbol (fish and tree)

14.6 Special precautions for user

Warning: Corrosive substances.

Danger code (Kemler): 80

EMS Number: F-A,S-B

Segregation groups: Heavy metals and their salts (including their organometallic compounds), mercury and mercury compounds

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
Transport category:	3
Tunnel restriction code:	E
UN "Model Regulation":	UN2809, MERCURY, ENVIRONMENTALLY HAZARDOUS, 8 (6.1), III

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 13897 Dentistry - Amalgam capsules
- Product complies with ISO 24234 Dentistry - Mercury and alloys for dental amalgam.
- Labelling according to ISO 24234

CAUTION: This product contains mercury

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)
Acute Tox. 2:	Acute toxicity, Hazard Category 2
Repr. 1B:	Reproductive toxicity, Hazard Category 1B
STOT RE 1:	Specific target organ toxicity - Repeated exposure, Hazard Category 1
Aquatic Acute 1:	Hazardous to the aquatic environment - AcuteHazard, Category 1
Aquatic Chronic 1:	Hazardous to the aquatic environment - Chronic Hazard, Category 1

Safety data sheet

According to 1907/2006/EC, Article 31

Printing date 13.03.2014 Version number 5 Revision: 10.03.2014

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

1.1 Product identifier

Trade name: UnoDent Unoloy 44 Capsules – Powder (FAF150-152, 170-172)

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 — Dental filling material
Amalgam

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@unodent.com.	

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to: Directive 67/548/EEC or Directive 1999/45/EC — Not applicable.

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

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 powder and mercury in predosed capsules.

· *Dangerous components:*			
CAS: 7440-22-4 *EINECS: 231-131-3*	*silver*	*substance with a Community workplace exposure limit*	*25-50%*
CAS: 7440-50-8 *EINECS: 231-159-6*	*copper*	*substance with a Community workplace exposure limit*	*25-50%*

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

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

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 cannot 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/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**	None under normal conditions of storage and use.

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.

Additional toxicological information:	Alloy powder & mercury are predosed in closed capsules, therefore the danger of exposition to mercury vapours are low.

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.

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

- European waste catalogue	
*18 01 10**	*amalgam waste from dental care*

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 13897 Dentistry - Amalgam capsules
- 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)