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1. Identification

Product Identifier

Trade name: Zenith: Type-T, Premium Dispersed Phase, Royale

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

No further relevant information available.

Application of the substance / mixture

Dental Amalgam

Details of the supplier of the safety data sheet Manufactured by:

DMG-America LLC 242 South Dean Street Englewood, NJ 07631 USA

Information Department:

Quality Assurance / Regulatory Affairs

Emergency telephone number:

24 Hour emergency Assistance:

INFOTRAC US + 1-800-535-5053

International + 1-201-894-5500

General SDS Assistance:

Information + 1-800-662-6383

2. Hazard(s) Identification

Classification of the substance or mixture

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

Very toxic

Very toxic by inhalation

Toxic

May Cause harm to unborn child. Toxic: danger of serious damage to health by prolonged exposure through inhalation.

Classification system

The classification was made according to the latest editions of international Substances lists, and expanded upon company literature and data.

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Label elements
Labeling according to EU guidelines
Code letter and hazard designation of product



Hazard-determining components of labeling:

Mercury

Risk Phrases

May cause harm to unborn child.

Very toxic by inhalation.

Toxic: danger of serious damage to health by prolonged exposure through inhalation.

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety Phrases

Avoid exposure - obtain special instructions before use.

Keep container in a well-ventilated place.

After contact with skin, wash immediately with plenty of soap and water.

Wear suitable protective clothing, gloves and eye/face protection.

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Use appropriate container to avoid environmental contamination.

Classification system NFPA ratings (scale 0 - 4)

Health = 4

Fire = 0

Reactivity = 0

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HMIS-ratings (scale 0 - 4)

REACTIVITY

*4

0

0

Health = *4

Fire = 0

Reactivity = 0

Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable. **vPvB:** Not applicable.

3. Composition / information on ingredients

Chemical characterization: Mixtures

Description:

Alloy powder and mercury in predosed capsules.

Dangerous components:

7439-97-6 mercury 50%

4. First-aid measures

Description of first aid measures

General information:

Immediately remove any clothing soiled by the product.

After inhalation:

Supply fresh air or oxygen; call for doctor.

In case of unconsciousness place patient stably in side position for transportation.

After skin contact:

Immediately wash with water and soap and rinse thoroughly.

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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; immediately call for medical help.

Most important symptoms and effects, both acute and delayed:

No further relevant information available.

Indication of any immediate medical attention and special treatment needed

Antidote: DMPS

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing agents:

The product is not flammable.

Use fire fighting measures that suit the environment.

Special hazards arising from the substance or mixture

In case of a fire very toxic mercury fumes will generate.

Fumes are heavier than air.

Advice for firefighters

Protective equipment:

Wear self-contained respiratory protective device.

Additional information:

Cool endangered receptacles with water spray.

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6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

Environmental precautions

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

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

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 vapors

Ensure adequate ventilation.

Dispose contaminated material as waste according to item 13.

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.

7. Handling and storage

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 protection against explosions and fires

Keep respiratory protective device available.

Conditions for safe storage, including any incompatibilities Storage

Requirements to be met by storerooms and receptacles

Store only in unopened original receptacles.

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Information about storage in one common storage facility

Not required.

Further information about storage conditions

Keep receptacle tightly sealed. Store receptacle in a well ventilated area.

Specific end use(s):

No further relevant information available.

8. Exposure controls / personal protection

Additional information about design of technical systems

No further data; see item 7.

Control parameters

Components with limit values that require monitoring at the workplace 7439-97-6 mercury

PEL Long-term value: 0.1 mg/m³

as Hg; see OSHA standard interpretation memo

REL Long-term value: 0.05* mg/m³ Ceiling limit value: 0.1 mg/m³

as Hg; *Vapor; Skin

TLV Long-term value: 0.025 mg/m³

as Hg; Skin; BEI

Ingredients with biological limit values

7439-97-6 mercury

BEI 35 µg/g creatinine

Medium: urine Time: prior to shift

Parameter: Total inorganic mercury (background

15 µg/L

Medium: blood

Time: end of shift at end of workweek

Parameter: Total inorganic mercury (background)

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Additional information:

The lists that were valid during the creation were used as basis.

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.

Do not inhale gases / fumes / aerosols.

Avoid contact with the eyes and skin.

Store protective clothing separately.

Breathing equipment

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory device that is independent of circulating air.

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.

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 and has to be observed.

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Eye protection

Tightly sealed goggles

9. Physical and chemical properties

Information on basic physical and chemical properties

General Information

The physical and chemical properties in this section refer to the mercury.

Appearance
Form: Fluid
Color: Silver grey
Odor: Odorless

Odor threshold: Not determined. pH-value: Not determined.

Change in condition

Melting point/Melting range: -38 °C (-36 °F) Boiling point/Boiling range: 356 °C (673 °F)

Flash point: Not applicable.

Auto igniting: Product is not self-igniting.

Danger of explosion: Product does not present an explosion hazard.

Explosion limits:

Lower: Not determined. **Upper:** Not determined.

Vapor pressure: Not determined.

Density at 20 °C (68 °F): 13.54 g/cm³ (112.991 lbs/gal)

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.

Other information No further relevant information available.

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10. Stability and reactivity

Reactivity

No further relevant information available.

Chemical stability

Stable under normal handling and storage conditions.

Thermal decomposition / conditions to be avoided

No decomposition if used according to specifications.

Possibility of hazardous reactions

No dangerous reactions known.

Conditions to avoid

No further relevant information available.

Incompatible materials

No further relevant information available.

Hazardous decomposition products

None under normal conditions of storage and use.

Additional information

Avoid contact with ammoniac, amines, metals and strong acids.

11. Toxicological information

Information on toxicological effects

Acute toxicity

Primary irritant effect

On the skin

No irritant effect.

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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

The product shows the following dangers according to internally approved calculation methods for preparation.

Harmful

Very toxic

Alloy powder and mercury are predosed in closed capsules, therefore the danger of exposition to mercury vapors are low.

Avoid exposure of mercury to pregnant person.

Carcinogenic categories

IARC (International Agency for Research on Cancer)

7439-97-6 mercury 3

NTP (National Toxicology Program)

None of the ingredients is listed.

12. Ecological information

Toxicity

Aquatic toxicity

No further relevant information available.

Persistence and degradability

No further relevant information available.

Bioaccumulative potential

No further relevant information available.

Mobility in soil

No further relevant information available.

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Ecotoxical effects

Remark

Very toxic for fish

Additional ecological information

General notes

Water hazard class 3 (Self-assessment): 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.

Results of PBT and vPvB assessment

PBT:

Not applicable.

vPvB:

Not applicable.

Other adverse effects No further relevant information available.

13. Disposal considerations

Waste treatment methods

Recommendation

Must be specially treated adhering to official regulations.

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

Uncleaned packagings

Recommendation: Disposal must be made according to official regulations.

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14. Transport information

UN-Number

DOT UN2809

ADR, IMDG, IATA 2809

UN proper shipping name

IMDG, IATA MERCURY

Transport hazard class(es)

DOT, IMDG, IATA

Class 8 Corrosive substances.

Label 8

ADR

Class 8 (C9) Corrosive substances

Label 8

Packing group

DOT, ADR, IMDG, IATA III

Environmental hazards:

Marine pollutant: Yes

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)

Transport in bulk according to Annex II of

MARPOL73/78 and the IBC Code Not applicable.

15. Regulatory information

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

Section 355 (extremely hazardous substances)

None of the ingredients is listed.

Section 313 (Specific toxic chemical listings)

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TSCA (Toxic Substances Control Act):

7439-97-6 mercury

Proposition 65

Chemicals known to cause cancer

None of the ingredients is listed.

Chemicals known to cause reproductive toxicity for females

None of the ingredients is listed.

Chemicals known to cause reproductive toxicity for males

None of the ingredients is listed.

Chemicals known to cause developmental toxicity

7439-97-6 mercury

Carcinogenic categories

EPA (Environmental Protection Agency)

7439-97-6 mercury D

TLV (Threshold Limit Value established by ACGIH)

7439-97-6 mercury A4

NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

Product related hazard information:

Hazard symbols:



Hazard-determining components of labeling

mercury

Risk phrases

May cause harm to the unborn child.

Also very toxic by inhalation.

Also toxic: danger of serious damage to health by prolonged exposure through Inhalation.

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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Safety phrases

Avoid exposure - obtain special instructions before use.

Keep container in a well-ventilated place.

After contact with skin, wash immediately with plenty of soap and water.

Wear suitable protective clothing, gloves and eye/face protection.

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Use appropriate container to avoid environmental contamination.

National regulations

Other regulations, limitations and prohibitive regulations

This product is classified as a medical device under US and Canadian regulations and by the US Food and Drug Administration and Health Canada.

Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

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.

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