

APVOLUTION M INGOTS

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE/PRODUCT AND MANUFACTURER/IMPORTER

1.1 Product identifier

Product/Trade name: APVolution M Ingots - Light, Medium, Dark, Dark Plus, Bleach, Dentin

CAS Number: 66402-68-4

EC number: 266-340-9

1.2 Application of the substance/mixture:- Leucite metal-ceramic, Manufacture of dental prothesis

1.3 Details of the manufacturer and importer:-

Manufacturer:

Aesthetic-Press GmbH
Paulinzella 8 A
07426 Königsee
Tel: +49(0)211-540 14 772
Fax: +49(0)211-204-9131

Importer:

Aesthetic-Press, LLC
7620 Massachusetts Ave.
New Port Richey, FL 34653
Tel: +1 (727) 493 4062
Fax: +1 (415) 723-7075
info@apdental.net
www.apdental.net

1.5 Emergency phone number: Emergency call 911 (for general SDS information call +1 (727) 493 4062)

2. HAZARD(S) IDENTIFICATION

2.1 GHS Classification:- This substance is not classified according to Globally Harmonized System (GHS).

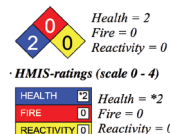
2.2 GHS Label elements, including precautionary statements:-

Hazard Pictogram: Void / **Signal word:** Void / **Hazard statements:** Void **Labelling according to EU**
guidelines: This substance is not subject to classification according to the source of literature known to us

2.3 Additional information:

Other hazards:- Avoid breathing sanding dust /swarf

Results of PBT and vPvB assessment; PBT: N/A **vPvB:** N/A



3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Chemical characterization: substances

3.2 CAS No. Description: 66402-68-4 ceramic materials

3.3 Identification Number

3.4 EC number: 266-340-9

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4. FIRST AID MEASURES

4.1 Description of necessary first aid measures:-

If inhaled: Grinding dust: Supply fresh air; consult doctor in case of complaints.

In case of skin contact: Generally the product does not irritate the skin.

In case of eye contact: Grinding dust: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor. Mechanical effects only.

If swallowed: Grinding dust: Rinse out mouth and then drink plenty of water. If symptoms persist consult doctor

4.2 Symptoms caused by exposure:- No further relevant information available

4.3 Medical attention and special treatment:- No further relevant information available

5. FIRE FIGHTING MEASURES

5.1 Suitable extinguishing equipment:- The product is not flammable

Suitable extinguishing media: The product is not flammable

Unsuitable extinguishing media: No further relevant information available.

5.2 Specific hazards arising from the substance/mixture/product:- No further relevant information available.

5.3 Special protective equipment and precautions for fire fighters:-

Special personal protective equipment: No further relevant information available

Precautions: No further relevant information available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:- No special measures required.

6.2 Environmental precautions:- No special measures required.

6.3 Methods and materials for containment and cleaning up:- Pick up mechanically.

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

7.1 Precautions for safe handling: Only adequately trained personnel should handle this product.

For use in dentistry only.

7.2 Conditions for safe storage, including any incompatibilities:- Store only in the original receptacle.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure control measures:- Occupational exposure limits

Ingredients with biological limit values:

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

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8.2 Biological monitoring:-The lists valid during the making were used as basis.

Exposure controls / Personal protective equipment / General protective and hygienic measures:

Usual hygienic measures for dental practice.

8.3 Control banding:-

Use good industrial hygiene practice and general ventilation.

8.4 Engineering controls:-Void

8.5 Individual protection measures include PPE:-

Eye/face protection:



Safety glasses

Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling). *Use tightly fitting safety glasses as per Australian Standard AS 1336 and AS/NZS 1337.*

Skin protection:



Protection of hands:

Not required.

Respiratory protection:

Use respiratory protective device against the effects of dust



9. PHYSICAL/CHEMICAL PROPERTIES

9.1 Information on physical/chemical properties:-

- a) **Appearance/Form:** Solid
- b) **Colour:** According to product specification
- c) **Odour:** Odourless
- d) **Odour threshold:** Not determined
- e) **pH value:** N/A
- f) **Melting point/melting range:** Not determined
- g) **Boiling point/boiling range:** N/A
- h) **Flash point:** Not determined
- m) **Vapour pressure 20oC:** Not determined
- i) **Ignition temperature:** Not determined
- j) **Self-igniting:** Product is not self-igniting
- k) **Danger of explosion:** Not determined

l) Upper/lower flammability or explosive limits:

Lower - Not determined

Upper - Not determined

n) Density at 20oC: N/A

o) Relative density: Not determined

p) Vapour density: N/A

q) Evaporation rate: N/A

r) Solubility in/miscibility with water: Insoluble

s) Partition coefficient: n- octanol/water: N/D

t) Viscosity: Dynamic - N/A, Kinematic - N/A

u) Solids content: Not determined

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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.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:-

Acute toxicity / Values relevant for classification:

Skin corrosion/irritation: No irritant effect

Serious eye damage/eye irritation: Respiratory or skin sensitization: No irritant effect

Germ cell mutagenicity: No further relevant information available.

Carcinogenicity: No further relevant information available.

Reproductive toxicity: No further relevant information available.

Specific target organ toxicity - single exposure: No further relevant information available.

Specific target organ toxicity - repeated exposure: No further relevant information available.

Aspiration hazard: No further relevant information available.

Additional information: No further relevant information available.

11.2 Information on possible routes of exposure:- No further relevant information available.

Short Term (Acute) Exposure: Swallowed: No further relevant information available.

Eyes: No further relevant information available.

Skin: No further relevant information available.

Inhaled: No further relevant information available.

Long Term (Chronic) Exposure: No further relevant information available.

Swallowed: No further relevant information available.

11.3 Early onset symptoms related to exposure:- No further relevant information available.

11.4 Delayed health effects from exposure:- No further relevant information available.

11.5 Exposure levels and health effects:- No further relevant information available.

11.6 Interactive effects:- No further relevant information available.

11.7 Other:- No further relevant information available.

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12. ECOLOGICAL INFORMATION

12.1 Ecotoxicity:- No further relevant information available.

12.2 Persistence/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.

12.5 Other adverse effects:- No further relevant information available.

Additional ecological information / General notes:-

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

12.6 Other adverse effects:-

Generally not hazardous for water

13. DISPOSAL CONSIDERATIONS

13.1 Disposal methods:-

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

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

14. TRANSPORT INFORMATION

UN number ADR / IMDG / IATA:- Void.

Acute toxicity / Values relevant for classification: Void.

UN proper shipping name or technical name:- ADR Void.

IMDG, IATA: Void.

Transport hazard class(es): Void.

Label: Void. Packaging group: Void.

Environmental hazards: Void.

Special precautions for user: Void.

Danger code: Void.

EMS Number: Void.

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Void.

Transport/Additional information: Void.

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture/product:-

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

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15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

16. OTHER INFORMATION

Key to abbreviations/acronyms used in Void SDS:- Void.

Key literature references/data sources used to compile SDS:- Void.

Copyright statement:-

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.

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). LC50: Lethal concentration, 50 percent.

LD50: Lethal dose, 50 percent.

Flam. Liq. 2: Flammable liquids, Hazard Category 2.

Flam. Liq. 3: Flammable liquids, Hazard Category 3.

Acute Tox. 4: Acute toxicity, Hazard Category 4.

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2.

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

Repr. 2: Reproductive toxicity, Hazard Category 2.

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3. STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2. Asp. Tox. 1: Aspiration hazard, Hazard Category 1.

*** Data compared to the previous version altered**