

**Safety Data Sheet**  
according to WHS Regulations

Printing date 27.07.2023

Revision: 27.07.2023

**1 Identification**

- **Product identifier**
- **Trade name:** Vit-I-escence™
- **Article number:**  
SDS 143-001.04R02, 358, 343, 344, 356, 360, 362, 408, 409, 418, 421, 423, 426, 435, 439, 440, 441, 442, 443, 482, 485, 1188, 1189, 1182, 1183, 1184, 1185, 1186, 1187, 478, 479, 486, 499, 1317, 1195, 1219, 1202, 1203, 1204, 1220, 2230, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2238-2248, 1205, 1223, 1227, 1228, 1229, 1212, 1196, 1197, 5016
- **Relevant identified uses of the substance or mixture and uses advised against**  
Professional Dental Esthetic Restorative Material
- **Application of the substance / the mixture** Professional Dental Esthetic Restorative Material
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ultradent Products, Inc.  
505 W. Ultradent Drive (10200 S)  
South Jordan, UT 84095-3942  
USA  
onlineordersupport@ultradent.com  
Ultradent Australia Pty Ltd.  
Level 22/2 Market Street  
Sydney NSW 2000  
Australia  
Email: info.anz@ultradent.com  
Toll Free: 1-800-290929
- **Further information obtainable from:** Customer Service
- **Emergency telephone number:**  
CHEMTREC (NORTH AMERICA) : (800) 424-9300  
(INTERNATIONAL) : +(703) 527-3887

**2 Hazard(s) Identification**

- **Classification of the substance or mixture**



Skin Sens. 1 H317 May cause an allergic skin reaction.

- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**  
Tetramethylene Dimethacrylate
- **Hazard statements**  
H317 May cause an allergic skin reaction.
- **Precautionary statements**  
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

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- P280 Wear protective gloves.  
 P362+P364 Take off contaminated clothing and wash it before reuse.  
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.  
 P321 Specific treatment (see on this label).  
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

### 3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

2082-81-7	Tetramethylene Dimethacrylate	⚠ Skin Sens. 1, H317; STOT SE 3, H335	≥1-<20%
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- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### 4 First Aid Measures

- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:**  
 Supply fresh air and to be sure call for a doctor.  
 In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**  
 If skin irritation continues, consult a doctor.  
 Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **Information for doctor:**  
 · **Most important symptoms and effects, both acute and delayed** No further relevant information available.  
 · **Indication of any immediate medical attention and special treatment needed**  
 No further relevant information available.

### 5 Fire Fighting Measures

- **Suitable extinguishing agents:**  
 Foam  
 Fire-extinguishing powder  
 Water haze  
 Carbon dioxide  
 Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Protective equipment:** Wear self-contained respiratory protective device.

### 6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
 Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
 Dispose contaminated material as waste according to item 13.  
 Ensure adequate ventilation.

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- **Reference to other sections**  
No dangerous substances are released.  
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

- **Handling:**
- **Precautions for safe handling:**  
Keep receptacles tightly sealed.  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of aerosols.
- **Information about fire - and explosion protection:** No special measures required.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** See product labeling.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** See product labelling.
- **Specific end use(s)** Professional Dental Esthetic Restorative Material

### 8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **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.
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Immediately remove all soiled and contaminated clothing.  
Wash hands before breaks and at the end of work.
- **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 and protective skin cream



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

Natural rubber, NR

The selection of 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**

0.1 - 0.2mm

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Penetration time: 5 min

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

- **Eye protection:** Goggles recommended during refilling
- **Body protection:** Protective work clothing

### 9 Physical and Chemical Properties

#### · General Information

#### · Appearance:

#### · Form:

Paste

#### · Colour:

Different according to colouring

#### · Odour:

Weak, characteristic

#### · 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:

101 °C

#### · Flammability (solid, gas):

Not applicable.

#### · Ignition temperature:

&gt;370 °C

#### · 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:

Not miscible or difficult to mix.

#### · Partition coefficient: n-octanol/water:

Not determined.

#### · Viscosity:

#### · Dynamic:

Not determined.

#### · Kinematic:

Not determined.

#### · Other information

No further relevant information available.

### 10 Stability and Reactivity

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

· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

#### · Possibility of hazardous reactions:

Photoreactive.

Danger of polymerisation.

· **Conditions to avoid:** No further relevant information available.

#### · Incompatible materials:

In presence of radical formers (e.g. peroxides), deoxidizing substances, and/or heavy metal ions, polymerization with heat release is possible.

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· **Hazardous decomposition products:** No dangerous decomposition products known.

### 11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **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** May cause an allergic skin reaction.
- **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.

### 12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **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.
- **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 together with household garbage. Do not allow product to reach sewage system.  
Dispose of contents/container in accordance with international, federal, state, and local regulations.
- **Uncleaned packaging:**
- **Recommendation:** Packagings that may not be cleansed are to be disposed of in the same manner as the product.
- **Recommended cleansing agents:** Alcohol

### 14 Transport information

- **UN-Number**
- **ADG, ADN, IMDG, IATA** not regulated

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· <b>UN proper shipping name</b> · <b>ADG, ADN, IMDG, IATA</b>	<i>not regulated</i>
· <b>Transport hazard class(es)</b> · <b>ADG, ADN, IMDG, IATA</b> · <b>Class</b>	<i>not regulated</i>
· <b>Packing group</b> · <b>ADG, IMDG, IATA</b>	<i>not regulated</i>
· <b>Environmental hazards:</b>	<i>Not applicable.</i>
· <b>Special precautions for user</b>	<i>Not Applicable</i>
· <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b>	<i>Not applicable.</i>
· <b>UN "Model Regulation":</b>	<i>not regulated</i>

### 15 Regulatory information

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

· **Australian Inventory of Industrial Chemicals**

*All ingredients are listed.*

· **Standard for the Uniform Scheduling of Medicines and Poisons**

*None of the ingredients is listed.*

· **Australia: Priority Existing Chemicals**

*None of the ingredients is listed.*

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** *None of the ingredients is listed.*

· **Chemical safety assessment:**

*Device is biocompatible when used as directed by dental professionals per ISO 10993-1*

### 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.*

· **Relevant phrases from Section 3**

*H317 May cause an allergic skin reaction.*

*H335 May cause respiratory irritation.*

· **Department issuing SDS:** *Environmental, Health, and Safety*

· **Contact:** *Customer Service*

· **Abbreviations and acronyms:**

*ADR: Accord relatif au transport international 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)*

*PBT: Persistent, Bioaccumulative and Toxic*

*vPvB: very Persistent and very Bioaccumulative*

*Skin Sens. 1: Skin sensitisation – Category 1*

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**Trade name: Vit-I-escence™***STOT SE 3: Specific target organ toxicity (single exposure) – Category 3*

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*· \* Data compared to the previous version altered.*

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