

Safety Data Sheet
acc. to OSHA HCS

Printing date 07/22/2021

Reviewed on 07/22/2021

1 Identification

- **Product identifier**
- **Trade name:** Vit-I-escence™
- **Article number:**
SDS 143-001.04, 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
- **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
- **Information department:** 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**



GHS07

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

- **Label elements**
- **GHS label elements**
Medical Devices, Cosmetics, and Drugs are exempt from the labeling requirements of the Globally Harmonized System (GHS).
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Health Hazard-determining components of labeling:**
Tetramethylene Dimethacrylate
- **Hazard statements**
May cause an allergic skin reaction.
- **Precautionary statements**
P261 *Avoid breathing dust/fume/gas/mist/vapors/spray*
P272 *Contaminated work clothing must not be allowed out of the workplace.*
P280 *Wear protective gloves.*
P302+P352 *If on skin: Wash with plenty of water.*
P333+P313 *If skin irritation or rash occurs: Get medical advice/attention.*
P321 *Specific treatment (see on this label).*
P363 *Wash contaminated clothing before reuse.*
P501 *Dispose of contents/container in accordance with local/regional/national/international regulations.*

(Contd. on page 2)

Safety Data Sheet

acc. to OSHA HCS

Printing date 07/22/2021

Reviewed on 07/22/2021

Trade name: Vit-I-escence™

(Contd. of page 1)

· **Classification system:**· **NFPA ratings (scale 0 - 4)**

Health = 0

Fire = 1

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

HEALTH 0 Health = 0

FIRE 1 Fire = 1

REACTIVITY 0 Reactivity = 0

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**· **Description:** Mixture of the substances listed below with nonhazardous additions.· **Dangerous components:**

2082-81-7 Tetramethylene Dimethacrylate

⚠ Skin Sens. 1, H317; STOT SE 3, H335

≥1-≤10%

4 First-aid measures

· **Description of first aid measures**· **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

· **Extinguishing media**· **Suitable extinguishing agents:**

Foam

Fire-extinguishing powder

Water haze

Carbon dioxide

Use fire fighting measures that suit the environment.

· **Special hazards arising from the substance or mixture** No further relevant information available.· **Advice for firefighters**· **Protective equipment:** Wear self-contained respiratory protective device.

US

(Contd. on page 3)

Safety Data Sheet

acc. to OSHA HCS

Printing date 07/22/2021

Reviewed on 07/22/2021

Trade name: Vit-I-escence™

(Contd. of page 2)

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.
- **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 protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **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/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:**
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 that were valid during the creation were used as basis.
- **Exposure controls**
- **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.
- **Breathing equipment:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **Protection of hands:**
Protective gloves and protective skin cream

(Contd. on page 4)

Safety Data Sheet

acc. to OSHA HCS

Printing date 07/22/2021

Reviewed on 07/22/2021

Trade name: Vit-I-escence™

(Contd. of page 3)



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 is based 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

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

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form:

Paste

Color:

Different according to coloring

- **Odor:**

Weak, characteristic

- **Odor threshold:**

Not determined.

- **pH-value:**

Not determined.

- **Change in condition**

Melting point/Melting range:

Undetermined.

Boiling point/Boiling range:

Undetermined

- **Flash point:**

101 °C

- **Flammability (solid, gaseous):**

Not applicable.

- **Ignition temperature:**

>370 °C

- **Decomposition temperature:**

Not determined.

- **Auto igniting:**

Product is not selfigniting.

- **Danger of explosion:**

Product does not present an explosion hazard.

- **Explosion limits:**

Lower:

Not determined.

Upper:

Not determined.

- **Vapor pressure:**

Not determined.

- **Density:**

Not determined

(Contd. on page 5)

Safety Data Sheet

acc. to OSHA HCS

Printing date 07/22/2021

Reviewed on 07/22/2021

Trade name: Vit-I-escence™

(Contd. of page 4)

· Relative density	Not determined
· Vapor 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
· Solvent content:	
VOC content:	0.00 %
	0.0 g/l / 0.00 lb/gal
VOC (EC)	0.00 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions**
Photoreactive.
Danger of polymerization.
- **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.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

(Contd. on page 6)

Safety Data Sheet

acc. to OSHA HCS

Printing date 07/22/2021

Reviewed on 07/22/2021

Trade name: Vit-I-escence™

(Contd. of page 5)

· **OSHA-Ca (Occupational Safety & Health Administration)**

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.
- **Behavior 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 (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 of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Packagings that cannot be cleansed are to be disposed of in the same manner as the product.
- **Recommended cleansing agent:** Alcohol

14 Transport information

- | | |
|---|-----------------|
| · UN-Number | |
| · DOT, ADN, IMDG, IATA | Not Regulated |
| · UN proper shipping name | |
| · DOT, ADN, IMDG, IATA | Not Regulated |
| · Transport hazard class(es) | |
| · DOT, ADN, IMDG, IATA | |
| · Class | Not Regulated |
| · Packing group | |
| · DOT, IMDG, IATA | Not Regulated |
| · Environmental hazards: | Not Applicable. |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code | Not Applicable. |

(Contd. on page 7)

Safety Data Sheet

acc. to OSHA HCS

Printing date 07/22/2021

Reviewed on 07/22/2021

Trade name: Vit-I-escence™

(Contd. of page 6)

· UN "Model Regulation": Not Regulated

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.

· **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

All components have the value ACTIVE.

· **Hazardous Air Pollutants**

None of the ingredients is listed.

· **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:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **ACGIH Carcinogenicity (American Conference of Governmental Industrial Hygienists)**

None of the ingredients is listed.

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

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.

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

· **Contact:** Customer Service

· **Date of preparation / last revision** 07/22/2021 / -

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

(Contd. on page 8)

Safety Data Sheet
acc. to OSHA HCS

Printing date 07/22/2021

Reviewed on 07/22/2021

Trade name: Vit-I-escence™

(Contd. of page 7)

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)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
VOC: Volatile Organic Compounds (USA, EU)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Skin Sens. 1: Skin sensitisation – Category 1
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

US