Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g) revised in 2012 and GHS Rev 03.

Issue date 05/07/2025 Reviewed on 05/07/2025

1 Identification

· **Product Identifier**

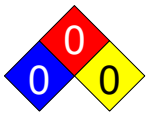
· **Trade Name: OrVance® Aligner Pontics and OrVance® Light Shade Aligner Pontics**
· **Relevant identified uses of the substance or mixture and uses advised against:**
· **Product Description:** Temporary pontic tooth to be used in clear orthodontic aligner and retainer trays.

· **Details of the Supplier of the Safety Data Sheet:**
· **Manufacturer/Supplier:**
OrVance LLC
6477 Cherry Meadow Dr. SE, Suite 5
Caledonia, MI 49316
1-888-508-1290
· **Emergency telephone number:** +1 888-508-1290

2 Hazard(s) Identification

· **Classification of the substance or mixture:**
The product does not need classification according to OSHA HazCom Standard 29 CFR paragraph (d) of §1910.1200(g) and GHS Rev 03.

· **Label elements:**
· **Hazard pictograms:** Non-Regulated Material
· **Signal word:** Non-Regulated Material
· **Hazard statements:** Non-Regulated Material
· **Unknown acute toxicity:**
This value refers to knowledge of known, established toxicological or ecotoxicological values.
0 % of the mixture consists of component(s) of unknown toxicity.
· **Classification system:** NFPA/HMIS Definitions: 0-Least, 1-Slight, 2-Moderate, 3-High, 4-Extreme
· **NFPA ratings (scale 0 - 4)**



Health = 0
Fire = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 0
Fire = 0
Physical Hazard = 0

· **Hazard(s) not otherwise classified (HNOC):** None known

* 3 Composition/Information on Ingredients

· **Chemical characterization: Substance**
· **Description:** Mixture of substances listed below with non-hazardous additions.

· **Dangerous Components:**

CAS: 540-97-6	Cyclohexasiloxane	≤1%
CAS: 541-02-6	Decamethylcyclopentasiloxane Flammable Liquids 4, H227; Eye Irritation 2B, H320	≤1%
CAS: 556-67-2 RTECS: GZ 4397000	Octamethylcyclotetrasiloxane Flammable Liquids 3, H226; Toxic to Reproduction 2, H361	≤1%

(Contd. on page 2)

Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g) revised in 2012 and GHS Rev 03.

Issue date 05/07/2025 Reviewed on 05/07/2025

Trade Name: OrVance® Aligner Pontics

· ***Additional information:***
The exact percentages of the ingredients of this mixture are considered to be proprietary and are withheld in accordance with the provisions of paragraph (i) of §1910.1200 of 29 CFR 1910.1200 Trade Secrets.

4 First-Aid Measures

· ***Description of first aid measures***
· ***General information:*** If symptoms persist, call a physician.
· ***After inhalation:***
Supply fresh air. If required, provide artificial respiration. Consult doctor if symptoms persist.
In case of unconsciousness place patient stably in the side position for transportation.
· ***After skin contact:***
Generally, the product does not irritate the skin.
If skin irritation occurs, consult a doctor.
· ***After eye contact:***
Rinse opened eye for several minutes under running water.
If eye irritation occurs, consult a doctor.
· ***After swallowing:*** If swallowed and symptoms occur, consult a 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:*** Use fire fighting measures that suit the environment.
· ***For safety reasons unsuitable extinguishing agents:*** No further relevant information.
· ***Special hazards arising from the substance or mixture:*** No further relevant information available.
· ***Advice for firefighters***
· ***Special protective equipment for firefighters:***
As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent) and full protective gear to prevent contact with skin and eyes.

6 Accidental Release Measures

· ***Personal precautions, protective equipment and emergency procedures:*** Not required.
· ***Environmental precautions:***
Inform respective authorities in case of seepage into water course or sewage system.
· ***Methods and material for containment and cleaning up:***
Dispose of contaminated material as waste according to section 13.
Ensure adequate ventilation.
Dispose of the collected material according to regulations.
· ***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.

· ***PAC-1:***		
540-97-6	Cyclohexasiloxane	150 mg/m³
556-67-2	Octamethylcyclotetrasiloxane	30 ppm
· ***PAC-2:***		
540-97-6	Cyclohexasiloxane	1,700 mg/m³

(Contd. on page 2)

Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g) revised in 2012 and GHS Rev 03.

Issue date 05/07/2025 Reviewed on 05/07/2025

Trade Name: OrVance® Aligner Pontics

556-67-2	Octamethylcyclotetrasiloxane	68 ppm
· **PAC-3:**		
540-97-6	Cyclohexasiloxane	9,900 mg/m³
556-67-2	Octamethylcyclotetrasiloxane	130 ppm

7 Handling and Storage

· **Handling**
· **Precautions for safe handling:**
Avoid creating and breathing dust/fume/gas/mist/vapors/spray.
Ensure good ventilation/exhaustion at the workplace.
· **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:** No special requirements.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** Keep receptacle tightly sealed.
· **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 section 7.

· **Control parameters:**
· **Components with occupational exposure limits:**
The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.
At this time, the other constituents have no known exposure limits.

556-67-2 Octamethylcyclotetrasiloxane	
WEEL	Long-term value: 10* ppm *OARS WEEL

· **Additional information:** The lists that were valid during the creation of this SDS were used as basis.

· **Exposure controls:**
· **Personal protective equipment**
· **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
· **Breathing equipment:** Not required.
· **Protection of hands:** Not required.
· **Material of gloves:** Not applicable.
· **Penetration time of glove material:** Not applicable.
· **Eye protection:** Not required.
· **Limitation and supervision of exposure into the environment:** None

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9 Physical and Chemical Properties

· **Information on basic physical and chemical properties**
· **General Information**
· **Appearance:**
Form: Solid
Color: Human Tooth colored

(Contd. on page 4)

Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g) revised in 2012 and GHS Rev 03.

Issue date 05/07/2025 Reviewed on 05/07/2025

Trade Name: OrVance® Aligner Pontics

· **Odor:**	None
· **Odor threshold:**	Not determined.
· **pH-value:**	Not determined.
· **Change in condition**	
Melting point/Melting range:	Not determined.
· **Flash point:**	None
· **Flammability (solid, gaseous):**	Not determined.
· **Ignition temperature:**	Not applicable
· **Decomposition temperature:**	Not determined.
· **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 applicable.
· **Density @ 20 °C (68 °F):**	.99-1.01 g/cm³ (8.2616-8.4285 lbs/gal)
· **Relative density:**	Not determined.
· **Vapor density:**	Not applicable.
· **Evaporation rate:**	Not applicable.
· **Solubility in / Miscibility with:**	
Water:	Not miscible or difficult to mix. Insoluble.
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· **Solvent content:**	
VOC content:	0.00 %
· **Other information:**	No further relevant information available.

10 Stability and Reactivity

· **Reactivity:** No further relevant information available.
· **Chemical stability:** Product is stable under normal 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:** No dangerous decomposition products known.

(Contd. on page 5)

Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g) revised in 2012 and GHS Rev 03.

Issue date 05/07/2025 Reviewed on 05/07/2025

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11 Toxicological Information

· **Information on toxicological effects:**
· **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**		
541-02-6 Decamethylcyclopentasiloxane		
Oral	LD50	>5,000 mg/kg (Rat)
Dermal	LD50	>2,000 mg/kg (Rabbit)
Inhalative	LC50/4 h	8.67 mg/l (Rat)
556-67-2 Octamethylcyclotetrasiloxane		
Oral	LD50	>5,000 mg/kg (Rat)
Inhalative	LC50/4 h	>5,000 mg/l (Rat)

· **Primary irritant effect:**
· **On the skin:** No irritating effect.
· **On the eye:** No irritating effect.
· **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:

· **Carcinogenic categories:**

· **IARC (International Agency for Research on Cancer):**
None of the ingredients are listed.
· **NTP (National Toxicology Program):**
None of the ingredients are listed.
· **OSHA-Ca (Occupational Safety & Health Administration):**
None of the ingredients are 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.
· **Ecotoxical effects:**
· **Remark:** Harmful to fish
· **Additional ecological information:**
· **General notes:**
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
Harmful to aquatic organisms
· **Results of PBT and vPvB assessment:**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects:** No further relevant information available.

(Contd. on page 6)

Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g) revised in 2012 and GHS Rev 03.

Issue date 05/05/2025 Reviewed on 05/07/2025

Trade Name: OrVance® Aligner Pontics

13 Disposal Considerations

· **Waste treatment methods**
· **Recommendation:**
Observe all federal, state and local environmental regulations when disposing of this material.

· **Uncleaned packaging**
· **Recommendation:** Disposal must be made according to official regulations.

14 Transport Information

· **UN-Number:**
· **DOT, ADR/ADN, IMDG, IATA** Non-Regulated Material
· **UN proper shipping name:**
· **DOT, ADR/ADN, IMDG, IATA** Non-Regulated Material
· **Transport hazard class(es):**

· **DOT, ADR/ADN, ADN, IMDG, IATA**
· **Class:** Non-Regulated Material
· **Packing group:**
· **DOT, ADR/ADN, IMDG, IATA** Non-Regulated Material
· **Environmental hazards:** Not applicable.
· **Special precautions for user:** Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:** Not applicable.
· **UN "Model Regulation":** Non-Regulated Material

15 Regulatory Information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture:**
No further relevant information available.
· **SARA (Superfund Amendments and Reauthorization):**

· **Section 355 (extremely hazardous substances):**
None of the ingredients are listed.

· **Section 313 (Specific toxic chemical listings):**
None of the ingredients are listed.

· **TSCA (Toxic Substances Control Act):**
All components have the value ACTIVE.

· **Hazardous Air Pollutants**
None of the ingredients are listed.

· **California Proposition 65:**

· **Chemicals known to cause cancer:**
None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for females:**
None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for males:**
None of the ingredients are listed.

· **Chemicals known to cause developmental toxicity:**
None of the ingredients are listed.

(Contd. on page 6)

Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g) revised in 2012 and GHS Rev 03.

Issue date 05/07/2025 Reviewed on 05/07/2025

Trade Name: OrVance® Aligner Pontics

· **New Jersey Right-to-Know List:**
None of the ingredients are listed.

· **New Jersey Special Hazardous Substance List:**
None of the ingredients are listed.

· **Pennsylvania Right-to-Know List:**
None of the ingredients are listed.

· **Pennsylvania Special Hazardous Substance List:**
None of the ingredients are listed.

· **Carcinogenic categories:**

· **EPA (Environmental Protection Agency):**
None of the ingredients are listed.

· **TLV (Threshold Limit Value established by ACGIH):**
None of the ingredients are listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health):**
None of the ingredients are listed.

· **GHS label elements** Non-Regulated Material
· **Hazard pictograms:** Non-Regulated Material
· **Signal word:** Non-Regulated Material
· **Hazard statements:** Non-Regulated Material

· **National regulations:**
The product is not subject to be labelled according with the prevailing version of the regulations on hazardous substances.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other Information

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create warranty, expressed or implied, and shall not establish a legally valid contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose.

· **Contact:**
· **Date of last revision/ revision number:** 02/14/2022 / 2
· **Abbreviations and acronyms:**
ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
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)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
VOC: Volatile Organic Compounds (USA, EU)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety and Health
OSHA: Occupational Safety & Health Administration
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit

(Contd. on page 8)

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REL: Recommended Exposure Limit
Flammable Liquids 3: Flammable liquids – Category 3
Flammable Liquids 4: Flammable liquids – Category 4
Eye Irritation 2B: Serious eye damage/eye irritation – Category 2B
Toxic to Reproduction 2: Reproductive toxicity – Category 2

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