OrthoDots®

MATERIAL SAFETY DATA SHEET

VERSION 5.0.0

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: OrthoDots® CLEAR

SYNONYMS: OrthoDots® Brand Orthodontic Protection

MANUFACTURER: OrVance LLC

ADDRESS: 6477 Cherry Meadow Dr. SE, Suite 5
Caledonia, MI 49316

IN CASE OF MEDICAL EMERGENCIES, PLEASE CONTACT YOUR LOCAL POISON CONTROL CENTER.

EMERGENCY PHONE: +1 **888-508-1290**

PRODUCT USE: Protection against intra-oral irritation from orthodontic appliances

ISSUE DATE: October 24, 2019

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT	CAS NO.	AMOUNT
Biomedical Grade Silicone	NA	Proprietary
Xanthan gum	11138-66-2	Proprietary

SECTION 3: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: This is an oral care product that is safe for consumers and other users under intended and reasonably foreseeable use.

POTENTIAL HEALTH EFFECTS:

EYES: NA

SKIN: Not expected to be irritating or sensitizing.

INGESTION: Swallowing this material is not likely to be harmful.

INHALATION: Not expected to be irritating to the respiratory system when used as intended.

SECTION 4: FIRST AID MEASURES

EYES: NA

SKIN: First Aid is not normally required. If irritation occurs, discontinue use.

INGESTION: First Aid is not normally required. If symptoms develop, contact a physician.

INHALATION: NA

SECTION 5: FIRE-FIGHTING MEASURES

FLASH POINT: Not applicable.

EXPLOSION HAZARD: No applicable information has been found.

EXTINGUISHING MEDIA: Use chemical foam, dry chemical, carbon dioxide, or water.

FIRE FIGHTING INSTRUCTIONS: Contact emergency personnel. Use self-contained breathing apparatus and full protective gear, if large quantities of product are involved. Hazardous decomposition products may be released. Thermal degradation may produce oxides of carbon and/or nitrogen, hydrocarbons and/or derivatives.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PROCEDURES FOR SPILL/LEAK CLEAN-UP:

FOR HOUSEHOLD SETTINGS: Sweep up material for disposal.

FOR NON-HOUSEHOLD SETTINGS: Sweep up material for disposal.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING: None

FOR HOUSEHOLD SETTINGS: No applicable information has been found.

FOR NON-HOUSEHOLD SETTINGS: No unusual handling or storage requirements. Storage in large quantities (as in warehouses) should be in a non-humid area.

CONDITIONS FOR SAFE STORAGE:

FOR HOUSEHOLD SETTINGS: No applicable information has been found.

FOR NON-HOUSEHOLD SETTINGS: No unusual handling or storage requirements. Storage in large quantities (as in warehouses) should be in a non-humid area.

OTHER RECOMMENDATIONS: None.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

FOR HOUSEHOLD SETTINGS: This is an oral care product that is safe for consumers and other users under intended and reasonably foreseeable use.

FOR NON-HOUSEHOLD SETTINGS: This is an oral care product that is safe for consumers and other users under intended and reasonably foreseeable use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

COLOR:	Colorless
APPEARANCE:	Solid
ODOR:	None
PHYSICAL STATE:	Semisolid
pH:	Not Applicable
BOILING POINT:	Not Applicable
MELTING POINT:	Not Applicable.
VAPOR DENSITY:	Not Applicable.
SPECIFIC GRAVITY:	0.99-1.01
SOLUBILITY IN WATER:	Insoluble except for adhesive component.
VOLATILE ORGANIC COMPOUNDS (VOC):	Complies with Federal and State regulations for VOC content.
VISCOSITY:	No data available.

SECTION 10: STABILITY AND REACTIVITY

CONDITIONS TO AVOID: No applicable information has been found.

OTHER RECOMMENDATIONS: None.

SECTION 11: TOXICOLOGICAL INFORMATION

This is a personal care wash or cosmetic product that is safe for consumers and other users under intended and reasonably foreseeable use. Additional information on toxicological endpoints is available from the supplier upon request.

CHRONIC EFFECTS: Finished product is not expected to have chronic health effects.

TARGET ORGANS: No adverse health effects on target organs expected for finished product.

CARCINOGENICITY: Finished product is not expected to be carcinogenic.

MUTAGENICITY: Finished product is not expected to be mutagenic.

TERATOGENICITY: Finished product is not expected to be teratogenic.

SECTION 12: ECOLOGICAL INFORMATION

The product ingredients are expected to be safe for the environment at concentrations predicted under normal use and accidental spill scenarios. Packaging components are compatible with the conventional solid waste management practices. Additional information is available from the supplier on request.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal should be in accordance with Federal, State/Provincial and Local regulations.

SECTION 14: TRANSPORT INFORMATION

Finished packaged product transported by ground (DOT):	Non-hazardous
Finished packaged product transported by vessel (IMDG):	Non-hazardous
Finished packaged product transported by air (IATA):	Non-hazardous

SECTION 15: REGULATORY INFORMATION

Regulated as a 510k exempt Class 1 Medical Device under FDA (US).

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SECTION 16: OTHER INFORMATION

DISCLAIMER:

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information contained here has been compiled from sources considered by OrVance.to be dependable and is accurate to the best of the company's knowledge. It is not meant to be an all-inclusive document on worldwide hazard communication regulations.

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