

Phase Ortho Material Safety Data Sheet

Section 1: Identification	
Product Names	1. Phase Ortho Aligners 2. Phase Ortho Retainers
Product Number	1. -001 Phase Ortho Aligners 2. -002 Phase Ortho Retainers
Manufacturer Information	
Name	Phase Ortho
Address	2501 Stanley Gault Pkwy, Louisville, KY 40223
Contact Information	(502) 780-5700 Phaseortho.com
Recommended Use of Product	
Recommended Use	These materials are intended for the manufacturing of orthodontic retainers and sequential orthodontic aligners, by way of thermoforming the sheets to 3D molds. This material is not to be redistributed or shared without explicit written consent from Phase Ortho management.
Restrictions on Use	None known

Section 2: Hazard(s) Identification	
GHS classification	
Combustible dust	
GHS label elements	
Signal Word	Warning
Hazard Statements	If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
Precautionary Statements	
Disposal	Dispose of contents/container to an approved waste disposal plant.
Other Hazards	
Heated material can cause thermal burns.	

Section 3: Composition/Information on Ingredients		
Chemical Name	CAS	Concentration (% w/w)
Polymer	Proprietary	Proprietary
Polymer	Proprietary	Proprietary

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Section 4: First-Aid Measures	
First Aid Instructions	
Eye contact	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Inhalation	Move to fresh air. Treat symptomatically. If symptoms persist, call a physician.
Skin Contact	Wash off with soap and water. If symptoms persist, call a physician. Cool skin rapidly with cold water after contact with molten material. Do not peel solidified product off the skin. Burns must be treated by a physician.
Ingestion	Seek medical advice
Most important symptoms and effects, both acute and delayed	
Eye contact	No known significant effects or critical hazards.
Inhalation	No known significant effects or critical hazards.
Skin Contact	Heated material can cause serious burns.
Ingestion	No known significant effects or critical hazards.
Notes to physician	
Treat symptomatically.	

Section 5: Fire-Fighting Measures	
Suitable extinguishing media	Use an extinguishing agent suitable for the surrounding fire.
Unsuitable extinguishing media	None known.
Specific hazards during fire fighting	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Hazardous combustion products	No hazardous combustion products are known
Special protective actions for fire-fighters	Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
Special protective equipment for fire-fighters	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

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Section 6: Accidental Release Measures	
Personal precautions, protective	Wear appropriate personal protective equipment. No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk-through spilled material. Put on appropriate personal protective equipment.
For emergency responders	If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".
Environmental precautions	Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).
Methods and materials for containment and cleaning	Sweep up and/or place into suitable containers for disposal.

Section 7: Handling and Storage	
Protective measures	Use with adequate ventilation. Local exhaust ventilation should be provided. Avoid creating dusty conditions and prevent wind dispersal. Take measures against static discharge. Keep away from sources of ignition.
Advice on safe handling	Wash thoroughly after handling. Use only in area provided with appropriate exhaust ventilation. Minimize dust generation and accumulation.
Advice on general occupational hygiene	Eating, drinking, and smoking should be prohibited in areas where this material is handled, stored, and processed. Workers should wash hands and face before eating, drinking, and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.
Conditions for safe storage, including any incompatibilities	Store in accordance with local regulations. Store in a dry, cool, and well-ventilated area, away from incompatible materials (see Section 10). Store in original container, protected from direct sunlight. Keep container tightly closed and sealed until ready for use. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

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Section 8: Exposure Controls/Personal Protection	
Control parameters	
Engineering controls	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.
Environmental exposure controls	Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.
Individual protection measures	
Hygiene measures	Wash hands, forearms, and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
Eye/face protection	Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.
Hand protection	Wear suitable gloves. When handling hot material, wear heat-resistant protective gloves that are able to withstand the temperature of molten product.
Body protection	Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Other skin protection	Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Respiratory protection	Use respiratory protection unless adequate local exhaust ventilation is provided, or exposure assessment demonstrates that exposures are within recommended exposure guidelines. Wear respiratory protection when its use is identified for certain contributing scenario.
Remarks	Ensure that eye flushing systems and safety showers are located close to the working place.

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Section 9: Physical and Chemical Properties	
Appearance	Circular sheets
Color	Clear
Odor	Not available
Odor threshold	Not available
pH	Not available
Melting point	Not available
Boiling point/Boiling range	Not available
Flash point	Not available
Evaporation rate	Not available
Flammability	Not available
Upper explosion limit/Upper flammability limit	Not available
Lower explosion limit/Lower flammability limit	Not available
Vapor pressure	Not available
Vapor density	Not available
Relative density	Not available
Solubility	Not available
Partition coefficient: n-octanol/water	Not available
Auto-ignition temperature	Not available
Decomposition temperature	Not available
Viscosity	Not available

Section 10: Stability and Reactivity	
Reactivity	
No specific test data related to reactivity available for this product or its ingredients.	
Chemical stability	
Stable under normal conditions	
Other	
Possibility of hazardous reactions	Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to avoid	Minimize dust generation and accumulation.
Incompatible materials	No specific data.
Hazardous decomposition products	No specific data.

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Section 11: Toxicological Information	
Acute toxicity	Does not have a cytotoxic effect.
Irritation/Corrosion	Does not elicit biologically significant irritation reactions.
Sensitization	Does not elicit irritation reactions.
Potential acute health affects	
Eye contact	No known significant effects or critical hazards.
Ingestion	No known significant effects or critical hazards.
Skin contact	No known significant effects or critical hazards.
Inhalation	No known significant effects or critical hazards.
Potential chronic health affects	
General	Not available
Mutagenicity	Not available
Carcinogenicity	Not available
Reproductive toxicity	Not available

Section 12: Ecological Information (non-mandatory)	
N/A	

Section 13: Disposal Considerations (non-mandatory)	
Disposal methods	The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14: Transport Information (non-mandatory)	
IATA-DGR	Not regulated as a dangerous good
IMDG-Code	Not regulated as a dangerous good
49 CFR	Not regulated as a dangerous good
Transport within user's premises	Always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

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Section 15: Regulatory Information (non-mandatory)	
SARA 304	Not Applicable
SARA 302	Not Applicable
SARA 311/312 Hazards	Combustible dust
SARA 313	This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
California Prop. 65	This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.
TSCA list	No substances are subject to a Significant New Use Rule. No substances are subject to TSCA 12(b) export notification requirements.

Section 16: Other Information	
Revision	1
Date of Implementation	January 22, 2024