

SAFETY DATA SHEET**TPE WHITE MEDICAL DEVICE**

Version Number 1.0
Revision Date 02/03/2021

Page 1 of 15
Print Date 02/04/2021

SAFETY DATA SHEET**TPE WHITE MEDICAL DEVICE****Section 1. Identification**

GHS product identifier : TPE WHITE MEDICAL DEVICE
Chemical name : Mixture
CAS number : Mixture
Other means of identification : CC10336714
Product type : solid

Relevant identified uses of the substance or mixture and uses advised against

Product use : Industrial applications.

Supplier's details : **AVIENT CORPORATION**
 33587 Walker Road, Avon Lake, OH 44012
 1 (440) 930-1000 or 1 (844) 4AVIENT

Emergency telephone number (with hours of operation) : CHEMTREC 1-800-424-9300 (24hrs for spill, leak, fire, exposure or accident).

Section 2. Hazards identification

This mixture has not been evaluated as a whole. Information provided on the health effects of this product is based on individual components. All ingredients are bound and potential for hazardous exposure as shipped is minimal. However, some vapors may be released upon heating and the end-user (fabricator) must take the necessary precautions (mechanical ventilation, respiratory protection, etc.) to protect employees from exposure. After handling, always wash hands thoroughly with soap and water.

OSHA/HCS status : While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

Classification of the substance or mixture : Not classified.

GHS label elements

Signal word : No signal word.
Hazard statements : No known significant effects or critical hazards.

SAFETY DATA SHEET**TPE WHITE MEDICAL DEVICE**

Version Number 1.0
Revision Date 02/03/2021

Page 2 of 15
Print Date 02/04/2021

Precautionary statements

Prevention : Not applicable.
Response : Not applicable.
Storage : Not applicable.
Disposal : Not applicable.
Supplemental label elements : None known.
Hazards not otherwise classified : None known.
 Not available.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture
Chemical name : Mixture
Other means of identification : CC10336714

CAS number/other identifiers

Ingredient name	%	CAS number
Titanium dioxide	>= 25 - <= 50	13463-67-7
Silica, amorphous	>= 1 - <= 3	7631-86-9

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures**Description of necessary first aid measures**

Eye contact : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur. In case of inhalation of decomposition products in a fire, symptoms may be

SAFETY DATA SHEET**TPE WHITE MEDICAL DEVICE**

Version Number 1.0
Revision Date 02/03/2021

Page 3 of 15
Print Date 02/04/2021

- delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Skin contact** : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
- Ingestion** : Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed**Potential acute health effects**

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Over-exposure signs/symptoms

- Eye contact** : No specific data.
- Inhalation** : No specific data.
- Skin contact** : No specific data.
- Ingestion** : No specific data.

Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

Section 5. Fire-fighting measures
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Extinguishing media

- Suitable extinguishing media** : In case of fire, use water spray (fog), foam, dry chemical or CO₂.
- Unsuitable extinguishing media** : None known.

SAFETY DATA SHEET

TPE WHITE MEDICAL DEVICE

Version Number 1.0
 Revision Date 02/03/2021

Page 4 of 15
 Print Date 02/04/2021

- Specific hazards arising from the chemical** : No specific fire or explosion hazard.
- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
 carbon dioxide
 carbon monoxide
 nitrogen oxides
 metal oxide/oxides
- 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.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : 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 up

- Small spill** : Move containers from spill area. Vacuum or sweep up material and place in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.
- Large spill** : Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Vacuum or sweep up material and place in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

SAFETY DATA SHEET

TPE WHITE MEDICAL DEVICE

Version Number 1.0
 Revision Date 02/03/2021

Page 5 of 15
 Print Date 02/04/2021

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8).
- 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 original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
Titanium dioxide	OSHA PEL 1989 (1989-03-01) TWA 10 mg/m ³ Form: Total dust OSHA PEL (1993-06-30) TWA 15 mg/m ³ Form: Total dust ACGIH TLV (1996-05-18) TWA 10 mg/m ³
Silica, amorphous	NIOSH REL (1994-06-01) TWA 6 mg/m ³

- Appropriate engineering controls** : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.
- 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.

SAFETY DATA SHEET**TPE WHITE MEDICAL DEVICE**

Version Number 1.0
Revision Date 02/03/2021

Page 6 of 15
Print Date 02/04/2021

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.

Skin protection

- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.
- 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** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties**Appearance**

- Physical state** : solid [Pellets.]
- Color** : WHITE
- Odor** : Faint odor.
- Odor threshold** : Not available.
- pH** : Not available.
- Melting point** : Not available.
- Boiling point** : Not available.
- Flash point** : Not available.
- Burning time** : Not available.
- Burning rate** : Not available.
- Evaporation rate** : Not available.

SAFETY DATA SHEET**TPE WHITE MEDICAL DEVICE**

Version Number 1.0
Revision Date 02/03/2021

Page 7 of 15
Print Date 02/04/2021

Flammability (solid, gas)	: Not available.
Lower and upper explosive (flammable) limits	: Lower: Not available. Upper: Not available.
Vapor pressure	: Not available.
Vapor density	: Not available.
Relative density	: Not available.
Solubility	: Not available.
Solubility in water	: insoluble in water.
Partition coefficient: n-octanol/water	: Not available.
Auto-ignition temperature	: Not available.
Decomposition temperature	: Not available.
SADT	: Not available.
Viscosity	: Dynamic: Not available. Kinematic: Not available.

Aerosol product

Heat of combustion	: Not available.
Ignition distance	: Not available.
Enclosed space ignition - Time equivalent	: Not available.
Enclosed space ignition - Deflagration density	: Not available.
Flame height	: Not available.
Flame duration	: 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 recommended storage and handling conditions (see Section 7).
Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to avoid	: Keep away from extreme heat and oxidizing agents.
Incompatible materials	: Keep away from strong acids. Oxidizer.
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

SAFETY DATA SHEET

TPE WHITE MEDICAL DEVICE

Version Number 1.0
 Revision Date 02/03/2021

Page 8 of 15
 Print Date 02/04/2021

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Titanium oxide				
	LC50 Inhalation Dusts and mists	Rat - Male	6.82 Mg/l	4 h
	LD50 Dermal	Rabbit	> 5,000 mg/kg	-

Conclusion/Summary : Mixture.Not fully tested.

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Titanium oxide	Skin - Mild irritant	Human	-	72 hrs	-
Silica	Eyes - Mild irritant	Rabbit	-	24 hrs	-

Conclusion/Summary

Skin : Mixture.Not fully tested.
Eyes : Mixture.Not fully tested.
Respiratory : Mixture.Not fully tested.

Sensitization

Conclusion/Summary

Skin : Mixture.Not fully tested.
Respiratory : Mixture.Not fully tested.

Mutagenicity

Conclusion/Summary : Mixture.Not fully tested.

Carcinogenicity

Conclusion/Summary : Mixture.Not fully tested.

Classification

Product/ingredient name	OSHA	IARC	NTP
Titanium oxide	-	2B	-
Silica	-	3	-

Reproductive toxicity

Conclusion/Summary : Mixture.Not fully tested.

SAFETY DATA SHEET**TPE WHITE MEDICAL DEVICE**

Version Number 1.0
Revision Date 02/03/2021

Page 9 of 15
Print Date 02/04/2021

Teratogenicity

Conclusion/Summary : Mixture.Not fully tested.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on the likely routes of exposure : Not available.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.
Skin contact : No known significant effects or critical hazards.
Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No specific data.
Inhalation : No specific data.
Skin contact : No specific data.
Ingestion : No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure**Short term exposure**

Potential immediate effects : Not available.
Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.
Potential delayed effects : Not available.

Potential chronic health effects

Conclusion/Summary : Mixture.Not fully tested.

General : No known significant effects or critical hazards.

SAFETY DATA SHEET

TPE WHITE MEDICAL DEVICE

Version Number 1.0
 Revision Date 02/03/2021

Page 10 of 15
 Print Date 02/04/2021

- Carcinogenicity** : No known significant effects or critical hazards.
- Mutagenicity** : No known significant effects or critical hazards.
- Teratogenicity** : No known significant effects or critical hazards.
- Developmental effects** : No known significant effects or critical hazards.
- Fertility effects** : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Product/ingredient name	Oral	Dermal	Inhalation (gases)	Inhalation (vapors)	Inhalation (dusts and mists)
TPE WHITE MEDICAL DEVICE	N/A	N/A	N/A	N/A	6.82 Mg/l
Titanium oxide	N/A	N/A	N/A	N/A	6.82 Mg/l

- Other information** : This mixture has not been evaluated as a whole for health effects. Exposure effects listed are based on existing health data for the individual components which comprise the mixture.

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
Titanium oxide	Acute LC50 > 1,000 Mg/l Marine water	Fish - Fundulus heteroclitus	96 h
	Acute LC50 3 Mg/l Fresh water	Crustaceans - Ceriodaphnia dubia	48 h
	Acute LC50 6.5 Mg/l Fresh water	Daphnia - Daphnia pulex	48 h
TPE WHITE MEDICAL DEVICE			
Remarks - Acute - Aquatic invertebrates.:	Chemicals are not readily available as they are bound within the polymer matrix.		

- Conclusion/Summary** : Chemicals are not readily available as they are bound within the polymer matrix.

Persistence and degradability

SAFETY DATA SHEET

TPE WHITE MEDICAL DEVICE

Version Number 1.0
 Revision Date 02/03/2021

Page 11 of 15
 Print Date 02/04/2021

Conclusion/Summary : Chemicals are not readily available as they are bound within the polymer matrix.

Conclusion/Summary : Chemicals are not readily available as they are bound within the polymer matrix.

Bioaccumulative potential
 Not available.

Mobility in soil

Soil/water partition coefficient (KOC) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

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.

United States - RCRA Acute hazardous waste "P" List: Not listed

United States - RCRA Toxic hazardous waste "U" List: Not listed

Section 14. Transport information

U.S.DOT 49CFR : Not regulated for transportation.
 Ground/Air/Water

International Air : Not classified as dangerous goods under transport regulations.

SAFETY DATA SHEET

TPE WHITE MEDICAL DEVICE

Version Number 1.0
 Revision Date 02/03/2021

Page 12 of 15
 Print Date 02/04/2021

ICAO/IATA

International Water : Not classified as dangerous goods under transport regulations.
 IMO/IMDG

Section 15. Regulatory information

- U.S. Federal regulations** :
 - United States - TSCA 12(b) - Chemical export notification:** None of the components are listed.
 - United States - TSCA 4(a) - Final Test Rules:** Not listed
 - United States - TSCA 4(a) - ITC Priority list:** Not listed
 - United States - TSCA 4(a) - Proposed test rules:** Not listed
 - United States - TSCA 4(f) - Priority risk review:** Not listed
 - United States - TSCA 5(a)2 - Final significant new use rules:** Not listed
 - United States - TSCA 5(a)2 - Proposed significant new use rules:** Not listed
 - United States - TSCA 5(e) - Substances consent order:** Not listed
 - United States - TSCA 6 - Final risk management:** Not listed
 - United States - TSCA 6 - Proposed risk management:** Not listed
 - United States - TSCA 8(a) - Chemical risk rules:** Not listed
 - United States - TSCA 8(a) - Dioxin/Furane precursor:** Not listed
 - United States - TSCA 8(a) - Chemical Data Reporting (CDR):** Not determined
 - United States - TSCA 8(a) - Preliminary assessment report (PAIR):** Listed **Quinacridone (C.I. Pigment Violet 19)**
 - United States - TSCA 8(c) - Significant adverse reaction (SAR):** Not listed
 - United States - TSCA 8(d) - Health and safety studies:** Not listed
 - United States - EPA Clean water act (CWA) section 307 - Priority pollutants:** Not listed
 - United States - EPA Clean water act (CWA) section 311 - Hazardous substances:** Not listed
 - United States - EPA Clean air act (CAA) section 112 - Accidental release prevention - Flammable substances:** Not listed
 - United States - EPA Clean air act (CAA) section 112 - Accidental release prevention - Toxic substances:** Not listed
 - United States - Department of commerce - Precursor chemical:** Not listed
- Clean Air Act Section 112(b) Hazardous Air Pollutants (HAPs)** : Not listed
- Clean Air Act Section 602 Class I** : Not listed

SAFETY DATA SHEET

TPE WHITE MEDICAL DEVICE

Version Number 1.0
 Revision Date 02/03/2021

Page 13 of 15
 Print Date 02/04/2021

Substances

Clean Air Act Section 602 Class II : Not listed

Substances

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

US. EPA CERCLA Hazardous Substances (40 CFR 302)

not applicable

SARA 311/312

Classification : Not applicable.

Composition/information on ingredients

No products were found.

Name	%	Classification
Titanium oxide	>= 25 - <= 50	CARCINOGENICITY - Category 2
Silica	>= 1 - <= 3	EYE IRRITATION - Category 2B

Not applicable.


State regulations

- Massachusetts** : None of the components are listed.
- New York** : None of the components are listed.
- New Jersey** : The following components are listed:
Titanium dioxide
- Pennsylvania** : The following components are listed:
Titanium dioxide

Silica, amorphous

Aluminum hydroxide

California Prop. 65

 **WARNING:** This product can expose you to Titanium dioxide, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

Ingredient name	No significant risk level	Maximum acceptable
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SAFETY DATA SHEET

TPE WHITE MEDICAL DEVICE

Version Number 1.0
 Revision Date 02/03/2021

Page 14 of 15
 Print Date 02/04/2021

		dosage level
Titanium dioxide	-	-

United States inventory (TSCA 8b) : All components are active or exempted.

Canada inventory : All components are listed or exempted.

International regulations

Inventory list

- Australia** : All components are listed or exempted.
- Canada** : All components are listed or exempted.
- China** : All components are listed or exempted.
- Europe inventory** : All components are listed or exempted.
- Japan** : All components are listed or exempted.
- New Zealand** : All components are listed or exempted.
- Philippines** : All components are listed or exempted.
- Republic of Korea** : All components are listed or exempted.
- Taiwan** : All components are listed or exempted.
- Turkey** : Not determined.
- United States** : All components are active or exempted.

Section 16. Other information

Hazardous Material Information System (U.S.A.)

Health	/	0
Flammability		0
Physical hazards		0

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings and the associated label are not required on SDSs or products leaving a facility under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered trademark and service mark of the American Coatings Association, Inc.

The customer is responsible for determining the PPE code for this material. For more information on HMIS® Personal Protective Equipment (PPE) codes, consult the HMIS® Implementation Manual.

History

- Date of printing** : 02/04/2021
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- Date of previous issue** : 00/00/0000
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SAFETY DATA SHEET**TPE WHITE MEDICAL DEVICE**

Version Number 1.0
Revision Date 02/03/2021

Page 15 of 15
Print Date 02/04/2021

Key to abbreviations

- : ATE = Acute Toxicity Estimate
- BCF = Bioconcentration Factor
- GHS = Globally Harmonized System of Classification and Labelling of Chemicals
- IATA = International Air Transport Association
- IBC = Intermediate Bulk Container
- IMDG = International Maritime Dangerous Goods
- LogPow = logarithm of the octanol/water partition coefficient
- MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
- UN = United Nations

References

- : Not available.

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist. Particularly this information may not be valid for such material used in conjunction with any other materials or in any process, unless specified in the text.