
SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Theratronode Electrodes
PRODUCT CODES: T1, T2, T3, T4, T5, T6, T7, T8, T9, T10, T11, T12, T13, T14, T15, T16, T17

MANUFACTURER: TheraSigma, LLC
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PRODUCT USE: For use with electrical stimulation such as TENS, NMES, IF.

SECTION 2: MATERIALS

MATERIALS:
Hydrogel (water-based formula)
Polyethylene Foam
Non-Woven Fabric (man-made fiber)
Nylon 6-6 Fabric with Silver Coating (man-made fiber)
Tricot Fabric (man-made fiber)
Carbon Film
Carbon Film with Silver Coating
Carbon Fiber Stranded Wire with Reinforcing Material
PVC Wire Jacket (does not contain DEHP or PAHs - ROHS compliant)
Metal Connector
PVC Overmold (does not contain DEHP or PAHs - ROHS compliant)
Release Liner (coated single side with silicone)
Low Density Polyethylene Zipper Bag

SECTION 3: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: No emergency hazards are expected.

ROUTES OF ENTRY: None expected.

POTENTIAL HEALTH EFFECTS

All products are in a fully cured state or are in a post-processed state. All products are inert solids or semi-solids.

EYES: None expected.

SKIN: None expected.

INGESTION: None expected.

INHALATION: None expected.

ACUTE HEALTH HAZARDS: None expected.

CHRONIC HEALTH HAZARDS: None expected.

SECTION 4: FIRST AID MEASURES

EYES: None expected.

SKIN: Wash with warm soapy water.

INGESTION: None expected.

INHALATION: None expected.

SECTION 5: FIRE-FIGHTING MEASURES

FLASH POINT: Not flammable.

EXTINGUISHING MEDIA: Use extinguishing media appropriate for the combined materials.

SPECIAL FIRE FIGHTING PROCEDURES: May give off hazardous fumes.

UNUSUAL FIRE AND EXPLOSION HAZARDS: None.

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES: Does not apply.

SECTION 7: HANDLING AND STORAGE

HANDLING AND STORAGE: Keep out of direct sunlight. Store at room temperature in sealed bag. Store in a cool, dry place.

OTHER PRECAUTIONS: Best stored at a temperature range between 41°F and 80°F. Wash all exposure areas with soap and water.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: None required.

VENTILATION : None required.

RESPIRATORY PROTECTION: None required.

EYE PROTECTION: Avoid contact with eyes.

SKIN PROTECTION: None required.

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: None required.

WORK HYGIENIC PRACTICES: Normal hygiene practices are recommended.

EXPOSURE GUIDELINES: None required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE: Varies.

ODOR: Slight non-noxious odor.

PHYSICAL STATE: Solid and semi-solid (Hydrogel)

BOILING POINT: Does not apply.

MELTING POINT: Does not apply.

FREEZING POINT: Does not apply.

VAPOR PRESSURE (mmHg): Does not apply.

VAPOR DENSITY (AIR = 1): Does not apply.

SPECIFIC GRAVITY (H₂O = 1): Does not apply.

EVAPORATION RATE: Does not apply.

SOLUBILITY IN WATER: Hydrogel is soluble over extended periods. All other materials are insoluble.

PERCENT VOLATILE: Does not apply

VOLATILE ORGANIC COMPOUNDS (VOC): Does not apply.

VISCOSITY: Does not apply.

SECTION 10: STABILITY AND REACTIVITY

STABILITY: Stable under normal conditions.

CONDITIONS TO AVOID (STABILITY): None known.

INCOMPATIBILITY (MATERIAL TO AVOID): None known.

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: Does not occur.

HAZARDOUS POLYMERIZATION: Does not occur.

CONDITIONS TO AVOID (POLYMERIZATION): Does not apply.

SECTION 11: TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION: TheraTrodE electrodes have passed Biocompatibility testing according to ISO 10993-1 for: Cytotoxicity, Delayed Contact Sensitization and Skin Irritation.

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION: No relevant studies have been identified.

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Dispose of in accordance with all local and federal regulations. Not recyclable, not biodegradable.

RCRA HAZARD CLASS: Does not apply.

SECTION 14: TRANSPORT INFORMATION

DOT, ICAO/IATA and IMDG do not regulate the transportation of this product.

SECTION 15: REGULATORY INFORMATION

There are no State Regulations for this product.
Contact TheraSigma, LLC for applicable U.S. Federal Regulations and International Regulations.

SECTION 16: OTHER INFORMATION

FDA 510(K): K112312

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