

SAFETY DATA SHEET
THERAPUTTY
(THERAPY OR THERAPEUTIC ELASTOMER)

Project Code: DEP2020-092

Date: September 30, 2020

Update: December 23, 2020

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1. Identification of the Preparation and of The Company

Product Name and/or code:	TheraPutty (Therapy or Therapeutic Elastomer)
Effective Date:	30-Sep-20
Manufacturer:	Fabrication Enterprises Inc 250 Clearbrook Rd STE 240 Elmsford, NY 10523
Information Contact:	(914) 345 - 9300
Chemtrec (24 hours)	(800) 424 - 9300 (For Spills Only)
Product Use:	A medical device used for therapy, rehabilitation, exercise of the hand.

2. Hazards Identification

Emergency Overview

Not a gum, do not chew or ingest (eat). Not a toy.

Classification of the Product: This is a class 1 medical device according to the USA FDA medical device rules and device listing in FDA product categories IOD and ION applicable for medical therapy and exercise. Similarly it is a class 1 medical device per EU CE medical device directive (MDD) and medical device regulation (MDR) for therapy and exercise rehabilitation.

Label Elements

Hazard Pictograms	Final product does not require a hazard pictogram.
Signal Word	Final product does not require a signal word.
Hazard Statement	Product is judged to be non hazardous. Not a gum, do not chew or ingest (eat).
Precaution Statement:	No precaution statement necessary.
<i>Children's Statement</i>	This medical device is intended for adults. It can be used safely by those under 18 years of age when supervised and monitored for safe and proper use as a medical rehabilitation or exercise device. When used by those under 18 years of age, healthcare supervision is required.
NFPA	Health: 0 Flammability: 0 Reactivity : 0 Health : 0
HMIS	Flammability: 0 Physical Hazard: 0
Regulation (EC) No. 1272/2008	Boric Acid: May damage fertility. May damage the unborn child. (H360FD) (<i>Boric acid is used in low amount suitable for medical device. Raw material spec written is about exposure to public if high volume enters landfill and public water supply.</i>)

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Substances of very high concern (SVHC)

Boric Acid: included in the candidate list for authorization.

REACH Directive 2011/65/EU Exemption: Substances do not need to be registered under REACH if they are manufactured or imported at less than 1 ton per year, per manufacturer/importer.

3. Composition/Information on Ingredients:

Substances:

Proprietary mixture that contains:

Boric Acid CAS No. 10043-35-3 EC/List No. 233-139-2 < 1.0 %

Mixture of the following chemicals:

The remainder of the formulation is non-hazardous, ingredients are proprietary.

Regulation (EC) No. 1272/2008 (CLP)

Ingredients are marked according to CLP Regulation (CLP-Regulation (EC) No 1272/2008) and no workplace-related occupational exposure limits are specified for any of the listed ingredients. These ingredients are regarded as trade secrets.

4. First Aid Measures

Inhalation

If affected, remove to fresh air.

Skin Contact

If affected, wash the affected area thoroughly with plenty of soap and water. If irritation occurs, contact a physician.

Eye Contact

Carefully flush with water for 15 minutes. If irritation occurs, contact a physician.

Ingestion

Drink water or milk to encourage elimination. Do not induce vomiting. Contact a physician or a health provider if symptoms occur.

5. Firefighting Measures

Extinguishing Media

Water, foam, carbon dioxide or dry chemical equipment.

Fire/Explosion Hazards

This product is not known to present any fire hazard.

Flashpoint/Flammability

Not flammable

6. Accidental Release Measures

Methods and Materials for Containment and Cleaning up

Contain spill. Recover as much as possible. Absorb remainder with an inert material. Place into closed container and store in a safe location to await disposal. Wash the spill area with soap and water.

7. Handling and Storage

Safe Handling

As a general rule, avoid eye contact. For personal protection, we recommend that employees wash thoroughly after handling product. Always wash before eating, smoking or using toilet facilities. Keep container closed when not in use. Keep container upright to prevent leakage.

Environmental precautions

As a general rule, no product should be released to the environment. Keep container closed when not in use.

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Storage Store between 50-100 deg. F., ideally 70 deg. F.

8. Exposure Controls/Personal Protection

Personal Protective Equipment	Not applicable for this product
Exposure Limits	None known for this product.
Respiratory and Ventilation	Not applicable for this product
Skin Protection	Not applicable for this product
Eye Protection	Not applicable for this product

9. Physical and Chemical Properties

Appearance	Polymeric mixture; rubber-like; semi-solid to gum-like.
Physical State	Rubber-like; semi solid.
Color	Various colors
Odor	Very little odor.
Boiling Point	Not applicable to this product.
Freezing Point	Not applicable to this product.
State (pH)	Not applicable to this product.
Specific Gravity	Not applicable to this product.
Viscosity	Not applicable to this product.
Flashpoint	Not applicable to this product.
Vapor Pressure	Not applicable to this product.
Vapor Density	Not applicable to this product.
Solubility in water	Not soluble.

10. Stability and Reactivity

Reactivity:	No dangerous reaction known under conditions of normal use.
Chemical Stability	Stable under recommended storage conditions.
Conditions to Avoid	None known for this product.
Incompatible materials	None known for this product.
Hazardous Decomposition Products	No dangerous decomposition products known. Decomposition products depend on conditions.

11. Toxicological Information

Health Effects	None known for the usual and ordinary uses of this product. There has been biocompatibility standard applied and the putty is suitable for skin contact associated with the intended hand rehabilitation/ therapy exercise.
Eye Effects	Not expected.
Skin Effects	Not expected.
Inhalation	Not expected to cause an inhalation hazard.
Sensitization	Not expected to be a skin sensitizer.

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Additional toxicological information: When used and handled according to specifications, the product does not have any harmful effects based on past experience and the information provided by the manufacturer.

12. Ecological Information

Toxicity:	Not expected to be harmful to the environment.
Aquatic toxicity	No information available.
Persistence and degradability	No information available.
Bio accumulative potential	No information available.
Mobility in soil	No information available.
<i>PBT and vPvB</i>	This product is not PBT/vPvB
Additional ecological information	As a general rule, no product should be released to the environment.

13. Disposal Considerations

Dispose of all waste material in accordance with all applicable federal, state and local regulations for the disposal of non-aqueous polymer waste. As a medical device, disposal into medical waste is suggested or recommended to avoid entering land waste or land fill areas that could cause exposure to public water supply. This is a voluntary action since the content volume and exposure is very low risk.

14. Transport Information

This product is not hazardous for shipping via any mode.

DOT	This regulation does not apply to the non-bulk material.
IMDG	This regulation does not apply to the non-bulk material.
ICAO/IATA	This regulation does not apply to the non-bulk material.

This information is not intended to convey all specific regulatory or operational requirements/information relating to this product. It is the responsibility of the transporting organization to follow all applicable laws, regulations and rules relating to the transportation of the materials.

15. Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture.

SARA	Not applicable to this product.
Section 355 (extremely hazardous substances)	Not applicable to this product.

Section 313 (Specific toxic chemical listing)	Not applicable to this product.
TSCA (Toxic Substance Control Act)	All ingredients are listed.

USA: California Proposition 65	As of September 30, 2020 this product contains no listed substances known to the State of California to cause cancer, birth defects or other reproductive harm, at concentrations which would require a warning under the statute.
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Carcinogenicity categories	Not applicable to this product.
EPA (Environmental Protection Agency)	Not applicable to this product.

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TLV (Threshold Limit Value established by ACGIH)	Not applicable to this product.
MAK (German Maximum Workplace Concentration)	Not applicable to this product.
NIOSH (National Institute for Occupational Safety & Health)	Not applicable to this product.
OSHA (Occupational Safety & Health Administration)	Not applicable to this product.
U.S. FDA Compliance	21 CFR Part 820 (Registration No: 3007280950, Device Listing: D063820, D201425)
EU CE Compliance	CE Medical Device Directive 93/42/EEC with Rule 1 of Annex IX including 2007/47/EC and Class 1 requirements per CE Medical Device Regulation (MDR); 2017/745/EC for EU Market, QMS Compliant GMP, ISO13485

16. Other Information

Product List

Product Number & Color Description

TF Blue
TF Green
TF Red
TF Tan
TF Yellow

Reason for Issue: Updated Product Information

The information contained in this Safety Data Sheet was compiled using the latest and most reliable information available to the preparer from the manufacturer. The information is provided without any warranty, express or implied regarding its correctness or accuracy nor will the manufacturer assume any liability for any loss or damage arising out of the use of this information including without limitation direct or indirect losses or expenses. To the extent permitted by law, no warranty express or implied regarding the product described herein shall be created by or inferred from any state or omission for this SDS. It is solely the responsibility of the user to determine safe conditions for use of this product and to assume liability for any loss, damage or expense whatsoever arising out of the product's improper use.

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Abbreviations and acronyms:

NFPA (SCALE 0-4) National Fire Protection Association (USA)

Health: 0	No unusual hazard.
Fire: 0	Not combustible.
Reactivity: 0	Stable: Not reactive when mixed with water.

HMIS (SCALE 0-4) Hazardous Materials Identification System (USA)

Health: 0	Minimal Hazard: No significant risk to health.
Fire: 0	Minimal Hazard: Materials that will not burn.
Physical Hazard: 0	Minimal Hazard: Materials that are normally stable, even under fire conditions, and will NOT react with water, polymerize, decompose, condense, or self-react. Non- explosives.

Regulation (EC) No. 1272/2008

Classification for the individual ingredients under CLP Labelling.

U.S. FDA

United States Food and Drug Administration

EU CE

European Union European Conformity

CFR

Code of Federal Regulations

MDD

CE Medical Device Directive

MDR

Medical Device Regulation

QMS

Quality Management System

GMP

Good Manufacturing Practice