

SILICONE SUPER-ABSORBENT DRESSINGS

SAFETY DATA SHEET

Revision Date: 29 July 2024

Complies with 29 CFR 1910.1200 (HCS) GHS

SECTION 1: PRODUCT & COMPANY IDENTIFICATION

1.1 PRODUCT IDENTIFIERS:

Product Name: Vitále® Silicone Foam Dressings

CATALOG NUMBER	DESCRIPTION	SIZE	UNITS/BOX
20234	Vitále® Silicone Super-Absorbent Dressing	3½" x 4" (9 cm x 10 cm)	10
20245	Vitále® Silicone Super-Absorbent Dressing	4¾" x 5½" (12 cm x 14 cm)	10
20267	Vitále® Silicone Super-Absorbent Dressing	6" x 7" (15 cm x 18 cm)	10
20280	Vitále® Silicone Super-Absorbent Dressing	8" x 10" (20 cm x 25 cm)	10
20290	Vitále® Sacral Silicone Super-Absorbent Dressing	7" x 6¾" (18 cm x 17 cm)	5
20292	Vitále® Sacral Silicone Super-Absorbent Dressing	6" x 5¾" (15 cm x 14.5 cm)	10

1.2 RELEVANT IDENTIFIED USES:

Identified Uses: Dressings for skin wounds

1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET:

Company: CellEra, LLC
Address: 1045 Reed Road, Unit C
Monroe, OH 45050 USA
Telephone Number: 513-539-1500
Fax Number: 513-539-1501

SECTION 2: HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE:

Not a hazardous substance or mixture.

2.2 GHS LABEL ELEMENTS, INCLUDING PRECAUTIONARY STATEMENTS:

Not a hazardous substance or mixture.

2.3 HAZARDS NOT OTHERWISE CLASSIFIED (HNOC) OR NOT COVERED BY GHS:

None

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 NO INGREDIENTS ARE HAZARDOUS ACCORDING TO OSHA CRITERIA.

No components need to be disclosed according to the applicable regulations.

SECTION 4: FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

If inhaled: Not considered an inhalation hazard.

In case of skin contact: This product is designed for skin contact and is not an irritant.

In case of eye contact: Not intended for contact with eye. If contact occurs, do not rub eyes. Flush eyes thoroughly with water.

If irritation occurs, contact a physician.

If swallowed: Abnormal entry route. Consult a physician.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE & DELAYED

Refer to Section 11: Toxicological Information

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

No data available.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 EXTINGUISHING MEDIA

Water Spray, carbon dioxide, dry chemical powder or foam

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

None known.

5.3 ADVICE FOR FIRE-FIGHTERS

Wear self-contained breathing apparatus for fire-fighting if necessary.

5.4 FURTHER INFORMATION

None known.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT & EMERGENCY PROCEDURES

For personal protection, see Section 8.

6.2 ENVIRONMENTAL PRECAUTIONS

None known.

6.3 METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP

No specific measures necessary. Pick up spilled material and dispose into a sealed container.

6.4 REFERENCE TO OTHER SECTIONS

For disposal, see Section 13.

SECTION 7: HANDLING AND STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING

Normal measures for preventive fire protection
For precautions see Section 2.2.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Store at temperatures specified in package insert, away from reach of small children. Keep containers sealed.

7.3 SPECIFIC END-USE(S)

Apart from the uses mentioned in section 1.2, no other specific uses are stipulated.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

Components with workplace control parameters:
Contains no substances with TLV's or any occupational exposure limit values.

8.2 EXPOSURE CONTROLS

Appropriate Engineering Controls:
This substance has no PEL. Use general institutional hygiene practice.

8.3 PERSONAL PROTECTIVE EQUIPMENT

Eye/Face Protection: No PPE's required.
Skin Protection: Handle with gloves using established institutional practice.
Body Protection: No PPE's required.
Respiratory Protection: No PPE's required.
Control of Environmental Exposure: Dispose used dressings as contaminated waste.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL & CHEMICAL PROPERTIES:

Appearance	Form: fiber pad with polyurethane film, silicone gel and polyethylene release film
Odor	None
Odor Threshold	no data available
pH	n/a
Melting Point	n/a
Freezing Point	n/a
Boiling Point	n/a
Flash Point	n/a
Evaporation Rate	n/a
Flammability	flammable
Explosion Limits	n/a
Vapor Pressure	n/a
Vapor Density	n/a
Density	n/a
Water Solubility	n/a
Partition Coefficient	n/a
Auto-ignition Temperature	n/a
Decomposition Temp.	n/a
Viscosity	n/a
Explosive Properties	n/a
Oxidizing Properites	n/a

9.2 OTHER SAFETY INFORMATION

No data available

SECTION 10: STABILITY & REACTIVITY

10.1 REACTIVITY

No data available.

10.2 CHEMICAL STABILITY

Stable under recommended storage conditions.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

No data available.

10.4 CONDITIONS TO AVOID

Keep product dry; water in container could cause exothermic reaction.

10.5 INCOMPATIBLE MATERIALS

No data available.

10.6 HAZARDOUS DECOMPOSITION PRODUCTS

When burned, carbon monoxide & nitrogen oxides.
In the event of fire, see Section 5.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

Acute toxicity: No acute or chronic toxic effects expected when used according to directions.

Inhalation: n/a

Dermal: No acute or chronic toxic effects expected.

Skin Corrosion/Irritation: No acute or chronic toxic effects expected.

Serious Eye Damage/Eye Irritation: No data available.

Respiratory or Skin Sensitization: No data available.

Germ Cell Mutagenicity: No data available.

Carcinogenicity:

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive Toxicity: No data available.

Specific Target Organ Toxicity--single exposure: No data available.

Specific Target Organ Toxicity--repeated exposure: No data available.

Aspiration Hazard: No data available.

Additional Information: RTECS not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 TOXICITY

No data available.

12.2 PERSISTENCE & DEGRADABILITY

No data available.

12.3 BIOACCUMULATIVE POTENTIAL

No data available.

12.4 MOBILITY IN SOIL

No data available.

12.5 RESULTS OF PBT AND VPVB ASSESSMENT

PBT/vPvB assessment not available as chemical safety assessment not required.

12.6 OTHER ADVERSE EFFECTS

No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS

Product: Offer surplus and non-recyclable products to a licensed disposal company.

Contaminated Packaging: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

DOT (US): Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

SECTION 15: REGULATORY INFORMATION

REACH No.: Not available. A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisioned for a later deadline.

SARA 302 Components: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components: 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.

SARA 311/312 Hazards: No SARA hazards.

Massachusetts Right to Know Components: No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right to Know Components: No components are subject to the Pennsylvania Right to Know Act.

New Jersey Right to Know Components: No components are subject to the New Jersey Right to Know Act.

California Prop 65 Components: This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

SECTION 16: OTHER INFORMATION

HMIS RATINGS:

Health	0
Flammability	1
Physical Hazard	0
Personal Protection	0

NFPA RATINGS:

Flammability	1
Health	0
Instability/Reactivity	0
Special Notice	0

ADDENDUM: ABBREVIATIONS & ACRONYMS

n/a: No applicable information found or available.

ACGIH: American Conference of Governmental Industrial Hygienists

CAS #: Chemical Abstracts Service Number

CFR: Code of Federal Regulations

DOT: Department of Transportation

FDA: Food & Drug Administration

GHS: Globally Harmonized System

HCS: Hazard Communications Standard

HMIS: Hazardous Materials Identification System

HNOC: Hazards Not Otherwise Classified

IARC: International Agency for Research on Cancer

IATA: International Air Transport Association

IMDG: International Maritime Dangerous Goods

MSDS: Manufacturer's Safety Data Sheet (obsolete)

NFPA: National Fire Protection Association

NTP: National Toxicity Program

OSHA: Occupational Safety and Health Administration

PBT: Persistent Bioaccumulative and/or Toxic Chemicals

PEL: Permissible Exposure Limit

PPE: Personal Protection Equipment

RCRA: Resource Conservation & Recovery Act

REACH: Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals (EU)

RTECS: Registry of Toxic Effects of Chemical Substances

SARA: Superfund Amendments and Reauthorization Act

SDS: Safety Data Sheet

TAMC: Total Aerobic Microbial Count

TLCP: Toxic Characteristic Leaching Procedure

TLV: Threshold Limit Value

TYMC: Total Combined Yeast & Mold Count

vPvB: (very) Accumulative, (very) Bioaccumulative and/or Toxic Chemicals

The information and recommendations presented in this SDS are based on sources believed to be accurate. CellEra, LLC assumes no liability for the accuracy or completeness of this information. It is the user's responsibility to determine the suitability of the information for their particular purposes.



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