



Safety Data Sheet

Revision Date: September 28, 2016

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:	Size:	Package:
20133	3"x3"	10/box
20144	4"x4"	10/box
20166	6"x6"	10/box
20190 (Sacral)	7"x6.75"	5/box

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: polyurethane/CMC foam/fiber pad with breathable polyurethane film, silicone gel & 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 Properties	n/a

9.1 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 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.
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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.
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Section 14: Transport Information

- DOT (US): Not dangerous goods
 - IMDG: Not dangerous goods
 - IATA: Not dangerous goods
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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.
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Section 16: Other Information

- HMS Ratings:
 - Health 0
 - Flammability 1
 - Physical Hazard 0
 - Personal Protection 0
 - NFPA Ratings:
 - Flammability 1
 - Health 0
 - Instability/Reactivity 0
 - Special Notice 0
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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

HMS: 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.