

Exofin® Fusion Skin Closure System, part 1 & part 2

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name : Exofin® Fusion Skin Closure System, part 1 - Adhesive

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

Use of the substance/mixture : Adhesive system for secure skin closure in surgical procedure.

1.3. Details of the supplier of the safety data sheet

Chemence Medical, Inc.
200 Technology Drive
Alpharetta, GA 30005-2222
T 770-664-6624

CS@Chemence-US.com - <http://www.Chemence-US.com>

1.4. Emergency telephone number

Emergency number : 1-800-424-9300; CHEMTREC® International Emergency number: 703-527-3887

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GHS-US classification

Flam. Liq. 4 H227
Skin Irrit. 2 H315
Eye Irrit. 2A H319
STOT SE 3 H335

2.2. Label elements

GHS-US labelling

Hazard pictograms (GHS-US) :



GHS07

Signal word (GHS-US) :

Warning

Hazard statements (GHS-US) :

H227 - Combustible liquid
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H335 - May cause respiratory irritation

Precautionary statements (GHS-US) :

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray
P271 - Use only in a well-ventilated area
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P302+P352 - IF ON SKIN: Wash with plenty of soap and water
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 - If eye irritation persists: Get medical advice/attention
P501 - Dispose of contents/container to local, regional, national, and international regulations.

2.3. Other hazards

WARNING: Cyanoacrylate. Eye irritant. Bonds skin and eyes in seconds. This adhesive gives a virtually immediate, strong bond: apply only to surfaces to be bonded. Seek medical attention for any eye or internal contact. Keep out of the reach of children.

SECTION 3: Composition/information on ingredients

Mixture

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Name	Product identifier	%	GHS-US classification
2-octyl cyanoacrylate monomer	(CAS No) 133978-15-1	90 - 99	Not classified
dibutyl sebacate	(CAS No) 109-43-3	1 - 10	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Seek medical attention.
- First-aid measures after skin contact : If unintended bonding of skin tissue occurs, peel of the adhesive, but do not pull skin apart. Application of petroleum jelly or acetone may help loosen the bond. As the epidermal layer grows the adhesive will naturally slough off.
- First-aid measures after eye contact : Rinse immediately with copious amounts of water and seek medical attention. If residual adhesive remains, apply topical ophthalmic ointment to help loosen the bond. Do not pull eye lids apart.
- First-aid measures after ingestion : If taken orally the product will polymerize rapidly, adhering to the mouth. Ensure breathing passages are clear. Saliva will separate any solidified product within two days. Prevent accidental swallowing. Seek medical attention.

4.2. Most important symptoms and effects, both acute and delayed

- Symptoms/injuries after inhalation : May cause respiratory irritation.
- Symptoms/injuries after skin contact : Will bond skin. May cause burns if dropped on clothing in contact with the skin. May cause allergic reaction on skin of acrylate sensitive individuals.
- Symptoms/injuries after eye contact : Causes eye irritation. May cause eye lids to bond.
- Symptoms/injuries after ingestion : May be harmful if swallowed.

4.3. Indication of any immediate medical attention and special treatment needed

If exposed or concerned, get medical advice and attention.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Alcohol-resistant foam. Dry powder. Carbon dioxide. Water spray or fog.
- Unsuitable extinguishing media : None.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : Combustible liquid.
- Explosion hazard : None known.
- Reactivity : No dangerous reactions known under normal conditions of use.

5.3. Advice for firefighters

- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Ensure adequate ventilation. Avoid all contact with skin, eyes, or clothing. Handle in accordance with good industrial hygiene and safety practice.

6.1.1. For non-emergency personnel

- Protective equipment : Use appropriate personal protection equipment (PPE).
- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection.
- Emergency procedures : Evacuate unnecessary personnel. Use appropriate personal protection equipment (PPE).
Ventilate area.

6.2. Environmental precautions

Do not allow water (or moist air) contact with this material. Avoid release to the environment. Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

- For containment : Contain and/or absorb spill with inert material, then place in suitable container.
- Methods for cleaning up : Use water spray to polymerize. Solidified material may be scraped from surfaces for disposal.

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Avoid contact with eyes, skin and clothing.
- Hygiene measures : Do not eat, drink or smoke in areas where product is used. Handle in accordance with good industrial hygiene and safety practice. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Keep away from direct sunlight. Keep cool. Store in a dry place. Keep container closed when not in use.
- Incompatible products : Amines. Oxidizing agents. Alkali metals. Water. Alcohols. Strong bases. Strong acids.
- Storage temperature : Refrigerated storage (2°C to 8°C) is recommended for optimum shelf life.

SECTION 8: Exposure controls/personal protection

Exposure controls

- Appropriate engineering controls : General (mechanical) room ventilation is expected to be satisfactory for normal handling.
- Hand protection : Use impervious gloves such as neoprene, nitrile, or rubber for hand protection.
- Eye protection : Chemical goggles or safety glasses.
- Skin and body protection : Wear suitable working clothes
- Respiratory protection : None required under normal product handling conditions.
- Other information : Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

- Physical state : Liquid
- Appearance : Clear liquid.
- Colour : Purple.
- Odour : Sharp.
- Boiling point : >300°F
- Flash point : >190°F
- Specific gravity : 0.933 g/mL at 23°C
- Solubility : Reacts with water.

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

Stable under normal conditions. Polymerises rapidly with water.

10.3. Possibility of hazardous reactions

Hazardous reactions will not occur under normal conditions.

10.4. Conditions to avoid

Direct sunlight. Heat, high temperature. Moisture, humidity.

10.5. Incompatible materials

Amines. Water. Alkalis. Oxidizing agent. Alcohols.

10.6. Hazardous decomposition products

Toxic fume. Carbon monoxide. Carbon dioxide. Nitrogen oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

dibutyl sebacate (109-43-3)

LD50 oral rat	14870 mg/kg (Rat)
ATE US (oral)	14870.000 mg/kg bodyweight

SECTION 12: Ecological information

12.1. Toxicity

No additional information available.

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12.2. Persistence and degradability

Exofin Fusion Skin Closure System	
Persistence and degradability	Not established.
dibutyl sebacate (109-43-3)	
Persistence and degradability	Biodegradable in water.

12.3. Bioaccumulative potential

Exofin Fusion Skin Closure System	
Bioaccumulative potential	Not established.
dibutyl sebacate (109-43-3)	
Bioaccumulative potential	Bioaccumable.

12.4. Mobility in soil

Considered very low due to rapid polymerization with water.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials	: Avoid release to the environment.

SECTION 14: Transport information

In accordance with DOT	: Not Regulated; Not hazardous for transport.
Proper Shipping Name	: N/A
Transport document description	: N/A
Hazard Class	: N/A
Packing Group	: N/A
UN-No.(DOT)	: None
DOT NA no.	: N/A
Marine Pollutant	: N/A

Additional information

IATA	: Not regulated
Other information	: Not hazardous for transport by air and sea.

SECTION 15: Regulatory information

15.1. US Federal regulations

dibutyl sebacate (109-43-3)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
2-octyl cyanoacrylate monomer	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2. International regulations

EU-Regulations

EUH202: Cyanoacrylate. Danger. Bonds skin and eyes in seconds. Keep out of the reach of children

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin Irrit. 2 H315
Eye Irrit. 2A H319
STOT SE 3 H335

15.3. US State regulations

Proposition 65 No Significant Risk Levels (NSRLs): This product contains no ingredient under Proposition 65 that is classified as a significant risk.

SECTION 16: Other information

Full text of H-phrases:

H227	Combustible liquid
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H335	May cause respiratory irritation

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SDS US (GHS HazCom 2012)

This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

Information presented herein has been compiled from sources considered to be accurate and reliable, but is not guaranteed to be so. Nothing herein shall be considered as recommending practices or products in violation of any patent, law or regulation. It is the user's responsibility to determine the suitability of any material for a specific purpose and to adopt such safety precautions as may be necessary. WE MAKE NO WARRANTIES REGARDING THE PRODUCTS AND DISCLAIM ALL EXPRESS OR IMPLIED WARRANTIES, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name : Exofin® Fusion Skin Closure System, part 2 – Self Adhesive Polyester Mesh

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

Use of the substance/mixture : Adhesive system for secure skin closure in surgical procedure.

1.3. Details of the supplier of the safety data sheet

Chemence Medical, Inc.
200 Technology Drive
Alpharetta, GA 30005-2222
T 770-664-6624

CS@Chemence-US.com - <http://www.Chemence-US.com>

1.4. Emergency telephone number

Emergency number : 1-800-424-9300; CHEMTREC® International Emergency number: 703-527-3887

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GHS-US classification

Not a hazardous substance or mixture.

2.2. Label elements

GHS-US labelling

Not a hazardous substance or mixture.

SECTION 3: Composition/information on ingredients

Mixture

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

SECTION 4: First aid measures

4.1 Description of first aid measures

First-aid measures general	: There is no known effect from chronic exposure to this product. Repeated or prolonged exposure is not known to aggravate medical conditions. If you feel unwell, seek medical advice. Never give anything by mouth to an unconscious person. (show the label where possible).
First-aid measures after inhalation	: Negligible hazard at room temperature. Assure fresh air breathing. Allow the victim to rest.
First-aid measures after skin contact	: Skin irritation is not expected under normal circumstances. In case of skin irritation: rinse skin with water/shower.
First-aid measures after eye contact	: Slight irritant in case of eye contact. Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

4.2 Indication of any immediate medical attention and special treatment needed

If exposed or concerned, get medical advice and attention.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Carbon oxides.

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5.3. Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid breathing vapours, mist or gas

6.1.1. For non-emergency personnel

Protective equipment	: Protective clothing. Gloves.
Emergency procedures	: Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
Emergency procedures	: Ventilate area.

6.2. Environmental precautions

No special environmental precautions required

6.3. Methods and material for containment and cleaning up

For containment	: Collect material and place into convenient waste disposal container. Keep in suitable, closed containers for disposal.
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7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Use only in a well-ventilated area.
Hygiene measures	: Handle in accordance with good industrial hygiene and safety practice. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Store in cool place. Keep container tightly closed in a dry and well-ventilated place.
Incompatible products	: Strong bases. Strong acids. Oxidizing agent.

SECTION 8: Exposure controls/personal protection

Exposure controls

Personal protective equipment	: Avoid all unnecessary exposure. Gloves. Protective clothing. Protective goggles. Safety glasses.
Hand protection	: Wear protective gloves.
Eye protection	: Chemical goggles or safety glasses.
Skin and body protection	: Wear suitable protective clothing.
Respiratory protection	: Respiratory protection is not required.
Other information	: Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Translucent solid
Melting point	: 250 – 260°C
Boiling point	: N/A
Flash point	: N/A
Vapour pressure	: N/A
Specific gravity	: ~1.38 g/cm ³
Solubility in water	: Negligible

9.2. Other information

Volatiles (Vol)%	: Negligible
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SECTION 10: Stability and reactivity

10.1. Reactivity

No reactivity hazard.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Polyester Mesh is chemically stable and resistant to attack by oils, solvents, weak acids and weak alkalies.
Polyester Mesh will hydrolyze at extreme temperatures and humidity.

10.5. Incompatible materials

Extreme temperatures and humidity. Strong acids. Strong bases. Oxidizing agents.

10.6. Hazardous decomposition products

CO, CO₂, soot and oxides of nitrogen.

SECTION 11: Toxicological information

Information on toxicological effects

No data available.

SECTION 12: Ecological information

12.1. Toxicity

No data available.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT).

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Polyester Mesh is not classified as a hazardous waste under the Resource Conservation and Recovery Act; can be disposed of in municipal landfill or incinerated. Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with DOT : Not Regulated; Not hazardous for transport.
Proper Shipping Name : N/A
Transport document description : N/A
Hazard Class : N/A
Packing Group : N/A
UN-No.(DOT) : None
DOT NA no. : N/A
Marine Pollutant : N/A

Additional information

Other information : Not hazardous for transport.
ADR : Not Regulated
Transport by sea : Not Regulated
Air transport : Not Regulated

SECTION 15: Regulatory information

15.1. US Federal regulations

Polyester Mesh

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. International regulations

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008. This substance is not classified as dangerous according to Directive 67/548/EEC.

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15.3. US State regulations

California Proposition 65: There are no Proposition 65 chemicals present in the polyester resin at levels that would require a warning under the California Safe Drinking Water and Toxic Enforcement Act.

SECTION 16: Other information

SDS US (GHS HazCom 2012)

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