

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations
Issue date: 12/1/2021 Revision date: 8/11/2023 Supersedes: 12/1/2021 Version: 1.1

SECTION 1: Identification

1.1. Identification

Product form	: Mixture
Name	: Exofin [®] High Viscosity Topical Skin Adhesive Precision Pen
Product code	: EP70412; EP72412; 3475; M1261
Other means of identification	: ET300

1.2. Recommended use and restrictions on use

Use of the substance/mixture	: Topical Skin Adhesive
Use of the substance/mixture	: Medical devices

1.3. Supplier

Manufacturer

Chemence Medical Inc.
200 Technology Dr
Alpharetta, 30005
T 770-664-6624 - F 678-820-3320
customerservice@chemence.com - www.chemencemedical.com

1.4. Emergency telephone number

Emergency number	: CHEMTREC [®] International Emergency number: 703-527-3887
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SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Not classified

2.2. GHS Label elements, including precautionary statements

GHS US labeling

Precautionary statements (GHS US)	: P262 - Do not get in eyes, on skin, or on clothing. P280 - Wear eye protection, protective gloves. 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.
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2.3. Other hazards which do not result in classification

Other hazards which do not result in classification	: Cyanoacrylate. Danger. Bonds skin and eyes in seconds. Keep out of the reach of children. Contact with skin through cellulose based fabrics (i.e cotton, rayon, linen, viscose) generates heat and may cause burns.
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Exofin[®] High Viscosity Topical Skin Adhesive Precision Pen

Safety Data Sheet

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

2.4. Unknown acute toxicity (GHS US)

No additional information available

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS US classification
dibutyl sebacate	CAS-No.: 109-43-3	≥ 5 – < 8	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335

Full text of hazard classes and H-statements : see section 16

SECTION 4: First-aid measures

4.1. Description of first aid measures

First-aid measures general	: Call a poison center/doctor/physician if you feel unwell. Do not pull bonded skin apart.
First-aid measures after inhalation	: To our knowledge, the product does not present any particular risk, under normal conditions of use.
First-aid measures after skin contact	: Remove all contaminated clothing and footwear. Do not remove clothing if it sticks to the skin. Gently wash with plenty of soap and water.
First-aid measures after eye contact	: Rinse immediately with plenty of water for 15 minutes. If the eyelid is bonded closed, do not force open. Cover with a gauze pad soaked in warm water. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: The product will polymerize immediately in the mouth, making it almost impossible to swallow, but beware of possible choking hazard. Saliva will separate the solidified product from the mouth within a few hours.

4.2. Most important symptoms and effects (acute and delayed)

Potential Adverse human health effects and symptoms	: Bonds skin and eyes in seconds.
Symptoms/effects	: Irritation of the eye tissue.
Symptoms/effects after inhalation	: None under normal use.
Symptoms/effects after skin contact	: Cyanoacrylates bond skin in seconds.
Symptoms/effects after eye contact	: Causes serious eye irritation. Cyanoacrylates bond eyelids in seconds.
Symptoms/effects after ingestion	: The product will polymerize immediately in the mouth, making it almost impossible to swallow, but beware of possible choking hazard.
Most Important Symptoms/Effects	: Bonds skin and eyes in seconds.

4.3. Immediate medical attention and special treatment, if necessary

An eyewash station should be available on the premises, near to any point of possible exposure. . Do not pull bonded skin apart. Treat symptomatically.



Exofin[®] High Viscosity Topical Skin Adhesive Precision Pen

Safety Data Sheet

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

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media : Dry powder. alcohol resistant foam. Carbon dioxide.
Unsuitable extinguishing media : Do not use extinguishing media containing water.

5.2. Specific hazards arising from the chemical

Fire hazard : Prolonged exposure to fire may cause containers to rupture/explode.
Reactivity in case of fire : May polymerize on exposure to temperature rise: pressure rise and possible bursting of container.
Hazardous decomposition products in case of fire : Combustion products may include the following: carbon oxides (CO, CO₂) (carbon monoxide, carbon dioxide) nitrogen oxides (NO, NO₂ etc.).

5.3. Special protective equipment and precautions for fire-fighters

Firefighting instructions : Do not enter fire area without proper protective equipment, including respiratory protection. Use water spray or fog for cooling exposed containers. Do not allow water to enter the vessels, a violent reaction may occur.
Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Mark out the contaminated area with signs and prevent access to unauthorized personnel. Avoid contact with eyes, skin and clothing.

6.1.1. For non-emergency personnel

Protective equipment : Gloves.
Emergency procedures : Do not touch or walk on the spilled product.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
Emergency procedures : Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. Stop the leak. Turn leaking containers leak-side up to prevent the escape of liquid. Cover spill with non combustible material, e.g.: sand/earth. (Do not use cloths; rags or other materials made from cellulose fibres).

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Contain the spilled material by bunding.
Methods for cleaning up : Take up liquid spill into absorbent material. (Do not use cloths; rags or other materials made from cellulose fibres). Or polymerize slowly with water (~10:1, adhesive : water) and then scrape up residue.
Other information : Dispose of materials or solid residues at an authorized site.



Exofin[®] High Viscosity Topical Skin Adhesive Precision Pen

Safety Data Sheet

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

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed	: Cyanoacrylates bond skin and eyelids in seconds.
Precautions for safe handling	: Wear protective gloves, eye protection.
Hygiene measures	: Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures	: Store in a well-ventilated place. Keep container tightly closed. Store away from direct sunlight or other heat sources.
Storage conditions	: Store in a well-ventilated place. Keep cool.
Incompatible products	: Oxidizing agent. Strong bases. Water. Amines. alcohols.
Incompatible materials	: heat. High temperature. Water, humidity. Protect from sunlight.
Storage temperature	: 2 – 25 °C
Storage area	: Store in a well-ventilated place.
Packaging materials	: Always store product in a container of the same material as original container.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exofin[®] High Viscosity Topical Skin Adhesive Precision Pen

No additional information available

dibutyl sebacate (109-43-3)

No additional information available

8.2. Appropriate engineering controls

Appropriate engineering controls	: Ambient humidity should be >35% to minimise discomfort. . An eyewash station should be available on the premises, near to any point of possible exposure. . Refer to section 7 of the SDS.
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8.3. Individual protection measures/Personal protective equipment

Personal protective equipment:

Safety glasses. Gloves.

Hand protection:				
Protective gloves				
Type	Material	Permeation	Thickness (mm)	Penetration
Disposable gloves	Nitrile rubber (NBR), Viton [®] II	3 (> 60 minutes)	>0,15	

Exofin® High Viscosity Topical Skin Adhesive Precision Pen

Safety Data Sheet

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

Eye protection:		
Safety glasses. (ANSI z87.1)		
Type	Field of application	Characteristics
Safety glasses	Droplet	With side shields
Skin and body protection:		
Lab coat. Normal overalls. Do not wear cellulose based protective clothing (i.e cotton, rayon, linen, viscose).		
Respiratory protection:		
Not required for normal conditions of use		

Personal protective equipment symbol(s):



SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Translucent.
Color	: Purple
Odor	: Virtually Odorless
Odor threshold	: < mg/m ³
pH	: substance/mixture reacts with water
Melting point	: No data available
Freezing point	: No data available
Boiling point	: ≈ 257 °C
Flash point	: > 127 °C 101.3 kPa
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: Not flammable.
Vapor pressure	: < 3.7 Pa @20 °C / 68 °F
Relative vapor density at 20°C	: No data available
Particle size	: Not applicable (Liquid)
Relative density	: ≈ 0.93
Solubility	: Soluble in acetone. Reacts with water. Water: 100 µg/l @ 30 °C and pH 5.2
Partition coefficient n-octanol/water (Log Pow)	: 0.776 @ 22 °C & pH 6.3
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: 325 – 650 cP
Explosion limits	: No data available
Explosive properties	: Not explosive.
Oxidizing properties	: Not oxidising.



Exofin[®] High Viscosity Topical Skin Adhesive Precision Pen

Safety Data Sheet

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

9.2. Other information

Other properties : Moisture sensitive.

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions. Polymerizes on exposure to water (moisture).

10.3. Possibility of hazardous reactions

Polymerizes on exposure to temperature rise: pressure build-up may cause closed container to burst.

10.4. Conditions to avoid

Heat. High temperature. Open flame. Water, humidity. Protect from sunlight.

10.5. Incompatible materials

Incompatible with water, humid air. Oxidizing agent. Strong bases. Amines. alcohols.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced. Combustion products may include the following: carbon oxides (CO, CO₂) (carbon monoxide, carbon dioxide) nitrogen oxides (NO, NO₂ etc.).

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral) : Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal) : Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation) : Not classified (Based on available data, the classification criteria are not met)

Exofin [®] High Viscosity Topical Skin Adhesive Precision Pen	
LD50 oral rat	> 5000 mg/kg body weight
2-Octyl Cyanoacrylate (133978-15-1)	
LD50 oral rat	> 5000 mg/kg body weight Animal: rat, Guideline: OECD 401 (Acute Oral Toxicity)
Polymer	
LD50 oral rat	> 2000 mg/kg body weight
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: substance/mixture reacts with water
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: substance/mixture reacts with water
Respiratory or skin sensitization	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)



Exofin[®] High Viscosity Topical Skin Adhesive Precision Pen

Safety Data Sheet

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

Reproductive toxicity : Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure : Not classified (Based on available data, the classification criteria are not met)

dibutyl sebacate (109-43-3)	
STOT-single exposure	May cause respiratory irritation.
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)
Viscosity, kinematic	: No data available
Potential Adverse human health effects and symptoms	: Bonds skin and eyes in seconds.
Symptoms/effects	: Irritation of the eye tissue.
Symptoms/effects after inhalation	: None under normal use.
Symptoms/effects after skin contact	: Cyanoacrylates bond skin in seconds.
Symptoms/effects after eye contact	: Causes serious eye irritation. Cyanoacrylates bond eyelids in seconds.
Symptoms/effects after ingestion	: The product will polymerize immediately in the mouth, making it almost impossible to swallow, but beware of possible choking hazard.
Most Important Symptoms/Effects	: Bonds skin and eyes in seconds.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.
Ecology - water : Not classified for aquatic hazard due to rapid polymerization in contact with water

dibutyl sebacate (109-43-3)	
LC50 - Fish [1]	> 10000 mg/l (OECD 203: Fish, Acute Toxicity Test, 96 h, Danio rerio, Semi-static system, Fresh water, Experimental value, Nominal concentration)
EC50 - Crustacea [1]	> 1000 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 48 h, Daphnia magna, Static system, Fresh water, Read-across, Locomotor effect)
ErC50 algae	> 1000 mg/l (OECD 201: Alga, Growth Inhibition Test, 72 h, Desmodesmus subspicatus, Static system, Fresh water, Read-across, Nominal concentration)

12.2. Persistence and degradability

Exofin[®] High Viscosity Topical Skin Adhesive Precision Pen	
Persistence and degradability	Biodegradability in water: no data available.
dibutyl sebacate (109-43-3)	
Persistence and degradability	Readily biodegradable in water.

12.3. Bioaccumulative potential

Exofin[®] High Viscosity Topical Skin Adhesive Precision Pen	
Partition coefficient n-octanol/water (Log Pow)	0.776 @ 22 °C & pH 6.3
Bioaccumulative potential	No bioaccumulation potential.

Exofin® High Viscosity Topical Skin Adhesive Precision Pen

Safety Data Sheet

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

dibutyl sebacate (109-43-3)	
BCF - Fish [1]	280.6 l/kg (BCFBAF v3.01, Estimated value, Fresh weight)
Partition coefficient n-octanol/water (Log Pow)	6.3 (QSAR, KOWWIN)
Bioaccumulative potential	Low potential for bioaccumulation (BCF < 500).

12.4. Mobility in soil

dibutyl sebacate (109-43-3)	
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	3.585 – 4.278 (log Koc, SRC PCKOCWIN v2.0, QSAR)
Ecology - soil	Low potential for mobility in soil.

12.5. Other adverse effects

No additional information available




SECTION 13: Disposal considerations

13.1. Disposal methods

- Waste treatment methods : The product can be polymerized slowly with water (ratio of 10:1, adhesive : water). Cured product can then be disposed of in land-fill sites by licensed contractors.
- Product/Packaging disposal recommendations : Do not dispose of the packaging without first carrying out the necessary cleaning.

SECTION 14: Transport information

In accordance with DOT / TDG / IMDG / IATA

DOT	TDG	IMDG	IATA
14.1. UN number			
3334	Not regulated	3334	3334
14.2. Proper Shipping Name			
Aviation regulated liquid, n.o.s. (CONTAINS Cyanoacrylate ester)	Not regulated	AVIATION REGULATED LIQUID, N.O.S. (CONTAINS Cyanoacrylate ester)	Aviation regulated liquid, n.o.s. (Cyanoacrylate ester)
14.3. Transport hazard class(es)			
9	Not regulated	9	9
 Not applicable	Not applicable		
14.4. Packing group			
Not applicable	Not regulated	Not applicable	III



Exofin[®] High Viscosity Topical Skin Adhesive Precision Pen

Safety Data Sheet

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

DOT	TDG	IMDG	IATA
14.5. Environmental hazards			
Dangerous for the environment: No	Not regulated	Dangerous for the environment: No Marine pollutant: No	Dangerous for the environment: No
No supplementary information available			

14.6. Special precautions for user

DOT

UN-No.(DOT)	: UN3334
DOT Special Provisions (49 CFR 172.102)	: A35 - This includes any material which is not covered by any of the other classes but which has an anesthetic, narcotic, noxious or other similar properties such that, in the event of spillage or leakage on an aircraft, extreme annoyance or discomfort could be caused to crew members so as to prevent the correct performance of assigned duties. A189 - Except where the defining criteria of another class or division are met, concentrations of formaldehyde solution: a. With less than 25 percent but not less than 10 percent formaldehyde, must be described as UN3334, Aviation regulated liquid, n.o.s; and b. With less than 10 percent formaldehyde, are not subject to this subchapter.
DOT Packaging Exceptions (49 CFR 173.xxx)	: 155
DOT Packaging Non Bulk (49 CFR 173.xxx)	: 204
DOT Quantity Limitations Passenger aircraft/rail (49 CFR 173.27)	: 450 L
DOT Quantity Limitations Cargo aircraft only (49 CFR 175.75)	: 450 L
DOT Vessel Stowage Location	: A - The material may be stowed "on deck" or "under deck" on a cargo vessel and on a passenger vessel.

TDG

Not regulated

IMDG

Special provision (IMDG)	: 960
Stowage category (IMDG)	: None
Properties and observations (IMDG)	: Not subject to the provisions of this Code but may be subject to provisions governing the transport of dangerous goods by other modes.

IATA

Transport regulations (IATA)	: Primary packs containing less than 500ml are unregulated by this mode of transport and may be shipped unrestricted.
PCA Excepted quantities (IATA)	: E1
PCA Limited quantities (IATA)	: Y964
PCA limited quantity max net quantity (IATA)	: 30kgG
PCA packing instructions (IATA)	: 964
PCA max net quantity (IATA)	: 100L
CAO packing instructions (IATA)	: 964
CAO max net quantity (IATA)	: 220L
Special provision (IATA)	: A27
ERG code (IATA)	: 9A

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable



Exofin[®] High Viscosity Topical Skin Adhesive Precision Pen

Safety Data Sheet

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

SECTION 15: Regulatory information

15.1. US Federal regulations

Exofin[®] High Viscosity Topical Skin Adhesive Precision Pen

SARA Section 311/312 Hazard Classes	Health hazard - Hazard Not Otherwise Classified (HNOC)
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All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory

15.2. International regulations

CANADA

2-Octyl Cyanoacrylate (133978-15-1)

Listed on the Canadian NDSL (Non-Domestic Substances List)

dibutyl sebacate (109-43-3)

Listed on the Canadian DSL (Domestic Substances List)

EU-Regulations

No additional information available

National regulations

No additional information available

15.3. US State regulations

No additional information available

SECTION 16: Other information

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

Revision date : 8/11/2023

Full text of H-phrases

H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation

Abbreviations and acronyms

CAS-No.	Chemical Abstract Service number
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate



Exofin® High Viscosity Topical Skin Adhesive Precision Pen

Safety Data Sheet

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

Abbreviations and acronyms	
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
ED	Endocrine disrupting properties
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
IOELV	Indicative Occupational Exposure Limit Value
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
EC50	Median effective concentration
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
VOC	Volatile Organic Compounds
WGK	Water Hazard Class
vPvB	Very Persistent and Very Bioaccumulative
SDS	Safety Data Sheet
PNEC	Predicted No-Effect Concentration
PBT	Persistent Bioaccumulative Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail

Hazard Rating

Health	: 0 Minimal Hazard - No significant risk to health
Flammability	: 1 Slight Hazard - Materials that must be preheated before ignition will occur. Includes liquids, solids and semi solids having a flash point above 200 F. (Class IIIB)
Physical	: 1 Slight Hazard - Materials that are normally stable but can become unstable (self-react) at high temperatures and pressures. Materials may react non-violently with water or undergo hazardous polymerization in the absence of inhibitors.



Exofin[®] High Viscosity Topical Skin Adhesive Precision Pen

Safety Data Sheet

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

Personal protection : B - Safety glasses, Gloves

Indication of changes:			
Section	Changed item	Change	Comments
	Revision date	Added	No additional information available
	SARA Section 311/312 Hazard Classes	Added	No additional information available
1	Product code	Modified	No additional information available
1	Name	Modified	No additional information available
1	Use of the substance/mixture	Added	No additional information available
1	Other means of identification	Added	No additional information available
4	First-aid measures general	Modified	No additional information available
4	First-aid measures after eye contact	Modified	No additional information available
4	Symptoms/effects after eye contact	Modified	No additional information available
4	Symptoms/effects after ingestion	Modified	No additional information available
5.1	Suitable extinguishing media	Modified	No additional information available
5.2	Fire hazard	Added	No additional information available
5.3	Firefighting instructions	Modified	No additional information available
6	General measures	Modified	No additional information available
6	Emergency procedures	Modified	No additional information available
7.1	Additional hazards when processed	Added	No additional information available
7.2	Incompatible materials	Modified	No additional information available
7.2	Storage temperature	Added	No additional information available
8.2	Eye protection	Modified	No additional information available
8.2	Appropriate engineering controls	Modified	No additional information available
8.2	Environmental exposure controls	Modified	No additional information available
8.2	Hand protection	Modified	No additional information available
8.2	Skin and body protection	Modified	No additional information available
9	Solubility	Added	No additional information available
9	pH	Added	No additional information available
9	Particle size	Added	No additional information available
9	Flammability (solid, gas)	Modified	No additional information available
9	Other properties	Added	No additional information available
13	Regional legislation (waste)	Added	No additional information available
13	Additional information	Added	No additional information available
16	Abbreviations and acronyms	Added	No additional information available



Exofin[®] High Viscosity Topical Skin Adhesive Precision Pen

Safety Data Sheet

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

16	Health	Added	No additional information available
16	Flammability	Added	No additional information available
16	Physical	Added	No additional information available
16	Personal protection	Added	No additional information available

Safety Data Sheet (SDS), USA

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

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