

Safety Data Sheet

Acticoat (with SILCRYST Nanocrystals) Moisture Control Dressing

1. Identification

1.1. Product identifier

Product Identity Acticoat (with SILCRYST Nanocrystals) Moisture Control Dressing
(Acticoat is a trademark of Smith & Nephew)

Alternate Names Acticoat ExFix

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

Intended use Medical device used for infection control.

Application Method See Technical Data Sheet.

1.3. Details of the supplier of the safety data sheet

Company Name Smith & Nephew
970 Lake Carillon Drive, Suite 110
St. Petersburg, FL 33716

Emergency

Customer Service: Smith & Nephew 1-800-876-1261

2. Hazard(s) identification

2.1. Classification of the substance or mixture

Acute Tox. 4;H332 Harmful if inhaled.

Eye Dam. 1;H318 Causes serious eye damage.

Skin Sens. 1;H317 May cause an allergic skin reaction.

Resp. Sens. 1;H334 May cause allergy or asthma symptoms of breathing difficulties if inhaled.

Carc. 2;H351 Suspected of causing cancer.

Aquatic Chronic 1;H410 Very toxic to aquatic life with long lasting effects.

2.2. Label elements

Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.



Danger

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H332 Harmful if inhaled.

H334 May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.

H351 Suspected of causing cancer.

H410 Very toxic to aquatic life with long lasting effects.

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[Prevention]:

- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P261 Avoid breathing dust / fume / gas / mist / vapors / spray.
- P271 Use only outdoors or in a well-ventilated area.
- P272 Contaminated work clothing should not be allowed out of the workplace.
- P273 Avoid release to the environment.
- P280 Wear protective gloves / eye protection / face protection.

[Response]:

- P302+352 IF ON SKIN: Wash with plenty of soap and water.
- P304+312 IF INHALED: Call a POISON CENTER or doctor / physician if you feel unwell.
- P305+351+338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing.
- P308+313 IF exposed or concerned: Get medical advice / attention.
- P310 Immediately call a POISON CENTER or doctor / physician.
- P321 Specific treatment (see information on this label).
- P333+313 If skin irritation or a rash occurs: Get medical advice / attention.
- P340 Remove victim to fresh air and keep at rest in a position comfortable for breathing.
- P341 If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
- P342+311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor / physician.
- P363 Wash contaminated clothing before reuse.
- P391 Collect spillage.

[Storage]:

- P405 Store locked up.

[Disposal]:

- P501 Dispose of contents / container in accordance with local / national regulations.

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3. Composition/information on ingredients

This product contains the following substances that present a hazard within the meaning of the relevant State and Federal Hazardous Substances regulations.

Ingredient/Chemical Designations	Weight %	GHS Classification	Notes
Urethane Prepolymer CAS Number: 0053426-99-6	10 - 25	Not Classified	[1]
Silver CAS Number: 0007440-22-4	1.0 - 10	Not Classified	[1][2]
Silver oxide CAS Number: 0020667-12-3	1.0 - 10	Ox. Sol. 1;H271 Eye Dam. 1;H318 Aquatic Acute 1;H400 Aquatic Chronic 1;H410	[1]
Polyethylene-polypropylene glycol CAS Number: 0009003-11-6	1.0 - 10	Aquatic Chronic 3;H412	[1]
Toluene di-isocyanate CAS Number: 0026471-62-5	0.10 - 1.0	Carc. 2;H351 Acute Tox. 2;H330 Eye Irrit. 2;H319 STOT SE 3;H335 Skin Irrit. 2;H315 Resp. Sens. 1;H334 Skin Sens. 1;H317 Aquatic Chronic 3;H412	[1]
Isocyanic acid, methylenedi-4,1-cyclohexylene ester CAS Number: 0005124-30-1	0.10 - 1.0	Acute Tox. 3;H331 Eye Irrit. 2;H319 STOT SE 3;H335 Skin Irrit. 2;H315 Resp. Sens. 1;H334 Skin Sens. 1;H317	[1][2]

In accordance with paragraph (i) of §1910.1200, the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

[1] Substance classified with a health or environmental hazard.

[2] Substance with a workplace exposure limit.

[3] PBT-substance or vPvB-substance.

*The full texts of the phrases are shown in Section 16.

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4. First aid measures

4.1. Description of first aid measures

General	In all cases of doubt, or when symptoms persist, seek medical attention. Never give anything by mouth to an unconscious person.
Inhalation	This dressing does not present an inhalation hazard.
Eyes	Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention.
Skin	Obtain medical attention in the event skin irritation develops or persists.
Ingestion	If swallowed obtain immediate medical attention. Keep at rest. Do NOT induce vomiting.

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

Overview	<u>Acute Effects</u> Temporary discoloration of affected areas or rashes and irritation in sensitized individuals. Eye: Corneal irritation may occur as a result of mechanical abrasion. In the event of eye irritation, flush eyes with flowing water. Skin: Skin irritation may result as an allergic reaction to the silver content of the dressing. Obtain medical attention in the event irritation develops or persists. Ingestion: Ingestion of the dressing may cause a choking hazard or internal blockage. Obtain medical attention. <u>Chronic Effects</u> Excessive or chronic exposure to silver by skin contact, ingestion or inhalation may cause Argyrosis - a local or generalized discoloration of the eyes, skin and mucous membranes, where grey or blue patches of pigmentation are formed. Possible cancer hazard. Contains an ingredient which may cause cancer based on animal data (See Section 3 and Section 15 for each ingredient). Risk of cancer depends on duration and level of exposure. See section 2 for further details.
Inhalation	Harmful if inhaled. May cause allergy or asthma symptoms of breathing difficulties if inhaled.
Eyes	Causes serious eye damage.
Skin	May cause an allergic skin reaction.

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5. Fire-fighting measures

5.1. Extinguishing media

Dressing is not reactive to water or other means of extinguishment. If involved in a fire, treat as a flammable solid.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition: Combustion may produce toluene, carbon monoxide, hydrogen cyanide, and nitrogen oxide.

Avoid breathing dust / fume / gas / mist / vapors / spray.

5.3. Advice for fire-fighters

A Self-Contained Breathing Apparatus should be worn.

Do not release runoff from fire control methods to sewers or waterways.

ERG Guide No. ----

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Put on appropriate personal protective equipment (see section 8).

6.2. Environmental precautions

Do not allow spills to enter drains or waterways.

Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

6.3. Methods and material for containment and cleaning up

Treat used dressing as medical waste. No special spill procedures required.

7. Handling and storage

7.1. Precautions for safe handling

No special handling procedures required. If used, handle as per medical waste.

See section 2 for further details. - [Prevention]:

7.2. Conditions for safe storage, including any incompatibilities

Handle containers carefully to prevent damage and spillage.

Incompatible materials: The silver coating is incompatible with these products: Acetylene, Acids, Amines, Ammonia, Hydrazine, Metal Sulfides, Peroxides, Strong oxidizers.

Store in a cool, dry environment. Keep away from moisture. Avoid extreme heat and strong oxidizing agents.

See section 2 for further details. - [Storage]:

7.3. Specific end use(s)

No data available.

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8. Exposure controls and personal protection

8.1. Control parameters

Exposure

CAS No.	Ingredient	Source	Value
0005124-30-1	Isocyanic acid, methylenedi-4,1-cyclohexylene ester	OSHA	No Established Limit
		ACGIH	TWA: 0.005 ppm
		NIOSH	C 0.01 ppm (0.11 mg/m ³)
		Supplier	No Established Limit
0007440-22-4	Silver	OSHA	TWA 0.01 mg/m ³
		ACGIH	TWA: 0.01 mg/m ³ STEL: 0.03 mg/m ³
		NIOSH	TWA 0.01 mg/m ³
		Supplier	No Established Limit
0009003-11-6	Polyethylene-polypropylene glycol	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit
0020667-12-3	Silver oxide	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit
0026471-62-5	Toluene di-isocyanate	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit
0053426-99-6	Urethane Prepolymer	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit

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Carcinogen Data

CAS No.	Ingredient	Source	Value
0005124-30-1	Isocyanic acid, methylenedi-4,1-cyclohexylene ester	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;
0007440-22-4	Silver	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;
0009003-11-6	Polyethylene-polypropylene glycol	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;
0020667-12-3	Silver oxide	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;
0026471-62-5	Toluene di-isocyanate	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: Yes
		IARC	Group 1: No; Group 2a: No; Group 2b: Yes; Group 3: No; Group 4: No;
0053426-99-6	Urethane Prepolymer	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;

8.2. Exposure controls

Respiratory	No special protection is required.
Eyes	No special protection is required.
Skin	No special protection is required.
Engineering Controls	None required.
Other Work Practices	Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

See section 2 for further details. - [Prevention]:

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9. Physical and chemical properties

Appearance	Silver/Grey Plastic Foam
Odor	Odorless
Odor threshold	Not determined
pH	Not available
Melting point / freezing point	177°C
Initial boiling point and boiling range	Not applicable
Flash Point	260°C
Evaporation rate (Ether = 1)	Not applicable
Flammability (solid, gas)	Not Applicable
Upper/lower flammability or explosive limits	Lower Explosive Limit: Not available Upper Explosive Limit: Not available
Vapor pressure (Pa)	Not applicable
Vapor Density	Not applicable
Specific Gravity	< 1
Solubility in Water	Sparingly
Partition coefficient n-octanol/water (Log Kow)	Not Measured
Auto-ignition temperature	Not available
Decomposition temperature	Not available
Viscosity (cSt)	Not applicable
VOC Content	Not available
Taste	Metallic

9.2. Other information

No other relevant information.

10. Stability and reactivity

10.1. Reactivity

Hazardous Polymerization will not occur.

10.2. Chemical stability

Stable under normal circumstances.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Avoid extreme heat and strong oxidizing agents.

10.5. Incompatible materials

The silver coating is incompatible with these products: Acetylene, Acids, Amines, Ammonia, Hydrazine, Metal Sulfides, Peroxides, Strong oxidizers.

10.6. Hazardous decomposition products

Combustion may produce toluene, carbon monoxide, hydrogen cyanide, and nitrogen oxide.

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11. Toxicological information

Acute toxicity

Ingredient	Oral LD50, mg/kg	Skin LD50, mg/kg	Inhalation Vapor LC50, mg/L/4hr	Inhalation Dust/Mist LC50, mg/L/4hr	Inhalation Gas LC50, ppm
Urethane Prepolymer - (53426-99-6)	No data available	No data available	No data available	No data available	No data available
Silver - (7440-22-4)	No data available	No data available	No data available	No data available	No data available
Silver oxide - (20667-12-3)	No data available	No data available	No data available	No data available	No data available
Polyethylene-polypropylene glycol - (9003-11-6)	11,200.00, Rat - Category: NA	5,600.00, Rabbit - Category: NA	No data available	No data available	No data available
Toluene di-isocyanate - (26471-62-5)	3,360.00, Rat - Category: 5	No data available	0.35, Rat - Category: 1	No data available	13.90, Rat - Category: 1
Isocyanic acid, methylenedi-4,1-cyclohexylene ester - (5124-30-1)	9,900.00, Rat - Category: NA	10,000.00, Rabbit - Category: NA	No data available	No data available	No data available

Note: When no route specific LD50 data is available for an acute toxin, the converted acute toxicity point estimate was used in the calculation of the product's ATE (Acute Toxicity Estimate).

Classification	Category	Hazard Description
Acute toxicity (oral)	---	Not Applicable
Acute toxicity (dermal)	---	Not Applicable
Acute toxicity (inhalation)	4	Harmful if inhaled.
Skin corrosion/irritation	---	Not Applicable
Serious eye damage/irritation	1	Causes serious eye damage.
Respiratory sensitization	1	May cause allergy or asthma symptoms of breathing difficulties if inhaled.
Skin sensitization	1	May cause an allergic skin reaction.
Germ cell mutagenicity	---	Not Applicable
Carcinogenicity	2	Suspected of causing cancer.
Reproductive toxicity	---	Not Applicable
STOT-single exposure	---	Not Applicable
STOT-repeated exposure	---	Not Applicable
Aspiration hazard	---	Not Applicable

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12. Ecological information

12.1. Toxicity

Very toxic to aquatic life with long lasting effects.

Toxic to aquatic life

Aquatic Ecotoxicity

Ingredient	96 hr LC50 fish, mg/l	48 hr EC50 crustacea, mg/l	ErC50 algae, mg/l
Urethane Prepolymer - (53426-99-6)	Not Available	Not Available	Not Available
Silver - (7440-22-4)	Not Available	Not Available	Not Available
Silver oxide - (20667-12-3)	Not Available	Not Available	Not Available
Polyethylene-polypropylene glycol - (9003-11-6)	Not Available	Not Available	Not Available
Toluene di-isocyanate - (26471-62-5)	133.00, Oncorhynchus mykiss	12.50, Daphnia magna	3,230.00 (96 hr), Skeletonema costatum
Isocyanic acid, methylenedi-4,1-cyclohexylene ester - (5124-30-1)	1.20, Danio rerio	Not Available	Not Available

12.2. Persistence and degradability

There is no data available on the preparation itself.

12.3. Bioaccumulative potential

Not Measured

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

This product contains no PBT/vPvB chemicals.

12.6. Other adverse effects

No data available.

13. Disposal considerations

13.1. Waste treatment methods

Observe all federal, state and local regulations when disposing of this substance.

If unused, the silver may be recovered by recycling.

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14. Transport information

	DOT (Domestic Surface Transportation)	IMO / IMDG (Ocean Transportation)	ICAO/IATA
14.1. UN number	Not Applicable	Not Regulated	Not Regulated
14.2. UN proper shipping name	Not Regulated	Not Regulated	Not Regulated
14.3. Transport hazard class(es)	DOT Hazard Class: Not Applicable	IMDG: Not Applicable Sub Class: Not Applicable	Air Class: Not Applicable
14.4. Packing group	Not Applicable	Not Applicable	Not Applicable
14.5. Environmental hazards			
IMDG	Marine Pollutant: Yes (Silver oxide)		
14.6. Special precautions for user			
	No further information		

15. Regulatory information

Regulatory Overview	The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.
Toxic Substance Control Act (TSCA)	All components of this material are either listed or exempt from listing on the TSCA Inventory.
WHMIS Classification	D2A E
US EPA Tier II Hazards	Fire: No Sudden Release of Pressure: No Reactive: No Immediate (Acute): Yes Delayed (Chronic): Yes
EPCRA 311/312 Chemicals and RQs (lbs):	
	Silver (1,000.00)
EPCRA 302 Extremely Hazardous:	
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.	
EPCRA 313 Toxic Chemicals:	
	Isocyanic acid, methylenedi-4,1-cyclohexylene ester
	Silver
	Silver oxide
	Toluene di-isocyanate
Proposition 65 - Carcinogens (>0.0%):	
	Chromium (VI)
	Toluene di-isocyanate
Proposition 65 - Developmental Toxins (>0.0%):	
	Chromium (VI)

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Proposition 65 - Female Repro Toxins (>0.0%):

Chromium (VI)

Proposition 65 - Male Repro Toxins (>0.0%):

Chromium (VI)

New Jersey RTK Substances (>1%):

Silver

Pennsylvania RTK Substances (>1%):

Silver

16. Other information

The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein. We accept no responsibility and disclaim all liability for any harmful effects which may be caused by exposure to our products. Customers/users of this product must comply with all applicable health and safety laws, regulations, and orders.

The full text of the phrases appearing in section 3 is:

H271 May cause fire or explosion; strong oxidizer.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H330 Fatal if inhaled.

H331 Toxic if inhaled.

H334 May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.

H335 May cause respiratory irritation.

H351 Suspected of causing cancer.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

H412 Harmful to aquatic life with long lasting effects.

This is the first version in the GHS SDS format. Listings of changes from previous versions in other formats are not applicable.

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