

SAFETY DATA SHEET

Conforms with OSHA Hazard Communication Standard (CFR 29 1910.1200) HazCom 2012



Product: Surgical Instrument Cleaner (REF 3-720, 3-725)

Revision Date: 05/29/2015

SECTION 1 - IDENTIFICATION

Product Identifier

Product Name: Surgical Instrument Cleaner

Product Code: 3-720, 3-725

Recommended Use of the Chemical and Restrictions on Use

Recommended Use: A biodegradable, Phosphate-free, concentrated formula for ultrasonic and manual cleaning of surgical instruments.

Restrictions on Use: Product is not a sterilizing agent. All instruments must be autoclaved after cleaning.

Details of the Supplier

Manufactured for: Integra York PA, Inc.
589 Davies Dr.
York, PA 17402 USA
1-866-854-8300

Emergency Phone Number

24-Hour Number: 1-800-535-5053

International: 1-352-323-3500

SECTION 2 – HAZARDS IDENTIFICATION

Classification of the substance or mixture:

Eye irritation, **Category 2B**; H320 - Causes eye irritation
Skin irritation, **Category 3**; H316 - Causes mild skin irritation
Environmental hazard, **Category 3**; H402 - Harmful to aquatic life
Health hazard, **Category 2**; H351 - Suspected of causing cancer

Label Elements

GHS label elements, including Hazard precautionary statements

Hazard pictogram(s):



Signal word: Warning

Hazard Statement(s):

Causes eye irritation. Causes mild skin irritation. Harmful to aquatic life. Suspected of causing cancer.

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Precautionary Statements:

P362+364: Take off contaminated clothing and wash it before reuse.

P305 +P351 +P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Other Hazards

Other hazards which do not result in classification: Acute hazards to the aquatic environment in large concentrations

SECTION 3 – COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	CAS Number	Concentration %
Proprietary Formulation	***	60% to 100%
Cocamide Diethanolamine	68603-42-9	3% to 7%

The specific chemical identify and exact percentage (concentration) of composition has been withheld as a trade secret in accordance with paragraph (i) of §1910.1200.

SECTION 4 – FIRST AID MEASURES

First Aid Measures

First aid measures for accidental exposure:

Skin Exposure:

May cause skin irritation. In case of contact, flush skin with plenty of water. Cover the irritated skin with an emollient. Remove contaminated clothing and shoes. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention if necessary.

Inhalation:

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Eye contact:

Causes eye irritation. Check for and remove any contact lenses. Immediately flush eyes with running water for at least 15 minutes, keeping eyelids open. Cold water may be used. Get medical attention.

Ingestion:

INDUCE VOMITING by sticking finger in throat. Lower the head so that the vomit will not reenter the mouth and throat. Loosen tight clothing such as a collar, tie, belt, or waistband. If the victim is not breathing, administer artificial respiration. Examine the lips and mouth to ascertain whether the tissues are damaged, a possible indication that the toxic material was ingested; the absence of such signs, however, is not conclusive. Seek immediate medical attention. Treat symptomatically and supportively.

Medical conditions possibly aggravated by exposure:

Suspected of causing cancer

Indication of any Immediate Medical Attention and Special Treatment Needed

Note to Physician: Treat symptoms and eliminate overexposure.

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SECTION 5 – FIRE-FIGHTING MEASURES

Extinguishing Media

Product may be combustible at high temperature.

SMALL FIRE: Use DRY chemical powder.

LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Specific Hazards Arising from Chemical

When heated to decomposition it emits acrid smoke and irritating fumes.

Hazardous Decomposition Materials (Under Fire Conditions):

These products are carbon oxides (CO, CO₂). Aldehydes or lactic, pyruvic or acetic acids may also be formed.

Protective Equipment and Precautions for Firefighters

None specified.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Evacuation Procedures and Safety:

None.

Containment of Spill:

Follow procedure described below under Cleanup and Disposal of Spill.

Cleanup and Disposal of Spill:

Mop up any spilled product and discharge in accordance with local/regional/national/international environmental disposal regulations.

Environmental and Regulatory Reporting:

None.

SECTION 7 – HANDLING AND STORAGE

Minimum/Maximum Storage Temperatures:

Store between 40° F and 120° F. Keep container closed when not in use.

Handling:

Avoid direct or prolonged contact with skin and eyes. If freezing occurs, thaw and remix before using. Frozen material may be thawed in a warm room. Avoid localized overheating. Vent drums while heating. Mix thoroughly to assure homogeneity.

Storage:

Store at room temperature. Store in tightly closed containers. Store in an area that is dry, well-ventilated; away from incompatible materials (see Section 10 • Stability and Reactivity).

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SECTION 8 – EXPOSURE CONTROL / PERSONAL PROTECTION

Introductory Remarks:

These recommendations provide general guidance for handling this product. Because specific work environments and material handling practices vary, safety procedures should be developed for each intended application. While developing safe handling procedures, do not overlook the need to clean equipment and piping systems for maintenance and repairs. Waste resulting from these procedures should be handled in accordance with Section 13 • Disposal Considerations. Assistance with selection, use and maintenance of worker protection equipment is generally available from equipment manufacturers.

Exposure Limits:

Chemical Name	Exposure Limits (TWA)	
	ACGIH	NIOSH
Cocamide diethanolamine	2 mg/m ³ TWA (as Diethanolamine)	3 ppm = 15 mg/m ³ (as Diethanolamine)
Propylene glycol*	-	-

* Propylene glycol occupational exposure limit: AIHA-WEEL 10 mg/m₃ 8 Hr. – TWA.

Total: Vapor & Particulates:

(Particulates Glycol): 8hr TWA = 474 mg/m³ (150 ppm);

(Particulates Only): 8hr TWA = 10 mg/m³

Engineering Controls:

Where engineering controls are indicated by use conditions or a potential for excessive exposure exists, the following traditional exposure control techniques may be used to effectively minimize employee exposures: General area dilution/exhaust ventilation.

Respiratory Protection:

Not required for properly ventilated area.

Eye/Face Protection:

Recommended, but not required.

Skin Protection:

Gloves are recommended but not required.

Work Practice Controls:

None required.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Physical Appearance: Light gold oily liquid

Odor: Characteristic scent

Odor threshold: Not determined

pH: 7.05 to 7.65

Melting point/freezing point: Not available

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Initial boiling point and boiling range: 100° C (212°F) at 760mmHg. Boiling range not determined.

Flash point: >140°F, Closed cup

Evaporation rate: As water

Flammability (solid, gas): Not determined

Upper/lower flammability or explosive limits: Not available

Vapor pressure: Not determined

Vapor density: Not determined

Specific Gravity: 1.03 to 1.10 at 20° C

Water Solubility: Completely soluble

Partition coefficient (n-octanol/water): No data available

Auto-ignition temperature: No data available

Decomposition temperature: No data available

Percent Volatiles by Volume: Nonvolatile

Viscosity: Not available

SECTION 10 – STABILITY AND REACTIVITY

Reactivity: No data available

Chemical stability: This material is stable under normal handling and storage conditions described in section 7

Possibility of hazardous reactions: Hazardous polymerization will not occur

Conditions to avoid: None

Incompatible materials: Oxidizing agents

Hazardous decomposition products: None

SECTION 11 – TOXICOLOGICAL INFORMATION

Acute Eye Irritation:

Toxicological Information and Interpretation:

Eye - Mild eye irritation.

Acute Dermal Irritation:

Toxicological Information and Interpretation:

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Skin - Mild irritant.

Acute Dermal Toxicity:

No test data found for product.

Acute Respiratory Irritation:

No test data found for product.

Acute Inhalation Toxicity:

No test data found for product.

Acute Oral Toxicity:

No test data found for product.

Chronic Toxicity:

This product contains substances that are considered by OSHA, NTP, IARC or ACGIH to be "probable" or "suspected" human carcinogens:

Cocamide Diethanolamine (neat):

Toxicological Data on Ingredients:

Acute Dermal LD₅₀ Rabbit: > 2 g/kg

Acute Oral LD₅₀ Rat: > 5 g/kg

Carcinogenicity Hazardous by OSHA criteria. Suspected of causing cancer. ACGIH Carcinogens confirmed animal carcinogen with unknown relevance to humans.

IARC Monographs. Overall Evaluation of Carcinogenicity:

Cocamide DEA (Alternative CAS 68155-07-7) (CAS 68603-42-9)

2B Possibly carcinogenic to humans.

IARC Monographs: Evidence of carcinogenicity in humans

Cocamide DEA (Alternative CAS 68155-07-7) (CAS 68603-42-9)

No data.

Sodium dodecylbenzenesulfonate (neat):

Toxicological Data on Ingredients:

Acute Oral LD₅₀ Rat: 438 mg/kg

Acute Oral LD₅₀ Mouse: 1330 mg/kg

Acute Intravenous LD₅₀ Mouse: 105 mg/kg

Propylene glycol (neat):

Toxicological Data on Ingredients:

Acute Oral LD₅₀ Rat: >20,000 mg/kg

Acute Dermal LD₅₀ Rabbit: >2,000 mg/kg

Sodium xylenesulfonate, (neat):

Toxicological Data on Ingredients:

Acute Oral LD₅₀ Rat: >16,200 mg/kg-bw

Acute Dermal LD₅₀ Rat: > 2000 mg/kg-bw

Acute Inhalation LC₅₀ Rat: >6.41 mg/l 232 min, (By analogy with similar materials)

LC₅₀ (96 hour): > 1000 mg/L (Oncorhynchus mykiss)

EC₅₀ (48 hour): >40.3 mg/LI (Daphnia magna, mobility)

EC₅₀ (96 hour): > 230 mg/L (Pseudokirchnerella subcapitata)

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SECTION 12 – ECOLOGICAL INFORMATION

Ecotoxicological Information:

Ecotoxicity in water (LC50): >5,000 mg/l 24 hours [Goldfish]. >10,000 mg/l 48 hours [guppy].
>10,000 mg/l 48 hours [water flea].
BOD5 and COD: Not available.

Products of Biodegradation:

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.
Toxicity of the Products of Biodegradation: The products of degradation are less toxic than the product itself.
Special Remarks on the Products of Biodegradation: Not available.

Persistence/degradability:

No data on persistence/degradability

Chemical Fate Information:

No data found for product.

SECTION 13 – DISPOSAL CONSIDERATIONS

Dispose of the product and container in accordance with all applicable local, state, federal and international regulations. Not classified as dangerous according to transport regulations.

SECTION 14 – TRANSPORT INFORMATION

This product is not hazardous as defined by 49 CFR 172.101 by the U.S. Department of Transportation.

Proper shipping name: Not regulated

Hazard class number and description: Not applicable

UN identification number: Not applicable

DOT label(s) required: Not applicable

Packaging group: Not applicable

Emergency response guidebook number (2004): Not applicable

Marine pollutant: Listed as a marine pollutant by the D.O.T. (49 CFR 172.101, Appendix B).

Transport Canada transportation of dangerous goods regulations: this product is not considered as dangerous goods, per transport Canada regulations.

SECTION 15 – REGULATORY INFORMATION

Inventory Status:

UNITED STATES (TSCA)	Y
CANADA (DSL)	Y
EUROPE (EINECS/ELINCS)	Y
AUSTRALIA (AICS)	Y
JAPAN (MITI)	Y
SOUTH KOREA (KECL)	Y

Y = All ingredients are on the inventory.

E = All ingredients are on the inventory or exempt from listing.

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P = One or more ingredients fall under the polymer exemption or are on the no longer polymer list. All other ingredients are on the inventory or exempt from listing.
N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing.

Additional Regulations:

US Federal Regulations

OSHA: Hazardous by definition of Hazard Communication Standard (29 CFR 1910.1200).

Other Classifications:

WHMIS (Canada):

CLASS D-2A: Material causing other toxic effects

DSCL (EEC):

R38- Irritating to skin.

US EPCRA (SARA Title III) Section 313 - Toxic Chemical: De minimis concentration

Diethanolamine (CAS 111-42-2) 1.0 %

US CERCLA Hazardous Substances: Reportable quantity

Diethanolamine (CAS 111-42-2) 100 lbs.

US EPCRA (SARA Title III) Section 313 - Toxic Chemical: Listed substance

Diethanolamine (CAS 111-42-2) Listed.

Reportable Quantity Reportable Quantity (RQ) of this product is 2011 pounds based upon Diethanolamine (111-42-2) which yielded the lowest resultant RQ according to the following formula: CERCLA ingredient RQ /% of that ingredient in the product.

CERCLA (Superfund) reportable quantity

Diethanolamine: 100

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Section 302 extremely hazardous substance: No

Section 311 hazardous chemical: Yes

Chemical Safety Assessment

No additional information available.

SECTION 16 – OTHER INFORMATION

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