SAFETY DATA SHEETS

This SDS packet was issued with item:

075001029

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

071086834 073034188 078005408 078371291 078564805

MATERIAL SAFETY DATA SHEET
Revised/Reviewed: June 18, 2010

Surgical Instrument Cleaner

A biodegradable, phosphate-free formula for ultrasonic and manual cleaning of surgical instruments.

Section 1- Product and Company Information

Manufactured by: Miltex, Inc., 589 Davies Drive, York, PA 17402
Information: 717-840-9335, 717-840-9347 (fax)
Chemical Name & Synonyms: --
Chemical Formula: --

Section 2 – Composition/ Information on Ingredients

Components: Water, Sodium Dodecylbenzene Sulfonate, Propylene Glycol, Linear Alcohol Ethoxylate, Cocamide Diethanolamide, Tetrasodium EDTA, Sodium Xylene Sulfonate, and Citric Acid.
OSHA PEL and ACGIH TLV information contains no data for all components.
This product is not identified as a hazardous material under criteria of OSHA Hazard Communication Standard 29 CFR 1910.1200.

Section 3 - Health Identification

Threshold Limit Value: Not established
Over Exposure Effects: Can cause skin and eye irritation. Vapor inhalation can irritate nose, throat, and respiratory tract. May cause nausea if ingested and Tretrasodium EDTA will sequester calcium, which could be harmful to bones.
Chronic Effects: Repeated excessive ingestion may cause central nervous system effects. Could be harmful to bone structure.
Carcinogenicity: No known carcinogenic effects. **NTP:** ND **IARCX:** ND **OSHA:** ND

LD (Oral): LD_{50} (oral) 630-1260 mg/kg (rats), 2.6 ml/kg (rabbit)
LC (Inhalation): 800mg/m3 (guinea pigs)
LD (Skin): 5.7 ml/kg (rabbit)

Section 4 - First Aid Measures

Eyes: Flush with tepid water for at least 15 minutes. Hold eyelids apart during flushing to ensure rinsing of entire eye and lid surface. *Do not* attempt to neutralize with chemical agents. Oil and ointments should not be used at this time. As needed, seek medical attention as soon as possible.
Skin: if in contact with skin, wash off with mild soap and water. Rinse with copious amounts of water. If dry skin results, apply a moisturizing cream or lotion.

Ingestion: *Do not* induce vomiting. Give a glass of water. If vomiting occurs, again give fluids. Do not give anything to an unconscious or convulsing person. Have medical personnel determine if evacuation of the stomach or induction of vomiting is necessary.
Inhalation: If any ill effects are noticed, remove person to fresh air.

Section 5 – Fire Fighting Measures

Flash Point (Test Method): Non-combustible
Auto Ignition Temperature: Not applicable
Flammable Limits – LEL: Not applicable UEL: None
Extinguishing Media: Water, carbon dioxide, and dry chemical
Special Fire Fighting Procedures: Self-contained breathing apparatus
Unusual Fire and Explosion Hazards: fire may produce irritating gas, fumes, or vapor (CO, Propionaldehyde). Exposed firefighters should wear MSHA/NIOSH approved self-contained breathing apparatus with full-face mask and full protective equipment.

Section 6 - Physical and Chemical Properties

Physical State: Liquid at ambient temperature.
Appearance and Odor: Clear yellow liquid with a slight ammonical odor.
Boiling Point (°C): N/A
Specific Gravity (Water=1): 1.05-1.09 pH: 7.05 – 7.65
Evaporation Rate (butyl acetate=1): Not determined Vapor Pressure (mm Hg): Not determined
Vapor Density (Air=1): Not determined Solubility in Water: Soluble

Section 7 – Stability and Reactivity

Stability: Stable
Conditions to Avoid: Contact with strong acids. Do not mix with bleach. Do not expose to high heat.
Incompatibility/Materials to Avoid: Strong oxidizing materials.
Hazardous Polymerization: Will not occur
Hazardous Decomposition Products: Irritating or toxic substances may be emitted upon thermal decomposition. In a fire situation, Propionaldehyde and CO could be emitted in the presence of limited oxygen. Aldehydes, acids, and ketones could also be released.

Section 8 – Accidental Release, Disposal, and Ecological Information

Spill Response: Soak up liquid with absorbent material and place the material in a chemical waste chemical container for disposal.
Waste Disposal Method: Dispose of in accordance with all applicable federal, state, and local regulations.
Ecological, General: Not determined.

Section 9 – Exposure Controls/ Personal Protection

Eye Protection: Goggles or lab safety glasses.
Respiratory Protection: Not required
Ventilation Recommendations: general room ventilation is normally sufficient.
Skin Protection: rubber or plastic gloves.
Other: As required to minimize skin contact.

Section 10 – Storage and Handling

Storage: Store in a cool, dry area. Keep container closed when not in use.
Handling: Use gloves to protect skin from drying and possible irritation. Application of a moisturizing compound will help prevent skin problems. Keep food away from the work area and wash hands and face thoroughly before eating.

Section 11 – Miscellaneous

Shipping information:
DOT Hazard Class: Not regulated DOT shipping Name: Cleaning Compound; Liquid
DOT Label Required: None RQ Quantity: N/A UN #: N/A DOT Guide #: N/A
Packaging Size: 8 oz. Bottles DOT Packaging Group: N/A Marine Pollutant: No

Regulatory Information
SARA Title III (Sect. 313) Toxic Chemicals: None (Sect. 302) EHS: None
(Sect.311, 312) HAZ Classified Acute: Yes Chronic: No Fire: No Reactivity: No Pressure: No
Suspect Carcinogen /IARC, NTP, OSHA: No

Liability Disclaimer: MSDS information is provided based on OSHA's Hazardous Communication Regulation and for use of the persons required to receive this information under this regulation. The information is neither designed nor recommended for any other use or for use by any other person, including compliance with other laws. Miltex does not warrant the suitability for use of this MSDS for any other material or product not specifically identified herein. Miltex does not warrant the accuracy or authenticity of this MSDS unless it has been obtained directly from Miltex, or posted or viewed on a Miltex website. This MSDS is based on information that is believed to be reliable, but may be subject to change as new information becomes available. Because it is not possible to anticipate all conditions of use, additional safety precautions may be required. Since the use of this material is not under Miltex's control, each user is responsible for making their own determination as to the safe and proper handling of this material in their own particular use of this material. Miltex makes no representation or warranty, either expressed or implied, including as to merchantability or fitness for a particular purpose.

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.

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.

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).

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:

	Exposure Limits (TWA)	
Chemical Name	**ACGIH**	**NIOSH**
Cocamide diethanolamine	2 mg/m3 TWA (as Diethanolamine)	3 ppm = 15 mg/m3(as Diethanolamine)
Propylene glycol*	-	-

* Propylene glycol occupational exposure limit: AIHA-WEEL 10 mg/m_3 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

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:

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 LD_{50} Rat: 438 mg/kg
Acute Oral LD_{50} Mouse: 1330 mg/kg
Acute Intravenous LD_{50} Mouse: 105 mg/kg

Propylene glycol (neat):
Toxicological Data on Ingredients:
Acute Oral LD_{50} Rat: >20,000 mg/kg
Acute Dermal LD_{50} Rabbit: >2,000 mg/kg

Sodium xylenesulfonate, (neat):
Toxicological Data on Ingredients:
Acute Oral LD_{50} Rat: >16,200 mg/kg-bw
Acute Dermal LD_{50} Rat: > 2000 mg/kg-bw
Acute Inhalation LC_{50} Rat: >6.41 mg/l 232 min, (By analogy with similar materials)
LC_{50} (96 hour): > 1000 mg/L (Oncorhynchus mykiss)
EC_{50} (48 hour): >40.3 mg/Ll (Daphnia magna, mobility)
EC_{50} (96 hour): > 230 mg/L (Pseudokirchnerella subcapitata)

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.

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

Issue Date: 05/29/2015

Revision Date: 05/29/2015

Liability Disclaimer: SDS information is provided based on OSHA's Hazardous Communication Regulation and for use of the persons required to receive this information under this regulation. The information is neither designed nor recommended for any other use or for use by any other person, including compliance with other laws. Integra York PA, Inc. (the "Company") does not warrant the suitability for use of this SDS for any other material or product not specifically identified herein. The Company does not warrant the accuracy or authenticity of this SDS unless it has been obtained directly from the Company, or posted or viewed on a Company website. This SDS is based on information that is believed to be reliable, but may be subject to change as new information becomes available. Because it is not possible to anticipate all conditions of use, additional safety precautions may be required. Since the use of this material is not under the Company's control, each user is responsible for making their own determination as to the safe and proper handling of this material in their own particular use of this material. The Company makes no representation or warranty, either expressed or implied, including as to merchantability or fitness for a particular purpose.