

**MATERIAL SAFETY DATA SHEET****CIDEX PLUS™ 28 DAY SOLUTION**

TM = Trademark

MSDS: 007

EFFECTIVE: 2/17/00

REVISION: C

CR 03300-9

SECTION 1 – IDENTIFICATION**MANUFACTURER'S NAME AND ADDRESS:**

ADVANCED STERILIZATION PRODUCTS
33 TECHNOLOGY DRIVE
IRVINE, CA 92618-2346

IDENTIFY: 3.4% Aqueous Glutaraldehyde Solution**Product Code:** 2785, 2786, 2683**Trade Name:** CIDEX PLUS™ 28 DAY SOLUTION**SYNONYMS:** CIDEX PLUS SOLUTION**CHEMICAL FAMILY:** Aldehydes**RTECS#:** MA 2450000 (glutaraldehyde)**MOLECULAR FORMULA:**OHCC₂ CH₂ CH₂CHO (glutaraldehyde)**MOLECULAR WEIGHT:** 100.11 (glutaraldehyde)**EMERGENCY TELEPHONE NUMBERS:**

Chemtrec (800) 262-8200

TELEPHONE NUMBER FOR PRODUCT ASSISTANCE:
(800) 755-5900**Hazardous Chemicals:** Glutaraldehyde**Route of Entry:**

- ✓ Inhalation
- ✓ Skin/eye
- ✓ Ingestion

Personal protection recommended:

- Glutaraldehyde-resistant gloves
- Fluid Repellent gown
- Protective eye wear

HMIS HAZARD RATINGS:

Health (Blue): 2

Reactivity (Yellow): 0

Flammability (Red): 0

Special Hazard: Irritant

SECTION 2 – HAZARDOUS INGREDIENTS / IDENTITY INFORMATION

| COMPONENTS: | CAS# | % | ASP Recommended Ceiling Limit | ACGIH TLV Ceiling Limit | OSHA PEL Ceiling Limit | OSHA 1910.1200 Hazard Comm. |
|------------------------|-----------|------|----------------------------------|--|---|--------------------------------|
| Glutaraldehyde(active) | 111-30-8 | <5 % | 0.1 ppm (0.4mg/m ³) | 0.05ppm ^a (0.2mg/m ³) | 0.2ppm ^b (0.8mg/m ³) | N/A |
| Water | 7732-18-5 | >95% | N/A | N/A | N/A | N/A |

^aIn May 1995 ACGIH issued a Notice of Intent to change the TLV ceiling limit to 0.05 ppm. This proposed ceiling limit has been adopted.

^bThe OSHA PEL for glutaraldehyde was invalidated, along with the PEL's of many other chemicals, on procedural grounds by court order in 1992, but may remain valid in some OSHA-approved state plans. In addition, federal OSHA can enforce the PEL for glutaraldehyde by means of its General Duty Clause.

SECTION 3 – PHYSICAL/CHEMICAL CHARACTERISTICS**APPEARANCE AND ODOR:** 2 components, clear, colorless liquid and powdered salts; solution turns green when activated. Sharp odor.**BOILING POINT:** 212°F/100°C (same as water)**SPECIFIC GRAVITY (75°F):**(H₂O=1) = 1.029g/cc**V.O.C. (g/L) = 0****MELTING POINT:** N/A**VAPOR PRESSURE:** 0.20 mm Hg at 20°C**EVAPORATION RATE:**

(butyl acetate=1) 1.0

VAPOR DENSITY: (Air=1) 1.1**pH:** 7.5 - 8.1 (activated)
3.2 - 4.3 (unactivated)**SOLUBILITY IN WATER:** 100% (complete)**ODOR THRESHOLD:** 0.04 ppm detectable (ACGIH)**FREEZING POINT:** 32°F/0°C (same as water)**SECTION 4 – FIRE AND EXPLOSION HAZARD DATA****FLASH POINT (TEST METHOD USED):** None (Tag Closed Cup ASTM D 56)

**MATERIAL SAFETY DATA SHEET****CIDEX PLUS™ 28 DAY SOLUTION**

TM = Trademark

MSDS: 007

EFFECTIVE: 2/17/00

REVISION: C

CR 03300-9

FLAMMABLE LIMITS IN AIR – LEL: not determined (aqueous system) **UEL:** not determined (aqueous system)**EXTINGUISHING MEDIA:** After water evaporates remaining material will burn. For small fires use carbon dioxide or dry chemical. For large fires use alcohol-type or all-purpose type foam, applied by manufacturer's recommended techniques.**SPECIAL FIRE FIGHTING HAZARD:** Self-contained breathing apparatus and protective clothing should be available to firemen.**UNUSUAL FIRE AND EXPLOSION HAZARDS:** None known.**TOXIC GASES PRODUCED:**

See SECTION 5 – REACTIVITY DATA – HAZARDOUS COMBUSTION OR DECOMPOSITION PRODUCTS.

SECTION 5 – REACTIVITY DATA**STABILITY:** Stable**CONDITIONS TO AVOID:** Avoid temperatures above 104°F(40°C) and evaporation of water.**INCOMPATIBILITY (MATERIALS TO AVOID):** Strongly alkaline materials (pH>10) and acids (pH<3) catalyze an aldol-type condensation, which is exothermic, but not expected to be violent.**HAZARDOUS COMBUSTION OR DECOMPOSITION PRODUCTS:** Burning can produce the following products: Carbon monoxide and/or carbon dioxide. Carbon monoxide is highly toxic if inhaled. Carbon dioxide in sufficient concentrations can act as an asphyxiant.**HAZARDOUS POLYMERIZATION:** Will not occur.**SECTION 6 – HEALTH HAZARD DATA****ROUTE(S) OF ENTRY – INHALATION:** yes **SKIN:** yes **INGESTION:** yes **EYE:** yes**SIGNS AND SYMPTOMS OF SINGLE OR REPEATED OVEREXPOSURE:****Eyes:** Solution contact with eyes may cause damage, including possible corneal injury, which could permanently impair vision if prompt first aid and medical treatment are not obtained. Vapor may cause stinging sensations in the eye, with excess tear production, blinking, and possibly a slight excess redness of the conjunctiva.**SKIN:** Direct contact may cause skin irritation or aggravate an existing dermatitis. Repeated exposure can result in sensitization and allergic contact dermatitis.**INHALATION:** Vapor is irritating to the respiratory tract. May cause stinging sensations in the nose and throat, discharge or, possibly, bleeding from the nose, coughing, symptoms of bronchitis, headache. Inhalation of vapor may cause asthma-like symptoms (chest discomfort and tightness, difficulty with breathing) as well as aggravate pre-existing asthma and inflammatory or fibrotic pulmonary disease. Heating the solution may result in more severe irritant effects.**INGESTION:** May cause irritation or chemical burns of the mouth, throat, esophagus, and stomach with discomfort in the mouth, throat, chest, and abdomen, nausea, vomiting, diarrhea, dizziness, faintness, and general systemic illness.

**MATERIAL SAFETY DATA SHEET****CIDEX PLUS™ 28 DAY SOLUTION**

TM = Trademark

MSDS: 007

EFFECTIVE: 2/17/00

REVISION: C

CR 03300-9

EMERGENCY AND FIRST AID PROCEDURE:

EYES: Immediately flush eyes with water and continue washing for at least 15 minutes. DO NOT remove contact lenses during the washing procedure. Obtain immediate medical attention, preferably from an ophthalmologist.

SKIN: Immediately remove contaminated clothing and shoes and flush skin with soap and water; continue washing for at least 15 minutes. If irritation persists, obtain medical attention. Wash clothing before reuse. Discard contaminated leather articles such as shoes or belts.

INHALATION: Remove to fresh air. Give artificial respiration if not breathing. If breathing is difficult, oxygen may be given by qualified personnel. If symptoms persist, obtain medical attention.

INGESTION: DO NOT INDUCE VOMITING. CALL PHYSICIAN OR YOUR LOCAL POISON CONTROL CENTER FOR MOST RECENT INFORMATION.

NOTE TO PHYSICIAN: Probable mucosal damage from oral exposure may contraindicate the use of gastric lavage.

HEALTH HAZARDS (ACUTE AND CHRONIC):

As listed under SIGNS AND SYMPTOMS OF SINGLE OR REPEATED EXPOSURE.

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: Skin contact may aggravate a pre-existing dermatitis. Inhalation of vapor may aggravate pre-existing asthma, bronchitis, and inflammatory or fibrotic pulmonary disease.

TOXICITY:

ORAL LD₅₀ (Rat) - Toxicity Rating 0: 4,250 mg/kg

OCULAR (Rabbit) - Toxicity Rating 3: Severe irritation and corneal opacity persisting more than seven days without reversion.

DERMAL LD₅₀ (Rabbit) - None by dermal route.

INHALATION LC₅₀ (Rat) - Irritating, but non-toxic at highest concentration achieved (2.89 ppm).

SIGNIFICANT LABORATORY DATA WITH POSSIBLE RELEVANCE TO HUMAN HAZARD EVALUATION

Several subchronic inhalation toxicity studies using rat and mice models have been reported in the literature. In one study¹, rats were exposed to 0 to 194 ppb (0.194 ppm) glutaraldehyde vapor daily for 90 days. In the 49 ppb and 194 ppb exposure groups, perinasal wetness and significantly decreased body weight were observed. "However, no damage to the nasal mucosa occurred, and although activities of several serum enzymes were elevated, no histopathological lesions were found in any organ." In a second study², rats and mice were exposed to 0, 62.5, 125, 250, 500, and 1000 ppb (1ppm) for 6 hours a day, and 5 days per week, for 13 weeks. Exposure of rats and mice to higher dose levels of glutaraldehyde vapor resulted in lesions confined to the nasal passages. However, "no pre-cancerous lesions like those occurring in animals receiving formaldehyde by inhalation for 13 weeks were detected in the present study with glutaraldehyde." Furthermore, in assessing the relevance of these results to human safety, it should be noted that the nasal passage structure of mice and rats is very different than that found in man.

Subchronic drinking water studies in rats, mice, and dogs using concentrations up of 1000 ppm showed no evidence for any target organ toxicity.¹ *In vitro* studies for genotoxicity using a variety of assays have given results varying from no activity, though equivocal, to weakly positive; however, all *in vivo* studies for genotoxicity have been uniformly negative.¹ Several developmental toxicity studies have demonstrated that at maternally nontoxic doses, glutaraldehyde does not produce fetotoxic, embryotoxic or teratogenic effects.¹ In a two-generation reproduction study involving continuous exposure of CD rats to glutaraldehyde up to 1000 ppm in drinking water, there were effect on parental body weight and food consumption at 1000 ppm (due to an aversion to the taste), but no adverse effects on reproductive performance.¹ In a chronic (2-year) continuous drinking water combined chronic toxicity-oncogenicity study using Fischer 344 rats, there was no evidence for non-oncogenic target organ toxicity.¹ The only possible oncogenicity- related finding was an increase in the incidence of large granular cell lymphocytic leukemia in female, but not male, rats.¹ The pattern of response suggests that it does not represent direct chemical carcinogenic activity but, rather, a modifying influence on the expression of this spontaneous and commonly occurring neoplasm in the Fischer 344 rat.¹ Repeated applications of aqueous solutions of glutaraldehyde to rat skin for 20 dosages over a 28-day period at 50, 100 or 150 mg/kg/day produced mild local inflammatory effects, but no evidence for target organ or tissue systemic toxicity.¹

¹ Union Carbide Corporation, UCARCIIDE 250 Antimicrobial (50% glutaraldehyde), Material Safety Data Sheet, 09/27/95, and B. Ballantyne, "Toxicology of Glutaraldehyde- Review of Studies and Human Health Effects," Union Carbide Corporation, 1995.

**MATERIAL SAFETY DATA SHEET****CIDEX PLUS™ 28 DAY SOLUTION****TM = Trademark****MSDS: 007****EFFECTIVE: 2/17/00****REVISION: C****CR 03300-9**

² F. Kari, "National Toxicology Program Technical Report on Toxicity Studies of Glutaraldehyde- Administered by Inhalation to F344/N Rats and B6C3F1 Mice," NIH Publication 93-3348, 1993.

LISTED CARCINOGENS:

NPP: No IARC MONOGRAPHS: No

OSHA: No

California Proposition 65: No

SECTION 7 – PRECAUTIONS FOR SAFE HANDLING AND USE

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED: Wear suitable protective equipment, including nitrile or butyl rubber gloves (MICRO-TOUCH™ Latex Gloves are acceptable if double-gloved and/or changed every 5 to 10 minutes), fluid resistant gown or apron, safety glasses or face shield, and OSHA/NIOSH-approved reusable or disposable full face respirator equipped with organic vapor cartridge mask. For SMALL spills, (1 gallon or less), wipe with sponge or mop down area with an equal mixture of household ammonia and water. Flush with large quantities of water down drain. For LARGE spills (greater than 1 gallon), disperse approximately 316 grams of sodium bisulfite powder per gallon of estimated CIDEX Solution spill. With a mop thoroughly blend the sodium bisulfite into the spilled CIDEX Solution. Allow 5 minutes for complete deactivation of glutaraldehyde. Flush deactivated spill down the drain with large amounts of water. For large spills, the addition of an absorbent may aid in containment of the spill. Dispose of the absorbent/deactivated glutaraldehyde according to your facility's waste disposal guidelines. Thoroughly rinse the mop and any sponges or paper towels used for final clean-up with large amounts of water. Discard paper towels or sponges in a tightly closed trash bag.

WASTE DISPOSAL METHOD: Dispose spent CIDEX PLUS Solution at the end of its use life, as determined by the CIDEX PLUS Solution Test Strip, down the drain, in accordance with state and local requirements. Flush thoroughly with large quantities of water. Rinse empty containers thoroughly with water, wrap container and put in trash. Do not reuse empty container.

EPA HAZARDOUS WASTE NUMBER: not applicable

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORING: Prior to activation, store product in original sealed container at controlled room temperature, 59°-86°F(15°-30°C).

SECTION 8 – TRANSPORTATION DATA & ADDITIONAL INFORMATIONDOT (ground)IATA (air)IMO (ocean)**PROPER SHIPPING NAME:** NOT REGULATED NOT RESTRICTED NOT REGULATED**HAZARD CLASS:** None None None**LABELS:** None Needed None Needed None Needed**PACKAGING:** None None None**ID#:** None None None**SPECIAL INSTRUCTIONS:** None None None**REPORTABLE QUANTITY:** None**SECTION 9 – CONTROL MEASURES****VENTILATION:**

ROUTINE: CIDEX PLUS Solution should be used in a well ventilated area in closed containers with tight fitting lids. Rooms where CIDEX PLUS Solution is used should be large enough to ensure adequate dilution of vapor and should have a minimum air exchange rate of 10 air exchanges per hour. If vapors are strong enough to be irritating to the nose (or eyes), the TLV is probably being exceeded and additional ventilation is needed. When general room ventilation is not adequate, use local exhaust hoods, or ductless fume hoods which contain filter media which absorb or inactivate glutaraldehyde vapor. All ventilation systems should pull air in at or below the glutaraldehyde vapor point of release in order to pull the vapor down and away from the user.

EMERGENCY: Not applicable**RESPIRATORY PROTECTION:**

**MATERIAL SAFETY DATA SHEET****CIDEX PLUS™ 28 DAY SOLUTION****TM = Trademark****MSDS: 007**

EFFECTIVE: 2/17/00

REVISION: C

CR 03300-9

None required, if adequate ventilation control measures are in place to control glutaraldehyde vapor levels below the TLV.

EMERGENCY: OSHA/NIOSH-approved full face respirator mask equipped with organic vapor cartridge, or self-contained breathing apparatus.

EYE PROTECTION: Safety goggles

EMERGENCY: Safety goggles and face shield; suitable eye wash (American National Standards Institute Z358.1-1990, or equivalent) should be readily available.

SKIN PROTECTION: To protect hands and forearms, wear gloves of appropriate type and length. MICRO-TOUCH Latex Gloves are acceptable, if changed frequently (i.e., every 5 or 10 minutes), and/or double gloved. Before using other latex glove, contact the glove manufacturer for permeation information to determine if their gloves are suitable for use with glutaraldehyde solutions. Nitrile rubber, butyl rubber, and some other synthetic rubber gloves, i.e., ALLERGARD™ Synthetic Surgical Gloves, are acceptable glove materials. Do not use neoprene rubber or polyvinyl chloride (vinyl) gloves, as glutaraldehyde may rapidly absorbed by these materials. Wear fluid resistant gowns or plastic aprons.

EMERGENCY: Gloves listed above; protective gown or apron; rubber boots.

WORK/HYGIENIC PRACTICES: Avoid contamination of food.

SECTION 10 – SPECIAL REQUIREMENTS**NONE****SECTION 11 – SIGNIFICANT CHANGES TO CIDEX SOLUTION MSDS**

Section 1: Added Chemtrec phone number and changed NFPA Ratings to HMIS Ratings.

Reduced HMIS Health Rating from 3 to 2

Section 2: ACGIH level reduced to 0.05 ppm.

Section 3: Added V.O.C. and temperature to specific gravity.

Section 6: Added Poison control center number.

Key: ACGIH =American Conference of Governmental & Industrial Hygienists

ASTM =American Society for Testing and Materials

CAS =Chemical Abstract Service

DOT =Department of Transportation

EPA =Environmental Protection Agency

IARC =International Agency for Research on Cancer

IATA =International Air Transportation Association

IMO =International Maritime Organization

LC =Lethal Concentration

LD = Lethal Dose

LEL = Lower Explosive Limit

NFPA = National Fire Protection Association

NIOSH = National Institute for Occupational Safety and Health

NTP = National Toxicology Program

OSHA = Occupational Safety & Health Administration

PEL = Permissible Exposure Limit

RTECS = Registry of Toxic Effects of Chemical Substances

TLV = Threshold Limit Value

UEL = Upper Explosive Level

We believe that the information contained herein is current as of the date this Material Safety Data Sheet. Since the use of this information and the conditions of the use of the product are not under the control of Advanced Sterilization Products, Inc., it is the user's obligation to determine conditions of safe use of the product. The data contained above are not to be taken as a warranty or representation for which Advanced Sterilization Products, Inc., assumes legal responsibility. They are offered only for your consideration and verification.