



# Material Safety Data Sheet

## 1. Product and Company Information

Trade name: Dr. Disinfectant (Glutaraldehyde solution 2% with Activator)

Address : Saudi Mais co. for medical products

P.O. Box: 3900 – Riyadh 14335 – 7599 – Saudi Arabia Tel. : +966 11  
2650184 Fax : 2650139 3<sup>rd</sup> Industrial Area, Al-kharj Road, Street No. 256

Date of Issue : Nov 2019

## 2. Composition/Information on Ingredients

Chemical name : Glutaraldehyde solution 2% with Activator  
Product type : Broad Spectrum Disinfectant  
Application : High Level Disinfectant for endoscopes and anaesthesia Accessories

Chemical Name	% by Weight	ACGIH TLV/OSHA PEL/Others
Glutaraldehyde	2%	Not Established
Others	1-5 %	

## 3. Hazards Identification

Corrosive Causes irreversible damage. Causes skin burns. May be fatal if swallowed. Prolonged or frequently repeated Skin contact may cause allergic reaction in some individuals. Plastic container, if present, may cause static ignition hazard. Aspiration may cause lung damage. Causes asthmatic signs and symptoms in hyper-reactive individuals.

### POTENTIAL HEALTH EFFECTS:

#### Inhalation:

Vapor is irritating to the respiratory tract, causing stinging sensations in the nose and throat, discharge from the nose, possibly bleeding from the nose, coughing, chest discomfort and tightness, difficulty with breathing, and headache. Heating the solution may result in more severe irritant effects.

#### Eye contact:

Liquid will cause a severe and persistent conjunctivitis, seen as excess redness and marked swelling of the conjunctiva and profuse discharge. Severe corneal injury may develop, which could permanently impair vision if prompt first-aid and medical treatment are not obtained. Vapor will cause stinging sensations in the eye with excess tear production, blinking, and possibly a slight excess redness of the conjunctiva.

#### Skin contact:

Brief contact will cause itching with mild to moderate local redness and possibly swelling. Prolonged contact may result in pain, severe redness and swelling, with ulceration, tissue destruction, and possibly bleeding into the inflamed area. Contact with solutions of glutaraldehyde may cause harmless yellow or brownish coloration of the skin.

#### Skin absorption:



Prolonged or widespread contact may result in the absorption of potentially harmful amounts of material.

**Swallowing:**

Moderately toxic. May cause moderate to marked irritation and possibly chemical burns of the mouth, throat, esophagus, and stomach. There will be discomfort or pain in the chest and abdomen, nausea, vomiting, diarrhea, dizziness, faintness, drowsiness, thirst, weakness, circulatory shock, collapse and coma. Aspiration into the lungs may occur during ingestion or vomiting, resulting in lung injury.

**Effects of repeated overexposure:**

Repeated skin contact may cause a cumulative dermatitis.

**Other effects of overexposure:**

May cause skin sensitization in a small portion of individuals and present as an allergic contact dermatitis. This usually results from contact with the liquid, but occasionally there may be a reaction to glutaraldehyde vapor. Will cause signs and symptoms of an asthmatic attack in hyper-reactive individuals.

**Medical conditions aggravated by exposure:**

Skin contact may aggravate an existing dermatitis. Inhalation of material may aggravate asthma and inflammatory or fibrotic pulmonary disease.

#### 4. First Aid Measures

**Inhalation:**

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

**Eye contact:**

Immediately flush eyes with water and continue washing for at least 15 minutes. DO NOT remove contact lenses, if worn. Obtain medical attention without delay, preferably from an ophthalmologist.

**Skin contact:**

Immediately remove contaminated clothing and shoes. Wash skin with soap and water. Obtain medical attention. Wash clothing before reuse. Discard contaminated leather articles such as shoes and belt.

**Swallowing:**

DO NOT INDUCE VOMITING. Do not give anything to drink. Obtain medical attention without delay.

**Notes to physician:**

The hazards of this material are due mainly to its severely irritant properties on skin and mucosal surfaces. Moderately toxic by swallowing. Moderately toxic by absorption across the skin. Due to the severely irritating or corrosive nature of the material, swallowing may lead to ulceration and inflammation of the upper alimentary tract with hemorrhage and fluid loss. Also, perforation of the esophagus or stomach may occur, leading to mediastinitis or peritonitis and the resultant complications. Any material aspirated during vomiting may cause lung injury.

Therefore, emesis should not be induced mechanically or pharmacologically. If it is considered necessary to evacuate the stomach contents, this should be done by means least likely to cause aspiration (e.g., gastric lavage after endotracheal intubation).



## 5. Fire Fighting Measures

### **Extinguishing media:**

Not-flammable (aqueous solution): After water evaporates, remaining material will burn. Use alcohol-type or allpurpose-type foam, applied by manufacturer's recommended techniques for large fires. Use carbon dioxide or dry chemical media for small fires.

**Extinguishing media to avoid:** No information currently available.

### **Special fire-fighting procedures:**

Use self-contained breathing apparatus and protective clothing.

**Unusual fire and explosion hazards:** None known.

### **Hazardeous combustion 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. Hazards

## 6. Accidental Release Measures

Wear suitable protective equipment. See Section labeled PERSONAL PROTECTION. Very low concentrations (5ppm or less of glutaraldehyde) can be degraded in a biological wastewater treatment system. Thus, small spills can be flushed with large quantities of water. Large quantities or 'slugs' can be harmful to the treatment system. Thus, large spills should be collected for disposal. It may also be possible to decontaminate spilled material by careful application of sodium hydroxide, ammonium or sodium bisulfite. Depending on conditions, considerable heat and fumes can be liberated by the decontamination reaction.

**Environmental precautions:** Toxic to fish; avoid discharge to natural waters.

## 7. Handling and Storage

### **General Handling:**

Do not get in eyes, on skin, on clothing. Avoid breathing vapor. Do not swallow. Do not handle or empty in presence of flammable vapor. Wear goggles, protective clothing and gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Keep container closed. Use with adequate ventilation.

### **Ventilation:**

General (mechanical) room ventilation is expected to be satisfactory if this material is kept in covered equipment or if the solution is highly diluted. However, if vapors are strong enough to be irritating to the nose (or eyes), the TLV is probably being exceeded and special ventilation may be required.

### **Other precautions:**

Must not be used in the form of a spray or aerosol.



## 8. Exposure Controls and Personal Protection

<u>COMPONENT</u>	<u>EXPOSURE LIMITS</u>
Glutaraldehyde	0.05ppm CEILING ACGIH
Methanol	200ppm TWA8 ACGIH

### **Personal Protection:**

#### **Respiratory protection:**

Use self-contained breathing apparatus in high vapor concentrations. If self-contained breathing apparatus is not available, a MSHA/NIOSH approved air purifying respirator equipped with an organic vapor cartridge should be used.

#### **Ventilation:**

General (mechanical) room ventilation is expected to be satisfactory if this material is kept in covered equipment or if the solution is highly diluted. However, if vapors are strong enough to be irritating to the nose (or eyes), the TLV is probably being exceeded and special ventilation may be required.

#### **Eye protection:**

Splash proof monogoggles or safety glasses with side shields in conjunction with a face shield.

**Protective gloves:** Polyethylene, Nitrile (NBR), Butyl

Other protective equipment: Chemical apron. Eye bath, Safety shower. Rubber Boots.

## 9. Physical and Chemical Properties

**Appearance:** Transparent colorless liquid

**pH:** Not currently available.

**Solubility in water (by weight):** 20°C 100%

**Odor:** Sharp, Fruity, Medicinal.

**Molecular weight:** 100.11 g/mol

**Boiling point (760mmHg):** ~100.5°C ~213°F As product.

**Freezing point:** ~-21°C ~ -6°F

**Specific gravity (H<sub>2</sub>O=1):** 1.129 at 20°C

**Vapor pressure (at 20°C):** 0.03 kPa Active Ingredient, 0.20mmHg Active Ingredient

**Vapor density (AIR=1):** 1.1

**Evaporation rate (Butyl Acetate = 1):** 1.0

**Flash point:**

**Closed Cup:** Tag Closed Cup ASTM D 56: None

**Open Cup:** Tag Closed Cup ASTM D 1310: None

**Autoignition temperature:** Not currently available.

**Flammable limits in air:**

**Lower:** Not determined, Aqueous System

**Upper:** Not determined, Aqueous Sy



## 10. Stability and Reactivity

### Conditions to avoid:

Avoid high temperature and evaporation of water.

**Incompatible materials:** Strong alkalies and acids catalyze an aldol-type condensation (exothermic, but not expected to be violent).

**Hazardous polymerization:** Will not occur.

**Conditions to avoid:** Temperatures above 100°C, Although polymerization may occur, it is not hazardous.

## 11. Toxicological information

### Acute Toxicity

**ORAL:** rat LD50 female 154 (116-206) mg/kg

**Major signs:** sluggishness, lacrimation, diarrhea, piloerection, perinasal encrustation.

**Gross pathology:** lungs, stomach, intestines discolored.

**ORAL:** rat LD50 male 246 (179-339) mg/kg

**Major signs:** sluggishness, lacrimation, diarrhea, piloerection, perinasal encrustation.

**Gross pathology:** lungs, stomach, intestines discolored

**PERCUTANEOUS:** rabbit LD50 24 hr occluded 2.54 (1.46-4.41)ml/kg

**Major signs:** necrosis at application site

**Gross pathology:** lungs, liver, spleen, kidneys discolored

**INHALATION:** dynamic generation of vapor Exposure Time 4h 163 ppm rat female Room temperature

**Kill Rate:** 0/5

**Major Signs:** blepharospasm, periocular wetness, audible respiration

**Gross pathology:** None.

**INHALATION:** static generation of substantially saturated vapor Exposure Time 4h rat female 20°C

**Kill Rate:** 0/5

**Major Signs:** blepharospasm

**Gross Pathology:** None

**INHALATION:** dynamic generation of vapor Exposure Time 4h 16.3 ppm rat male Room temperature

**Kill Rate:** 0/5

**Major Signs:** blepharospasm, periocular wetness, audible respiration

**Gross Pathology:** None.

**INHALATION:** static generation of substantially saturated vapor Exposure Time 4h rat male 20°C

**Kill Rate:** 0/5

**Major Signs:** blepharospasm

**Gross Pathology:** None

**INHALATION:** Aerosol Exposure Time 4h LC50 0.48 (0.41-0.59) ml/l

**Major Signs:** heavy or irregular breathing, nasal discharge, gasping, nasal encrustation

**Gross Pathology:** lungs discolored.

**IRRITATION:**

**SKIN:** rabbit 4 hr covered 2/6 with necrosis

**SKIN:** rabbit 1 hr occluded minor to severe erythema and edema with necrosis, scabbing, desquamation, and alopecia



**SKIN:** rabbit 3 min occluded minor erythema

**EYE:** rabbit 0.005 ml severe corneal injury, iritis, swelling and necrosis of eyelid

**EYE:** rabbit 0.5ml 5% solution in water severe corneal injury, iritis, swelling and necrosis of eyelid.

**EYE:** rabbit 0.5ml 1% solution in water trace corneal injury SENSITIZATION (ANIMAL AND HUMAN STUDIES)

**Guinea Pig Maximization Test:** intradermal injection of a 0.1% glutaraldehyde solution and topical administration of a 5% solution. Evidence of delayed contact hypersensitivity in 68% of test animals upon challenge.

#### **Chronic Toxicity and Carcinogenicity**

Subchronic drinking water studies in rats, mice and dogs using glutaraldehyde concentrations up to 1000 ppm showed no evidence for any target organ toxicity. In vitro studies for genotoxicity using a variety of assays have given results varying from no activity, through equivocal, to weakly positive; however, in all vivo studies for genotoxicity have been uniformly negative. Several developmental toxicity studies have demonstrated that at maternally nontoxic doses, glutaraldehyde does not produce fetotoxic, embryotoxic or teratogenic effects. In 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. The only possible oncogenicity-related finding was an increase in the incidence of large granular cell lymphocytic leukemia in female, but not male, rats. The pattern of the 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.

#### **Significant Data with Possible Relevance to Humans**

Studies in humans have shown that glutaraldehyde is neither phototoxic nor a photosensitizer. Subchronic drinking water studies in rats, mice and dogs using concentrations up to 1000 ppm showed no evidence for any target organ toxicity. In vitro studies for genotoxicity using a variety of assays have given results varying from no activity through equivocal, to weakly positive; however, all in vivo studies for genotoxicity have been uniformly negative. Several developmental toxicity studies have demonstrated that at maternally nontoxic doses, glutaraldehyde does not produce fetotoxic, embryotoxic or teratogenic effects. In a two-generation reproduction study involving continuous exposure of CD rats to glutaraldehyde up to 1000 ppm, in drinking water there were effects on parental body weight and food consumption at 1000 ppm (due to an aversion to the taste), but no adverse effects on reproductive performance. In a chronic 2-year continuous drinking water combined chronic toxicity-oncogenicity study using Fischer 344 rats, there was no evidence for nononcogenic target organ toxicity. The only possible oncogenicity-related finding was an increase in the incidence of large granular cell lymphocytic leukemia in female, but not male, rats. The pattern of the 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. Repeated applications of aqueous solutions of glutaraldehyde to the rat skin for 20 doses 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. An extensive clinical survey has been conducted on nursing staff in 59 endoscopy units (340 currently employed workers and 18 former employees); investigational procedures included detailed questionnaire, sensitization to common allergens, blood for IgE measurements, lung function tests, peak flow diaries, and measurement of workplace glutaraldehyde vapor concentrations. About two-thirds of current employees had ocular, nasal, or lower respiratory tract symptoms, but these were more prevalent for non-work conditions. The only effect correlated with glutaraldehyde exposure was nasal irritation.



There was a slight, but no statistically or biologically significant, decrease in FEVI for those with lower respiratory tract symptoms. There were no indications of asthma and no objective evidence for respiratory sensitization.

## 12. Ecological information

**Ecotoxicity to microorganisms:** Bacterial/NA LC50 16 h 50 mg/l

**Ecotoxicity to aquatic invertebrates:** Daphnia LC50 48 h 11.5 mg/l

**Confidence limits:** 9.4 - 14.2 mg/l

**Ecotoxicity to fish:** Blue gill LC50 96 h 22 mg/l

## 13. Disposal Considerations

### **Waste disposal method:**

Atomize into a very hot incinerator fire or mix with a suitable flammable solvent, and incinerate where permitted under appropriate Federal, State and local regulations. High water content may dampen flame. Dispose in accordance with all applicable Federal, State, Provincial, and local environmental regulations. Empty containers should be recycled or disposed of through an approved waste management facility.

### **Disposal considerations:**

Disposal methods identified are for the product as sold. For proper disposal of used material, an assessment must be completed to determine the proper and permissible waste management options permissible under applicable rules, regulations and/or laws governing your location

## 14. Transport Information

No information available.

## 15. Regulatory Information

Label : Dr. Disinfectant (Glutaraldehyde solution 2% with Activator)

Ref. No. : MD-2250

## 16. Other Information

The above information is given to the best of our knowledge and belief. The data is partially taken from the literature (different sources). For further information

Contact: Saudi Mais co. for medical products

P.O. Box : 3900 – Riyadh 14335 – 7599 – Saudi Arabia

Tel. : +966 11 2650184

Fax : 2650139

3<sup>rd</sup> Industrial Area, Al-kharj Road, Street No. 256