1.) Identification of the substance/mixture and of the company/undertaking

Trade name

CIDEX® Activated Glutaraldehyde Solution

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

Relevant identified uses of the substance or mixture

High level disinfection

Details of the supplier of the safety data sheet

Address

Advanced Sterilization Products
a division of Johnson & Johnson Medical Ltd.
Pinewood Campus, Nine Mile Ride
Wokingham, Berkshire, UK RG40 3EW

Telephone no. +44 (0)1344 871081

Fax no. +44 (0)1344 871171

Information provided by / telephone

Technical Queries: +44 (0)1344 871081; UK Freephone: 0800 864060

Emergency telephone

01865 407333

Advice on Safety Data Sheet

contact@medgb.jnj.com

2.) Hazards identification

Classification of the substance or mixture

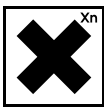
Classification in accordance with Directive 67/548/EEC or 1999/45/EC

Xi; R41
Xn; R20/22
Xi; R37/38
R42/43

Label elements

Labelling according to Directive 1999/45/CE

Hazard symbols



Harmful

Hazardous component(s) to be indicated on label, contains:

Glutaral

R phrases

20/22	Harmful by inhalation and if swallowed.
37/38	Irritating to respiratory system and skin.
41	Risk of serious damage to eyes.
42/43	May cause sensitisation by inhalation and skin contact.

S phrases

26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
36/37/39	Wear suitable protective clothing, gloves and eye/face protection.
45	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
51	Use only in well-ventilated areas.

3.) Composition / information on ingredients

Chemical characterization

aqueous solution

Hazardous ingredients

Glutaral

EC no.	203-856-5	Index no.	605-022-00-X	CAS no.	111-30-8
Concentration	>= 2,2	<= 2,7	%-b.w.		
Classification	T; R23/25	C; R34	R42/43	N; R50	
Hazard symbols	T, N	R phrases	23/25-34-42/43-50		

4.) First aid measures

General information

In case of accident or if you feel unwell, seek medical advice immediately.

After inhalation

Remove affected person from the immediate area. Ensure supply of fresh air. In case of breathing difficulties give oxygen. In case of persisting adverse effects consult a physician.

After skin contact

Wash off immediately with soap and water. Consult a doctor if skin irritation persists. Remove contaminated clothing immediately and dispose of safely.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). Seek medical assistance.

After ingestion

Summon a doctor immediately and show label or packaging. Rinse out mouth and give plenty of water or milk to drink. Do not induce vomiting. Never give anything by mouth to an unconscious person.

Advice to doctor

Hazards

Probable mucosal damage from oral exposure may contraindicate the use of gastric lavage.

Treatment

Treat symptomatically.

5.) Fire-fighting measures

Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases

None known

Other information

Product itself does not burn. Adapt extinguisher and fire-fighting measures to fire in the environment. Cool endangered containers with water spray jet.

6.) Accidental release measures

Personal precautions

Refer to protective measures listed in sections 7 and 8.

Environmental precautions
Do not discharge into the drains/surface waters/groundwater. Do not discharge into the subsoil/soil.

Methods for cleaning up/taking up
Pick up with absorbent material (e.g., sand, sawdust, general-purpose binder). When picked up, treat material as prescribed under heading "Disposal considerations".

7.) Handling and storage

Handling

Advice on safe handling
Product inherent handling risks must be minimised taking the appropriate measures for protection and preventive actions. The working process should be designed to rule out the release of hazardous substances or skin contact as far it is possible by the state of the art. Open and handle container with care.

Advice on protection against fire and explosion
No special measures necessary.

Storage

Requirements for storage rooms and vessels
Containers which are opened must be carefully resealed and kept upright to prevent leakage.

Advice on storage assembly
Do not store together with: Acids; Alcalies; Reducing agents; Oxidizing agents

Further information on storage conditions
Keep container tightly closed, cool and dry. Protect from atmospheric moisture and water.

Recommended storage temperature

Value	max.	40	° C

8.) Exposure controls / personal protection

Exposure limit values

Glutaral

CAS no.	111-30-8
EC no.	203-856-5

List of approved workplace exposure limits (WELs) / EH40

Glutaraldehyde

TWA	0,2	mg/m³	0,05	ml/m³
STEL	0,2	mg/m³	0,05	ml/m³
Skin resorption / sensibilisation	Sen			

Exposure controls

Personal protective equipment

Respiratory protection
If workplace exposure limits are exceeded, a respiration protection approved for this particular job must be worn. In case of aerosol and mist formation, take appropriate measures for breathing protection in the event workplace threshold values are not specified.

Hand protection
In case of intensive contact, wear protective gloves (EN 374). Check in any case suitability of protective glove for the specific workplace conditions (e.g. mechanical resistance, product compatibility, antistatic properties). The glove manufacturer’s instructions and information regarding storage, care and replaceme

Appropriate Material	rubber

Inappropriate material	neoprene
Appropriate Material	nitrile
Inappropriate material	PVC

Eye protection
Tightly fitting safety glasses (EN 166).

Skin protection
Normal chemical work clothing.

General protective and hygiene measures
Do not eat, drink or smoke during work time. Keep away from foodstuffs and beverages. Wash hands before breaks and after work. Provide eye wash fountain in work area. Do not inhale vapours.

9.) Physical and chemical properties

General information

Form	liquid
Colour	colourless; faint fluorescent yellow/green when activated
Odour	aldehyde-like

Important health, safety and environmental information

Changes in physical state

Type	Freezing point		
Value	<	0	° C
Type	Boiling point		
Value	>	100	° C

Flash point

Remarks	not applicable

Density

Value	1,0	g/ml
Reference temperature	20	° C

Solubility in water

Remarks	soluble

pH value

Value	3,0	- 4,6
Remarks	relating to the product as supplied	
Value	8,2	- 8,9
Remarks	activated	

10.) Stability and reactivity

Conditions to avoid
Temperatures > 40°C

Materials to avoid
Acids; Alcalis; Reducing agents; Oxidizing agents; Water

Hazardous decomposition products
No hazardous decomposition products known.

Thermal decomposition

Remarks	No decomposition if used as prescribed.

11.) Toxicological information

Acute toxicity

Acute oral toxicity
Remarks No data available.

Acute dermal toxicity
Remarks No data available.

Acute inhalational toxicity
Remarks No data available.

Irritant/corrosive effects

Irritant effect on skin
Evaluation irritant

Irritant effect on eyes
Evaluation irritant - risk of strong eye injuries

Respiratory tract irritation
Evaluation irritant

Sensitisation
Evaluation sensitizing

Effects after repeated or prolonged exposition (subacute, subchronic, chronic)
Remarks Repeat dose inhalation studies for up to 90 days have reported lesions to the nasal passage at concentrations as low as 125 ppb glutaraldehyde.
Remarks Repeat application to the skin has not shown any evidence of dermal toxicity at glutaraldehyde concentration less than 5%.

Mutagenicity
Positive results have been obtained for in vitro mutagenicity studies for glutaraldehyde but in vivo studies have only shown negative results.

Reproduction toxicity
Administration in diet at the maximum tolerated dose caused no adverse reproductive effects. Embryotoxicity and foetotoxicity was observed only at levels that also caused maternal toxicity.

Experience in practice
Irritating to skin. Irritates respiratory tract. Danger of acute eye damage. Sensitisation possible through inhalation. Possibility of sensitisation through skin contact.

Other information
Product specific toxicological data are not known. Exercise customary precautions when handling chemicals.

12.) Ecological information

Results of PBT and vPvB assessment
PBT assessment
The product is not considered to be a PBT.
vPvB assessment
The product is not considered to be a vPvB.

Other information
Glutaraldehyde is considered to be very toxic to aquatic organisms in its concentrated form. However, at the concentrations present in this product, acute toxicity to the aquatic environment is not expected. Do not discharge product unmonitored into the environment.

13.) Disposal considerations

Product

Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company.

Packaging

Residuals must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal. Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

14.) Transport information

Other information

The product is not defined under national/international road, rail, sea and air transport regulations as a hazardous material.

15.) Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances

Remarks	Annex I, part 1 + 2: not mentioned. With regard to possibly appropriate decomposition products see Chapter 10.

16.) Other information

Sources of key data used to compile the data sheet:

EC Directive 67/548/EC resp. 99/45/EC as amended in each case.
Regulation (EC) No 1907/2006 (REACH), 1272/2008 (CLP) as amended in each case.
EC Directives 2000/39/EC, 2006/15/EC, 2009/161/EC
National Threshold Limit Values of the corresponding countries as amended in each case.
Transport regulations according to ADR, RID, IMDG, IATA as amended in each case.
The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding chapter.

Relevant R-phrases (chapter 3):

23/25	Toxic by inhalation and if swallowed.
34	Causes burns.
42/43	May cause sensitisation by inhalation and skin contact.
50	Very toxic to aquatic organisms.

Department issuing safety data sheet

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This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.