

SEKUMATIC FD**Section: 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING****1.1 Product identifier**

Product name : SEKUMATIC FD
Product code : 103189E
Use of the Substance/Mixture : Instrument Disinfectant
Substance type: : Mixture

For professional users only.

Product dilution information : No dilution information provided.

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

Identified uses : Medical devices . Semi-automatic process
Recommended restrictions on use : Reserved for industrial and professional use.

1.3 Details of the supplier of the safety data sheet

Company : Ecolab Ltd.
PO Box 11; Winnington Avenue
Northwich, Cheshire, United Kingdom CW8 4DX
+ 44 (0)1606 74488
ccs@ecolab.com

1.4 Emergency telephone number

Emergency telephone number : Food & Beverage, Institutional, Agriculture, Textile Hygiene:
Northwich: +44 (0)1606 74488
Healthcare Leeds: +44 (0)113 232 2480
Healthcare Swansea: +44 (0)1235 239670
Poison Information Centre telephone number : Not Available

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Section: 2. HAZARDS IDENTIFICATION**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Acute toxicity, Category 4	H302
Acute toxicity, Category 4	H332
Skin corrosion, Category 1B	H314
Serious eye damage, Category 1	H318

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Respiratory sensitization, Category 1	H334
Skin sensitization, Category 1	H317
Specific target organ toxicity - single exposure, Category 3, Respiratory system	H335

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H302 + H332 Harmful if swallowed or if inhaled
 H314 Causes severe skin burns and eye damage.
 H317 May cause an allergic skin reaction.
 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 H335 May cause respiratory irritation.

Precautionary Statements : **Prevention:**
 P280 Wear protective gloves/ eye protection/ face protection.
 P284 Wear respiratory protection.
Response:
 P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
 P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
 P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P310 Immediately call a POISON CENTER/doctor.

Hazardous components which must be listed on the label:
 glutaraldehyde
 methanol

2.3 Other hazards

None known.

Section: 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Hazardous components

Chemical Name	CAS-No. EC-No. REACH No.	ClassificationREGULATION (EC) No 1272/2008	Concentration: [%]
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glutaraldehyde	111-30-8 203-856-5 01-2119455549-26	Acute toxicity Category 3; H301 Acute toxicity Category 3; H331 Skin corrosion Category 1B; H314 Respiratory sensitization Category 1; H334 Skin sensitization Category 1; H317 Acute aquatic toxicity Category 1; H400	>= 20 - < 25
methanol	67-56-1 200-659-6 01-2119433307-44	** Flammable liquids Category 2; H225 Acute toxicity Category 3; H301 Acute toxicity Category 3; H331 Acute toxicity Category 3; H311 Specific target organ toxicity - single exposure Category 1; H370	>= 0.1 - < 0.25
Substances with a workplace exposure limit :			
ethanol	64-17-5 200-578-6 01-2119457610-43	Flammable liquids Category 2; H225	>= 5 - < 10

For the full text of the H-Statements mentioned in this Section, see Section 16.

Section: 4. FIRST AID MEASURES

4.1 Description of first aid measures

- In case of eye contact : Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention immediately.
- In case of skin contact : Wash off immediately with plenty of water for at least 15 minutes. Use a mild soap if available. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention immediately.
- If swallowed : Rinse mouth with water. Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Get medical attention immediately.
- If inhaled : Remove to fresh air. Treat symptomatically. Get medical attention.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11 for more detailed information on health effects and symptoms.

4.3 Indication of immediate medical attention and special treatment needed

Treatment : Treat symptomatically.

Section: 5. FIREFIGHTING MEASURES

5.1 Extinguishing media

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

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- Specific hazards during firefighting : Fire Hazard
Keep away from heat and sources of ignition.
Flash back possible over considerable distance.
Beware of vapours accumulating to form explosive concentrations.
Vapours can accumulate in low areas.
- Hazardous combustion products : Decomposition products may include the following materials:
Carbon oxides
nitrogen oxides (NOx)
Sulphur oxides
Oxides of phosphorus

5.3 Advice for firefighters

- Special protective equipment for firefighters : Use personal protective equipment.
- Further information : Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. In the event of fire and/or explosion do not breathe fumes.

Section: 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

- Advice for non-emergency personnel : Ensure adequate ventilation. Remove all sources of ignition. Keep people away from and upwind of spill/leak. Avoid inhalation, ingestion and contact with skin and eyes. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Ensure clean-up is conducted by trained personnel only. Refer to protective measures listed in sections 7 and 8.
- Advice for emergency responders : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials.

6.2 Environmental precautions

- Environmental precautions : Do not allow contact with soil, surface or ground water.

6.3 Methods and materials for containment and cleaning up

- Methods for cleaning up : Eliminate all ignition sources if safe to do so. Stop leak if safe to do so. Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13). Flush away traces with water. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway.

6.4 Reference to other sections

- See Section 1 for emergency contact information.
For personal protection see section 8.
See Section 13 for additional waste treatment information.

Section: 7. HANDLING AND STORAGE

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7.1 Precautions for safe handling

- Advice on safe handling : Do not ingest. Do not get in eyes, on skin, or on clothing. Do not breathe dust/fume/gas/mist/vapours/spray. Use only with adequate ventilation. Keep away from fire, sparks and heated surfaces. Take necessary action to avoid static electricity discharge (which might cause ignition of organic vapours). Wash hands thoroughly after handling.
- Hygiene measures : Handle in accordance with good industrial hygiene and safety practice. Remove and wash contaminated clothing before re-use. Wash face, hands and any exposed skin thoroughly after handling. Provide suitable facilities for quick drenching or flushing of the eyes and body in case of contact or splash hazard.

7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : Keep away from heat and sources of ignition. Keep away from oxidizing agents. Keep out of reach of children. Keep container tightly closed. Store in suitable labeled containers.
- Storage temperature : 0 °C to 25 °C

7.3 Specific end uses

- Specific use(s) : Medical devices . Semi-automatic process

Section: 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
glutaraldehyde	111-30-8	TWA	0.05 ppm 0.2 mg/m3	UKCOSSTD
Further information	53+5 4	Substances that can cause occupational asthma (also known as asthmagens and respiratory sensitisers) can induce a state of specific airway hyper-responsiveness via an immunological, irritant or other mechanism. Once the airways have become hyper-responsive, further exposure to the substance, sometimes even to tiny quantities, may cause respiratory symptoms. These symptoms can range in severity from a runny nose to asthma. Not all workers who are exposed to a sensitiser will become hyper-responsive and it is impossible to identify in advance those who are likely to become hyper-responsive. 54 Substances that can cause occupational asthma should be distinguished from substances which may trigger the symptoms of asthma in people with pre-existing airway hyper-responsiveness, but which do not include the disease themselves. The latter substances are not classified asthmagens or respiratory sensitisers.		
	55	Wherever it is reasonably practicable, exposure to substances that can cause occupational asthma should be prevented. Where this is not possible, the primary aim is to apply adequate standards of control to prevent workers from becoming hyper-responsive. For substances that can cause occupational asthma, COSHH requires that exposure be reduced as low as is reasonably practicable. Activities giving rise to short-term peak concentrations should receive particular attention when risk management is being considered. Health surveillance is appropriate for all employees exposed or liable to be exposed to a substance which may cause occupational asthma and there should be appropriate consultation with an occupational health professional over the degree of risk and level of surveillance.		

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	Sen	Capable of causing occupational asthma. The identified substances are those which: - are assigned the risk phrase 'R42: May cause sensitisation by inhalation'; or 'R42/43: May cause sensitisation by inhalation and skin contact' or - are listed in section C of HSE publication 'Asthmagen? Critical assessments of the evidence for agents implicated in occupational asthma' as updated from time to time, or any other substance which the risk assessment has shown to be a potential cause of occupational asthma.		
	56	The 'Sen' notation in the list of WELs has been assigned only to those substances which may cause occupational asthma.		
		STEL	0.05 ppm 0.2 mg/m3	UKCOSSTD
Further information	53+54	Substances that can cause occupational asthma (also known as asthmagens and respiratory sensitisers) can induce a state of specific airway hyper-responsiveness via an immunological, irritant or other mechanism. Once the airways have become hyper-responsive, further exposure to the substance, sometimes even to tiny quantities, may cause respiratory symptoms. These symptoms can range in severity from a runny nose to asthma. Not all workers who are exposed to a sensitiser will become hyper-responsive and it is impossible to identify in advance those who are likely to become hyper-responsive. 54 Substances that can cause occupational asthma should be distinguished from substances which may trigger the symptoms of asthma in people with pre-existing airway hyper-responsiveness, but which do not include the disease themselves. The latter substances are not classified asthmagens or respiratory sensitisers.		
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	56	The 'Sen' notation in the list of WELs has been assigned only to those substances which may cause occupational asthma.		
ethanol	64-17-5	TWA	1,000 ppm 1,920 mg/m3	UKCOSSTD
Further information	2	Where no specific short-term exposure limit is listed, a figure three times the long-term exposure should be used		
methanol	67-56-1	TWA	200 ppm 266 mg/m3	UKCOSSTD
Further information	Sk	Can be absorbed through skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.		
		STEL	250 ppm 333 mg/m3	UKCOSSTD
Further information	Sk	Can be absorbed through skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.		

DNEL

methanol	:	End Use: Workers Exposure routes: Dermal Potential health effects: Acute systemic effects Value: 40 mg/cm2
		End Use: Workers

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	<p>Exposure routes: Inhalation Potential health effects: Acute systemic effects Value: 260 mg/m3</p>
	<p>End Use: Workers Exposure routes: Inhalation Potential health effects: Acute local effects Value: 260 mg/m3</p>
	<p>End Use: Workers Exposure routes: Dermal Potential health effects: Long-term systemic effects Value: 40 mg/cm2</p>
	<p>End Use: Workers Exposure routes: Inhalation Potential health effects: Long-term systemic effects Value: 260 mg/m3</p>
	<p>End Use: Workers Exposure routes: Inhalation Potential health effects: Long-term local effects Value: 260 mg/m3</p>
	<p>End Use: Consumers Exposure routes: Dermal Potential health effects: Acute systemic effects Value: 8 mg/cm2</p>
	<p>End Use: Consumers Exposure routes: Inhalation Potential health effects: Acute systemic effects Value: 50 mg/m3</p>
	<p>End Use: Consumers Exposure routes: Ingestion Potential health effects: Acute systemic effects Value: 8 ppm</p>
	<p>End Use: Consumers Exposure routes: Inhalation Potential health effects: Acute local effects Value: 50 mg/m3</p>
	<p>End Use: Consumers Exposure routes: Dermal Potential health effects: Long-term systemic effects Value: 8 mg/cm2</p>
	<p>End Use: Consumers Exposure routes: Inhalation Potential health effects: Long-term systemic effects Value: 50 mg/m3</p>
	<p>End Use: Consumers Exposure routes: Ingestion Potential health effects: Long-term systemic effects Value: 8 ppm</p>

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	End Use: Consumers Exposure routes: Inhalation Potential health effects: Long-term local effects Value: 50 mg/m ³
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PNEC

methanol	: Fresh water Value: 154 mg/l
	Marine water Value: 15.4 mg/l
	Intermittent use/release Value: 1540 mg/l
	Sediment Value: 570.4 mg/kg
	Soil Value: 23.5 mg/kg
	Sewage treatment plant Value: 100 mg/l

8.2 Exposure controls

Appropriate engineering controls

Engineering measures : Effective exhaust ventilation system. Maintain air concentrations below occupational exposure standards.

Individual protection measures

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice. Remove and wash contaminated clothing before re-use. Wash face, hands and any exposed skin thoroughly after handling. Provide suitable facilities for quick drenching or flushing of the eyes and body in case of contact or splash hazard.

Eye/face protection (EN 166) : Safety goggles
Face-shield

Hand protection (EN 374) : Recommended preventive skin protection
Gloves
Nitrile rubber
butyl-rubber
Breakthrough time: 1 – 4 hours
Minimum thickness for butyl-rubber 0.7 mm for nitrile rubber 0.4 mm or equivalent (please refer to the gloves manufacturer/distributor for advise).
Gloves should be discarded and replaced if there is any indication of degradation or chemical breakthrough.

Skin and body protection (EN 14605) : Personal protective equipment comprising: suitable protective gloves, safety goggles and protective clothing

Respiratory protection (EN : None required if airborne concentrations are maintained below the

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143, 14387) exposure limit listed in Exposure Limit Information. Use certified respiratory protection equipment meeting EU requirements(89/656/EEC, 89/686/EEC), or equivalent, when respiratory risks cannot be avoided or sufficiently limited by technical means of collective protection or by measures, methods or procedures of work organization.

Environmental exposure controls

General advice : Consider the provision of containment around storage vessels.

Section: 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	: liquid
Colour	: colourless
Odour	: Disinfectants
pH	: 3.5, 100 %
Flash point	: 55 °C closed cup, Does not sustain combustion.
Odour Threshold	: Not applicable and/or not determined for the mixture
Melting point/freezing point	: Not applicable and/or not determined for the mixture
Initial boiling point and boiling range	: Not applicable and/or not determined for the mixture
Evaporation rate	: Not applicable and/or not determined for the mixture
Flammability (solid, gas)	: Not applicable and/or not determined for the mixture
Upper explosion limit	: Not applicable and/or not determined for the mixture
Lower explosion limit	: Not applicable and/or not determined for the mixture
Vapour pressure	: Not applicable and/or not determined for the mixture
Relative vapour density	: Not applicable and/or not determined for the mixture
Relative density	: 1.04
Water solubility	: soluble
Solubility in other solvents	: Not applicable and/or not determined for the mixture
Partition coefficient: n-octanol/water	: Not applicable and/or not determined for the mixture
Auto-ignition temperature	: Not applicable and/or not determined for the mixture
Thermal decomposition	: Not applicable and/or not determined for the mixture
Viscosity, kinematic	: Not applicable and/or not determined for the mixture
Explosive properties	: Not applicable and/or not determined for the mixture
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

9.2 Other information

Not applicable and/or not determined for the mixture

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Section: 10. STABILITY AND REACTIVITY

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

10.4 Conditions to avoid

Heat, flames and sparks.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

Decomposition products may include the following materials:

Carbon oxides
nitrogen oxides (NO_x)
Sulphur oxides
Oxides of phosphorus

Section: 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation, Eye contact, Skin contact

Product

Acute oral toxicity : Acute toxicity estimate : 738.92 mg/kg

Acute inhalation toxicity : 4 h Acute toxicity estimate : 2.48 mg/l

Acute dermal toxicity : Acute toxicity estimate : > 2,000 mg/kg

Skin corrosion/irritation : There is no data available for this product.

Serious eye damage/eye irritation : There is no data available for this product.

Respiratory or skin sensitization : There is no data available for this product.

Carcinogenicity : There is no data available for this product.

Reproductive effects : There is no data available for this product.

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- Germ cell mutagenicity : There is no data available for this product.
- Teratogenicity : There is no data available for this product.
- STOT - single exposure : There is no data available for this product.
- STOT - repeated exposure : There is no data available for this product.
- Aspiration toxicity : There is no data available for this product.

Components

- Acute oral toxicity : glutaraldehyde
LD50 rat: 150 mg/kg
- ethanol
LD50 rat: 10,470 mg/kg

Components

- Acute inhalation toxicity : glutaraldehyde
4 h LC50 rat: > 0.5 mg/l
- ethanol
4 h LC50 rat: 117 mg/l

Components

- Acute dermal toxicity : ethanol
LD50 rabbit: > 15,800 mg/kg

Potential Health Effects

- Eyes : Causes serious eye damage.
- Skin : Causes severe skin burns. May cause allergic skin reaction.
- Ingestion : Causes digestive tract burns.
- Inhalation : May cause allergic respiratory reaction. May cause respiratory tract irritation. May cause nose, throat, and lung irritation.
- Chronic Exposure : Health injuries are not known or expected under normal use.

Experience with human exposure

- Eye contact : Redness, Pain, Corrosion
- Skin contact : Redness, Pain, Irritation, Corrosion, Allergic reactions
- Ingestion : Corrosion, Abdominal pain
- Inhalation : Respiratory irritation, Cough, May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Section: 12. ECOLOGICAL INFORMATION

12.1 Ecotoxicity

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Environmental Effects : This product has no known ecotoxicological effects.

Product

Toxicity to fish : no data available

Toxicity to daphnia and other aquatic invertebrates : no data available

Toxicity to algae : no data available

Components

Toxicity to fish : methanol
96 h LC50: 15,400 mg/l

ethanol
96 h LC50 Pimephales promelas (fathead minnow): > 100 mg/l

Components

Toxicity to daphnia and other aquatic invertebrates : glutaraldehyde
48 h EC50 Daphnia: 0.35 mg/l

methanol
48 h EC50: > 10,000 mg/l

Components

Toxicity to algae : methanol
72 h EC50: 22,000 mg/l

12.2 Persistence and degradability

Product

no data available

Components

Biodegradability : glutaraldehyde
Result: Readily biodegradable.

methanol
Result: Readily biodegradable.

ethanol
Result: Readily biodegradable.

12.3 Bioaccumulative potential

no data available

12.4 Mobility in soil

no data available

12.5 Results of PBT and vPvB assessment

Product

Assessment : This substance/mixture contains no components considered to be

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either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

no data available

Section: 13. DISPOSAL CONSIDERATIONS

Dispose of in accordance with the European Directives on waste and hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

13.1 Waste treatment methods

- Product : Where possible recycling is preferred to disposal or incineration. If recycling is not practicable, dispose of in compliance with local regulations. Dispose of wastes in an approved waste disposal facility.
- Contaminated packaging : Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers. Dispose of in accordance with local, state, and federal regulations.
- Guidance for Waste Code selection : Organic wastes containing dangerous substances. If this product is used in any further processes, the final user must redefine and assign the most appropriate European Waste Catalogue Code. It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable European (EU Directive 2008/98/EC) and local regulations.

Section: 14. TRANSPORT INFORMATION

The shipper/consignor/sender is responsible to ensure that the packaging, labeling, and markings are in compliance with the selected mode of transport.

Land transport (ADR/ADN/RID)

- 14.1 UN number : 3265
- 14.2 UN proper shipping name : CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S.
(Glutaraldehyde)
- 14.3 Transport hazard class(es) : 8
- 14.4 Packing group : III
- 14.5 Environmental hazards : No
- 14.6 Special precautions for user : None

Air transport (IATA)

- 14.1 UN number : 3265
- 14.2 UN proper shipping name : Corrosive liquid, acidic, organic, n.o.s.
(Glutaraldehyde)

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14.3 Transport hazard : 8
class(es)
14.4 Packing group : III
14.5 Environmental hazards : No
14.6 Special precautions for : None
user

Sea transport (IMDG/IMO)

14.1 UN number : 3265
14.2 UN proper shipping : CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S.
name
(Glutaraldehyde)
14.3 Transport hazard : 8
class(es)
14.4 Packing group : III
14.5 Environmental hazards : No
14.6 Special precautions for : None
user
14.7 Transport in bulk : Not applicable.
according to Annex II of
MARPOL 73/78 and the IBC
Code

Section: 15. REGULATORY INFORMATION

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

National Regulations

Take note of Dir 94/33/EC on the protection of young people at work.

Other regulations : The Chemicals (Hazard Information and Packaging for Supply) Regulations.
The Control of Substances Hazardous to Health Regulations.
Health and Safety at Work Act.

15.2 Chemical Safety Assessment

This product contains substances for which Chemical Safety Assessments are still required.

Section: 16. OTHER INFORMATION

Full text of H-Statements

H225 Highly flammable liquid and vapour.
H301 Toxic if swallowed.
H311 Toxic in contact with skin.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H331 Toxic if inhaled.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H370 Causes damage to organs.
H400 Very toxic to aquatic life.

SEKUMATIC FD**Full text of other abbreviations**

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Prepared by : Regulatory Affairs

Numbers quoted in the MSDS are given in the format: 1,000,000 = 1 million and 1,000 = 1 thousand. 0.1 = 1 tenth and 0.001 = 1 thousandth

REVISED INFORMATION: Significant changes to regulatory or health information for this revision is indicated by a bar in the left-hand margin of the SDS.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

ANNEX: EXPOSURE SCENARIOS**DPD+ Substances:**

The following substances are the lead substances that contribute to the mixture Exposure Scenario according to the DPD+ Rule:

Route	Substance	CAS-No.	EINECS-No.
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Respiratory sensitiser	glutaraldehyde	111-30-8	203-856-5
Ingestion	glutaraldehyde	111-30-8	203-856-5
Inhalation	glutaraldehyde	111-30-8	203-856-5
Dermal	glutaraldehyde	111-30-8	203-856-5
Eyes	glutaraldehyde	111-30-8	203-856-5
aquatic environment	glutaraldehyde	111-30-8	203-856-5

To calculate if your downstream Operating Conditions and Risk management Measures are safe, please calculate your risk factor at the website below:

www.ecetoc.org/tra

Short title of Exposure Scenario : **Medical devices . Semi-automatic process**

Use descriptors

- Main User Groups : Professional uses: Public domain (administration, education, entertainment, services, craftsmen)
- Sectors of end-use : **SU22:** Professional uses: Public domain (administration, education, entertainment, services, craftsmen)
- Process categories : **PROC1:** Use in closed process, no likelihood of exposure
PROC8a: Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at non-dedicated facilities
- Product categories : **PC35:** Washing and cleaning products (including solvent based products)
- Environmental Release Categories : **ERC8a:** Wide dispersive indoor use of processing aids in open systems