Safety Data Sheet

according to Regulation (EC) No 1907/2006

Henry Schein SafeSept Max Instrument disinfection concentrate FV (including variants)

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Henry Schein SafeSept Max Instrument disinfection concentrate FV (including variants)

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

Use of the substance/mixture

Instrument disinfectant

1.3. Details of the supplier of the safety data sheet

Manufacturer:
Henry Schein Inc.
135 Duryea Road
Melville, NY 11747 / USA

Authorized EU Representative:
Henry Schein Services GmbH
Monzastrasse 2a
63225 Langen / Germany

Contact:
cbdeurope@henryschein.com
www.henryscheinbrand.com
Tel: +49 6103 757 5000

Responsible for the Safety Data Sheet: **Regulatory Affairs Europe** - cbdeurope@henryschein.com
Responsible for the safety data sheet: **sds@gbk-ingelheim.de**

1.4 Emergency Number

INTERNATIONAL: +49 (0)6132 84463 - GBK GmbH (24h 7d/w - 365d/a)
In England and Wales: NHS 111 In Scotland: NHS 24 - dial 111

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories:
Acute toxicity: Acute Tox. 3
Acute toxicity: Acute Tox. 4
Skin corrosion/irritation: Skin Corr. 1B
Serious eye damage/eye irritation: Eye Dam. 1
Respiratory or skin sensitisation: Resp. Sens. 1
Respiratory or skin sensitisation: Skin Sens. 1A
Specific target organ toxicity - single exposure: STOT SE 3
Hazardous to the aquatic environment: Aquatic Chronic 3
Hazard Statements:
Toxic if swallowed.
Harmful if swallowed.
Causes severe skin burns and eye damage.
Causes serious eye damage.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.
May cause respiratory irritation.
Harmful to aquatic life with long lasting effects.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

Glutaraldehyde
Alkylether carboxylic acid
Sulphonic acid, C14-17-sec-alcane, sodium salt

Signal word: Danger

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Pictograms:



Hazard statements

H331	Toxic if inhaled.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317	May cause an allergic skin reaction.
H335	May cause respiratory irritation.
H412	Harmful to aquatic life with long lasting effects.

Precautionary statements

P260	Do not breathe vapours.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P330+P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or 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.
P273	Avoid release to the environment.
P405	Store locked up.
P501	Dispose of contents/container to approved disposal company or local collection.

Special labelling of certain mixtures

EUH071	Corrosive to the respiratory tract.

2.3. Other hazards

Not known.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Aqueous solution

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Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
111-30-8	Glutaraldehyde			< 15 %
	203-856-5	605-022-00-X	01-2119455549-26	
	Acute Tox. 2, Acute Tox. 3, Skin Corr. 1B, Resp. Sens. 1, Skin Sens. 1A, STOT SE 3, Aquatic Acute 1 (M-Factor = 1), Aquatic Chronic 2; H330 H301 H314 H334 H317 H335 H400 H411 EUH071			
67-63-0	Propan-2-ol			< 15 %
	200-661-7	603-117-00-0	01-2119457558-25	
	Flam. Liq. 2, Eye Irrit. 2, STOT SE 3; H225 H319 H336			
	Alkylether carboxylic acid			< 15 %
	Skin Irrit. 2, Eye Dam. 1; H315 H318			
112-34-5	2-(2-Butoxyethoxy)ethanol			< 10 %
	203-961-6	603-096-00-8	01-2119475104-44	
	Eye Irrit. 2; H319			
97489-15-1	Sulphonic acid, C14-17-sec-alcane, sodium salt			< 5 %
	307-055-2		01-2119489924-20	
	Acute Tox. 4, Skin Irrit. 2, Eye Dam. 1; H302 H315 H318			
111-87-5	1-Octanol			< 5 %
	203-917-6		01-2119486978-10	
	Eye Irrit. 2, Aquatic Chronic 3; H319 H412			

Full text of H and EUH statements: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

Remove contaminated soaked clothing immediately.
If you feel unwell, seek medical advice.

After inhalation

Move to fresh air in case of accidental inhalation of vapours.
In the event of symptoms refer for medical treatment.

After contact with skin

In case of contact with skin wash off immediately with plenty of water.
Consult a doctor if skin irritation persists.

After contact with eyes

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
Seek medical treatment by eye specialist.

After ingestion

Do not induce vomiting.
Rinse out mouth and give plenty of water to drink.
Summon a doctor immediately.

4.2. Most important symptoms and effects, both acute and delayed

Toxic if inhaled.

Harmful if swallowed.
May cause an allergic skin reaction.
Causes severe skin burns and eye damage.
May cause respiratory irritation.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Corrosive to the respiratory tract.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptoms.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Alcohol-resistant foam, dry chemical, carbon dioxide (CO2), water-spray.

Unsuitable extinguishing media

Full water jet.

5.2. Special hazards arising from the substance or mixture

Fire may produce:
Irritant/corrosive, flammable as well as toxic distillation gases (carbonization gases).
Carbon monoxide (CO), carbon dioxide (CO2), sulphur oxides (SOx) and phosphorus oxides (POx).

5.3. Advice for firefighters

Wear self-contained breathing apparatus and protective suit.

Additional information

Cool containers at risk with water spray jet.
Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

In case of vapour formation use respirator.
Avoid contact with skin, eyes and clothing.
Ensure adequate ventilation.
Use personal protective clothing.

6.2. Environmental precautions

Do not discharge into the drains/surface waters/ground water.

6.3. Methods and material for containment and cleaning up

Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder).
Shovel into suitable container for disposal.

6.4. Reference to other sections

Observe protective instructions (see Sections 7 and 8).
Information for disposal see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Keep container tightly closed.
Keep a good ventilation and air-exhaust at the place of work.
Avoid contact with skin, eyes and clothing.

Advice on protection against fire and explosion

No special protective measures against fire required.

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7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep containers tightly closed in a dry, well-ventilated place.

Advice on storage compatibility

Incompatible with:
Oxidizing agents
Acids and bases.

Further information on storage conditions

Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

Instrument disinfectant

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m³	fibres/ml	Category	Origin
112-34-5	2-(2-Butoxyethoxy)ethanol	10	67.5		TWA (8 h)	WEL
		15	101.2		STEL (15 min)	WEL
111-30-8	Glutaraldehyde	0.05	0.2		TWA (8 h)	WEL
		0.05	0.2		STEL (15 min)	WEL
67-63-0	Propan-2-ol	400	999		TWA (8 h)	WEL
		500	1250		STEL (15 min)	WEL

8.2. Exposure controls

Appropriate engineering controls

Ensure adequate ventilation, especially in confined areas.

Protective and hygiene measures

Do not inhale vapours.
Wash hands before breaks and immediately after handling the product.
When using do not eat or drink.
Avoid contact with skin, eyes and clothing.
Remove and wash contaminated clothes before re-use.

Eye/face protection

Safety goggles with side protection (EN 166).
Eye wash bottle with pure water (EN 15154).

Hand protection

Also suitable are gloves made of:
Polychloropren - CR (0,5 mm): Breakthrough time > 4 h
Nitrile rubber/nitrile latex - NBR (0,35 mm): Breakthrough time > 4h
Butyl rubber - Butyl (0,5 mm): Breakthrough time > 8 h
Fluoro-rubber - FKM (0.4 mm): Breakthrough time > 8 h
Polyvinyl chloride - PVC (0.5 mm): Breakthrough time > 4 h
This recommendation refers exclusively to the chemical compatibility and the lab test conforming to EN 374 carried out under lab conditions.
Requirements can vary as a function of the use. Therefore it is necessary to adhere additionally to the recommendations given by the manufacturer of protective gloves.

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Skin protection

Long sleeved clothing (EN 368).

Respiratory protection

In case of insufficient ventilation wear suitable respiratory equipment (gas filter type A) (EN 14387).

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	Various, depending on coloration
Odour:	Aldehyde-like

		Test method
pH-Value:	3,5 - 4,5	(Concentrate)

Changes in the physical state

Initial boiling point and boiling range:	approx. 100 °C
Flash point:	> 100 °C
Lower explosion limits:	n.d.
Upper explosion limits:	
Ignition temperature:	n.d.
Density (at 20 °C):	approx. 1,02 g/cm³
Water solubility: (at 20 °C)	Miscible

9.2. Other information

No data available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No decomposition if stored and applied as directed.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Reactions with acids, alkalies and oxidizing agents

10.4. Conditions to avoid

To avoid thermal decomposition, do not overheat.

10.5. Incompatible materials

Strong acids and oxidizing agents
Bases.

10.6. Hazardous decomposition products

Irritant/corrosive, flammable as well as toxic distillation gases (carbonization gases).
Carbon monoxide (CO), carbon dioxide (CO2), sulphur oxides (SOx) and phosphorus oxides (POx).

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

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Toxic if inhaled.
Harmful if swallowed.
No toxicological data available.

Irritation and corrosivity

Causes severe skin burns and eye damage.

Sensitising effects

May cause allergy or asthma symptoms or breathing difficulties if inhaled. (Glutaraldehyde)
May cause an allergic skin reaction. (Glutaraldehyde)

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

May cause respiratory irritation. (Glutaraldehyde)

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Additional information on tests

Classification in compliance with the assessment procedure specified in the Regulation (EC) no 1272/2008.

Practical experience

Other observations

Corrosive to the respiratory tract.

SECTION 12: Ecological information

12.1. Toxicity

Ecological data are not available.
Harmful to aquatic life with long lasting effects.

12.2. Persistence and degradability

The surfactant(s) contained in this preparation complies(comply) with the biodegradability criteria as laid down in Regulation (EC) No.648/2004 on detergents. Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

According to Regulation (EC) No 1907/2006 (REACH) none of the substances, contained in this product are a PBT / vPvB substance.

12.6. Other adverse effects

Hazardous water pollutant.

Further information

Product is not allowed to be discharged into aquatic environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

Where possible recycling is preferred to disposal.
Can be incinerated, when in compliance with local regulations.

Waste disposal number of waste from residues/unused products

070699 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics; wastes not otherwise specified

Contaminated packaging

Empty containers should be taken for local recycling, recovery or waste disposal.
Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse.
Packaging that cannot be cleaned should be disposed of like the product.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number:	UN 2922
14.2. UN proper shipping name:	CORROSIVE LIQUID, TOXIC, N.O.S. (Glutaraldehyde)
14.3. Transport hazard class(es):	8
14.4. Packing group:	III
Hazard label:	8+6.1



Classification code:	CT1
Limited quantity:	5 L / 30 kg
Excepted quantity:	E1
Transport category:	3
Hazard No:	86
Tunnel restriction code:	E

Inland waterways transport (ADN)

14.1. UN number:	UN 2922
14.2. UN proper shipping name:	CORROSIVE LIQUID, TOXIC, N.O.S. (Glutaraldehyde)
14.3. Transport hazard class(es):	8
14.4. Packing group:	III
Hazard label:	8+6.1



Classification code:	CT1
Limited quantity:	5 L / 30 kg
Excepted quantity:	E1

Marine transport (IMDG)

14.1. UN number:	UN 2922
14.2. UN proper shipping name:	CORROSIVE LIQUID, TOXIC, N.O.S. (Glutaral)
14.3. Transport hazard class(es):	8
14.4. Packing group:	III
Hazard label:	8+6.1



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Marine pollutant:	No
Limited quantity:	5 L / 30 kg
Excepted quantity:	E1
EmS:	F-A, S-B

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number:	UN 2922
14.2. UN proper shipping name:	CORROSIVE LIQUID, TOXIC, N.O.S. (Glutaral)
14.3. Transport hazard class(es):	8
14.4. Packing group:	III
Hazard label:	8+6.1



Limited quantity Passenger:	1 L
Passenger LQ:	Y841
Excepted quantity:	E1
IATA-packing instructions - Passenger:	852
IATA-max. quantity - Passenger:	5 L
IATA-packing instructions - Cargo:	856
IATA-max. quantity - Cargo:	60 L

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: no

14.6. Special precautions for user

Take the usual precautions when handling with chemicals.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

The transport takes place only in approved and appropriate packaging.

SECTION 15: Regulatory information

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

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 55: 2-(2-Butoxyethoxy)ethanol

2004/42/EC (VOC): < 15%

Additional information

Regulation (EC) No 648/2004 (Regulation on detergents):

5 - 15% Anionic surfactants, fragrances

National regulatory information

Employment restrictions: Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

Water contaminating class (D): 2 - clearly water contaminating

Additional information

Consider Chemical prohibition regulation.

15.2. Chemical safety assessment

For this substance a chemical safety assessment has not been carried out.

This Safety Data Sheet corresponds to the criteria of www.compliance-footprint.com

SECTION 16: Other information

Changes

Changes in chapter: 2, 3, 4, 11, 14, 15

Abbreviations and acronyms

ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route
RID = Règlement concernant le transport international ferroviaire de marchandises dangereuses
ADN = Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure
IMDG = International Maritime Code for Dangerous Goods
IATA/ICAO = International Air Transport Association / International Civil Aviation Organization
MARPOL = International Convention for the Prevention of Pollution from Ships
IBC-Code = International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
REACH = Registration, Evaluation, Authorization and Restriction of Chemicals
CAS = Chemical Abstract Service
EN = European norm
ISO = International Organization for Standardization
DIN = Deutsche Industrie Norm
PBT = Persistent Bioaccumulative and Toxic
vPvB = Very Persistent and very Bio-accumulative
LD = Lethal dose
LC = Lethal concentration
EC = Effect concentration
IC = Median immobilisation concentration or median inhibitory concentration

Relevant H and EUH statements (number and full text)

H225	Highly flammable liquid and vapour.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H331	Toxic if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
EUH071	Corrosive to the respiratory tract.

Further Information

Data of items 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities.
The information describes exclusively the safety requirements for the product(s) and is based on the present level of our knowledge.
The delivery specifications are contained in the corresponding product sheet.
This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.
(n.a. = not applicable; n.d. = not determined)

This Safety Data Sheet corresponds to the criteria of www.compliance-footprint.com

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)

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