

SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006

SEKUSEPT AKTIV

Section: 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE **COMPANY/UNDERTAKING**

1.1 Product identifier

Product name : SEKUSEPT AKTIV

UFI : C391-S8PQ-K10W-GW3P

Product code 114388E

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 . Dipping process

Recommended restrictions

on use

: Reserved for industrial and professional use.

1.3 Details of the supplier of the safety data sheet

Company : Ecolab Deutschland GmbH

Ecolab-Allee 1

40789 Monheim am Rhein, Germany +49 (0)2173 599 0

OfficeService.DEDUS@ecolab.com

1.4 Emergency telephone number

Emergency telephone

number

: +32-(0)3-575-5555 Trans-european, German speaking, 24/7

or +49 32 212249407 German speaking, 24/7

Poison Information Centre : +49 (0)551 38318854

telephone number

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Version 1.9

Section: 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Serious eye damage, Category 1 H318

2.2 Label elements

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Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms

Signal Word : Danger

Hazard Statements : H318 Causes serious eye damage.

Precautionary Statements : **Prevention:**

P280e Wear eye protection/face protection.

Response:

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: Sodium carbonate peroxyhydrate

2.3 Other hazards

Do not mix with bleach or other chlorinated products – will cause chlorine gas.

Section: 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Hazardous components

Chemical Name	CAS-No. EC-No. REACH No.	Classification REGULATION (EC) No 1272/2008	Concentration : [%]
Sodium carbonate peroxyhydrate	15630-89-4 239-707-6 01-2119457268-30	Oxidizing solids Category 3; H272 Acute toxicity Category 4; H302 Serious eye damage Category 1; H318 Serious eye damage/eye irritation Category 1 25 - 100 % Serious eye damage/eye irritation Category 2A 10 - 25 % Serious eye damage/eye irritation Category 2B 1 - 10 % Oxidizing solids Category 3 70 - 100 %	>= 30 - < 50
citric acid	77-92-9 201-069-1 01-2119457026-42	Eye irritation Category 2; H319 Specific target organ toxicity - single exposure Category 3; H335	>= 10 - < 20
Sodium Carbonate	497-19-8 207-838-8 01-2119485498-19	Eye irritation Category 2; H319	>= 2.5 - < 5

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Benzotriazole	95-14-7 202-394-1 01-2119979079-20	Acute toxicity Category 4; H302 Eye irritation Category 2; H319 Chronic aquatic toxicity Category 2; H411	>= 1 - < 2.5
Alcohols, C12-15- branched and linear, ethoxylated propoxylated	120313-48-6 POLYMER	Skin irritation Category 2; H315 Serious eye damage Category 1; H318 Acute aquatic toxicity Category 1; H400 Chronic aquatic toxicity Category 3; H412 M = 1	>= 1 - < 2.5

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 : Rinse with plenty of water.

If swallowed : Rinse mouth. Get medical attention if symptoms occur.

If inhaled : Remove to fresh air. Treat symptomatically. Get medical attention

if symptoms occur.

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

Specific hazards during

firefighting

: Not flammable or combustible.

Hazardous combustion

products

: Depending on combustion properties, decomposition products

may include following materials:

Carbon oxides

nitrogen oxides (NOx)

5.3 Advice for firefighters

Special protective equipment : Use personal protective equipment.

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for firefighters

Further information : Collect contaminated fire extinguishing water separately. This

must not be discharged into drains. 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. 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 : Sweep up and shovel into suitable containers for disposal.

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

7.1 Precautions for safe handling

Advice on safe handling : Do not get in eyes, on skin, or on clothing. Use only with adequate

ventilation. Wash hands thoroughly after handling. Do not breathe dust. Do not mix with bleach or other chlorinated products — will cause chlorine gas. In case of mechanical malfunction, or if in contact with unknown dilution of product, wear full Personal

Protective Equipment (PPE).

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 guick 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 out of reach of children. Keep container tightly closed. Store

in suitable labeled containers.

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Storage temperature : 0 °C to 25 °C

7.3 Specific end uses

Specific use(s) : Medical devices . Dipping 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
citric acid	77-92-9		AGW (Inhalable fraction)	2 mg/m3	TRGS 900
Further information	Υ	When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child			

DNEL

End Use: Workers Exposure routes: Inhalation Potential health effects: Long-term local effects Value: 10 mg/m3 End Use: Consumers Exposure routes: Inhalation Potential health effects: Acute local effects Value: 10 mg/m3	

8.2 Exposure controls

Appropriate engineering controls

Engineering measures : Good general ventilation should be sufficient to control worker

exposure to airborne contaminants.

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) : No special protective equipment required.

Skin and body protection

(EN 14605)

: No special protective equipment required.

Respiratory protection (EN

143, 14387)

: When respiratory risks cannot be avoided or sufficiently limited by technical means of collective protection or by measures, methods

or procedures of work organization, consider the use of certified respiratory protection equipment meeting EU requirements

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(89/656/EEC, (EU) 2016/425), or equivalent, with filter type:P

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

Physical state : solid

Colour : white with coloured particles

Odour : Perfumes, fragrances

pH : 8.0, 1 %

Particle characteristics

Assessment : no data available
Particle size : no data available
Particle Size Distribution : no data available
Dustiness : no data available
Specific surface area : no data available
Surface charge/Zeta : no data available

potential

Shape : no data available
Crystallinity : no data available
Surface treatment : no data available

/Coatings

Flash point : Not applicable.

Odour Threshold : Not applicable and/or not determined for the mixture

Melting point/freezing point : Not applicable and/or not determined for the mixture

Boiling point, initial boiling : Not applicable and/or not determined for the mixture point and boiling range

Evaporation rate : Not applicable and/or not determined for the mixture

Flammability : 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

Density and / or relative

octanol/water (log value)

density

Water solubility

: soluble

: 0.9

Solubility in other solvents : Not applicable and/or not determined for the mixture Partition coefficient: n- : 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

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Viscosity, kinematic : Not applicable and/or not determined for the mixture Explosive properties : Not applicable and/or not determined for the mixture

Oxidizing properties : Yes

9.2 Other information

Not applicable and/or not determined for the mixture

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

Do not mix with bleach or other chlorinated products – will cause chlorine gas.

10.4 Conditions to avoid

None known.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

Depending on combustion properties, decomposition products may include following materials: Carbon oxides nitrogen oxides (NOx)

Section: 11. TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

exposure

Product

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

Acute inhalation toxicity : There is no data available for this product.

Acute dermal toxicity : There is no data available for this product.

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

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

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irritation

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.

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 : Sodium carbonate peroxyhydrate LD50 rat: 1,034 mg/kg

citric acid LD50 rat: 11,700 mg/kg

Sodium Carbonate LD50 rat: 2,800 mg/kg

Benzotriazole LD50 rat: 735 mg/kg

Components

Acute dermal toxicity : Benzotriazole LD50 rabbit: > 10,000 mg/kg

Potential Health Effects

Eyes : Causes serious eye damage.

Skin : Health injuries are not known or expected under normal use.

Ingestion : Health injuries are not known or expected under normal use.

Inhalation : Health injuries are not known or expected under normal use.

Chronic Exposure : Health injuries are not known or expected under normal use.

Experience with human exposure

Eye contact : Redness, Pain, Corrosion

Skin contact : No symptoms known or expected.

Ingestion : No symptoms known or expected.

Inhalation : No symptoms known or expected.

11.2 Information on other hazards

Further information : no data available

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Section: 12. ECOLOGICAL INFORMATION

12.1 Toxicity

Environmental Effects : This product has no known ecotoxicological effects.

Product

Toxicity to fish : no data available Toxicity to daphnia and other : no data available

aquatic invertebrates

Toxicity to algae : no data available

Components

Toxicity to fish : citric acid

96 h LC50 Fish: > 100 mg/l

Sodium Carbonate

96 h LC50 Lepomis macrochirus (Bluegill sunfish): 300 mg/l

Benzotriazole

96 h LC50 Fish: 28 mg/l

Alcohols, C12-15-branched and linear, ethoxylated propoxylated

96 h LC50 Brachydanio rerio (zebrafish): 0.55 mg/l

Components

aquatic invertebrates

Toxicity to daphnia and other : Sodium carbonate peroxyhydrate 48 h EC50 Daphnia: 4.9 mg/l

Sodium Carbonate

48 h EC50 Ceriodaphnia (water flea): 213.5 mg/l

Benzotriazole 48 h EC50: 91 mg/l

Alcohols, C12-15-branched and linear, ethoxylated propoxylated

48 h EC50: 55 mg/l

Components

Toxicity to algae : Benzotriazole

72 h EC50 algae: 15.4 mg/l

Alcohols, C12-15-branched and linear, ethoxylated propoxylated

72 h EC50: 0.5 mg/l

12.2 Persistence and degradability

Product

Biodegradability : The surfactants contained in the product are biodegradable

according to the requirements of the detergent regulation

648/2004/EC

Components

Biodegradability : Sodium carbonate peroxyhydrate

Result: Not applicable - inorganic

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citric acid

Result: Readily biodegradable.

Sodium Carbonate

Result: Not applicable - inorganic

Benzotriazole

Result: Poorly biodegradable

Alcohols, C12-15-branched and linear, ethoxylated propoxylated

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

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

higher.

12.6 Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher

12.7 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 : Do not contaminate storm water drains, natural waterways or soil

with chemical or used container. Where possible recycling is preferred to disposal or incineration. If recycling is not practicable, dispose of contents/container in accordance 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 : Inorganic wastes containing dangerous substances. If this product

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selection

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 or ID

number

14.2 UN proper shipping

14.3 Transport hazard

class(es) 14.4 Packing group

14.5 Environmental hazards 14.6 Special precautions for

user

: Not dangerous goods

: Not dangerous goods

: Not dangerous goods

: Not dangerous goods : Not dangerous goods

: Not dangerous goods

Air transport (IATA)

14.1 UN number or ID : Not dangerous goods

number

14.2 UN proper shipping

name

14.3 Transport hazard

class(es)

14.5 Environmental hazards 14.6 Special precautions for

14.4 Packing group

user

: Not dangerous goods

: Not dangerous goods

: Not dangerous goods : Not dangerous goods

: Not dangerous goods

Sea transport (IMDG/IMO)

14.1 UN number or ID

number

14.2 UN proper shipping

name

14.3 Transport hazard

class(es)

14.4 Packing group 14.5 Environmental hazards 14.6 Special precautions for

user

14.7 Maritime transport in bulk according to IMO

instruments

: Not dangerous goods

: Not dangerous goods

: Not dangerous goods

: Not dangerous goods

: Not dangerous goods : Not dangerous goods

: Not dangerous goods

Section: 15. REGULATORY INFORMATION

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

according to Detergents 30 % and more: Oxygen-based bleaching agents Regulation EC 648/2004 less than 5 %: Phosphonates, Non-ionic surfactants

> Other constituents: Perfumes Contains: Disinfectants

Seveso III: Directive : Not applicable.

2012/18/EU of the European Parliament and of the Council on the control of majoraccident hazards involving dangerous substances.

Candidate List of Substances : Not applicable.

of Very High Concern for

Authorisation

National Regulations

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

Hazard class for water : WGK 1

Classification according to AwSV, Annex 1

German storage class : 13

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out on the product.

Section: 16. OTHER INFORMATION

Procedure used to derive the classification according to REGULATION (EC) No 1272/2008

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Classification	Justification		
Serious eye damage 1, H318	Calculation method		

Full text of H-Statements

H272	May intensify fire; oxidiser.
H302	Harmful if swallowed.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.

Toxic to aquatic life with long lasting effects. H411 Harmful to aquatic life with long lasting effects. H412

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; AIIC - Australian Inventory of Industrial Chemicals; 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 -

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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; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals 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

Exposure Scenario: Medical devices. Dipping process

Life Cycle Stage : Widespread use by professional workers

Product category PC35 Washing and cleaning products (including solvent based

products)

Contributing scenario controlling environmental exposure for:

Environmental release : ERC8a Wide dispersive indoor use of processing aids in open category

systems

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Daily amount per site : 7.5 kg

Type of Sewage Treatment

Plant

: Municipal sewage treatment plant

Contributing scenario controlling worker exposure for:

Process category : **PROC13** Treatment of articles by dipping and pouring

Exposure duration : 60 min

Operational conditions and

risk management measures

: Indoor

Local Exhaust Ventilation is not required

General ventilation Ventilation rate per hour 1

Skin Protection : see section 8

Respiratory Protection : see section 8

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