

Safety Data Sheet

According to Regulation (EC) No 1907/2006

Suma Med Super LPH

Revision: 2024-08-07 Version: 06.3

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

1.1 Product identifier

Trade name: Suma Med Super LPH

UFI: APX4-S02M-U00R-RFJ8

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

Product use: Hard surface cleaner.

for cleaning of medical devices For professional use only.

Uses other than those identified are not recommended. Uses advised against:

 $\begin{array}{l} \textbf{SWED - Sector-specific worker exposure description:} \\ \textbf{AISE_SWED_PW_8b_2} \\ \textbf{AISE_SWED_PW_1_1} \end{array}$

AISE_SWED_PW_4_1

1.3 Details of the supplier of the safety data sheet

Diversey Europe Operations BV, De Corridor 4, 3621ZB Breukelen [Maarssenbroeksedijk 2, 3542DN Utrecht], The Netherlands

Contact details

Tandur Hf.

Hesthálsi 12, 110 Reykjavík

Tel. 5101200, Email: tandur@tandur.is

1.4 Emergency telephone number

Seek medical advice (show the label or safety data sheet where possible).

Poison Center: (+354) 543-2222 Emergency services: 112.

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Corrosive to metals, Category 1 (H290)

2.2 Label elements



Signal word: Warning.

Hazard statements:

H290 - May be corrosive to metals.

2.3 Other hazards

No other hazards known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Ingredient(s)	EC number	CAS number	REACH	Classification	Notes	Weight
			number			percent
potassium carbonate	209-529-3	584-08-7	6-36	Specific target organ toxicity - Single exposure, Category 3 (H335) Skin irritation, Category 2 (H315) Eye irritation, Category 2 (H319)		3-10

Workplace exposure limit(s), if available, are listed in subsection 8.1.

ATE, if available, are listed in section 11.

For the full text of the H and EUH phrases mentioned in this Section, see Section 16..

SECTION 4: First aid measures

4.1 Description of first aid measures

Inhalation: Get medical attention or advice if you feel unwell.

Skin contact: Wash skin with plenty of lukewarm, gently flowing water. If skin irritation occurs: Get medical advice

or attention.

Eye contact: Rinse cautiously with water for several minutes. If irritation occurs and persists, get medical

attention.

Ingestion: Rinse mouth. Immediately drink 1 glass of water. Never give anything by mouth to an unconscious

person. Get medical attention or advice if you feel unwell.

Self-protection of first aider: Consider personal protective equipment as indicated in subsection 8.2.

4.2 Most important symptoms and effects, both acute and delayed

Inhalation:No known effects or symptoms in normal use.Skin contact:No known effects or symptoms in normal use.Eye contact:No known effects or symptoms in normal use.Ingestion:No known effects or symptoms in normal use.

4.3 Indication of any immediate medical attention and special treatment needed

No information available on clinical testing and medical monitoring. Specific toxicological information on substances, if available, can be found in section 11.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Carbon dioxide. Dry powder. Water spray jet. Fight larger fires with water spray jet or alcohol-resistant foam.

5.2 Special hazards arising from the substance or mixture

No special hazards known.

5.3 Advice for firefighters

As in any fire, wear self contained breathing apparatus and suitable protective clothing including gloves and eye/face protection.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

No special measures required.

6.2 Environmental precautions

Dilute with plenty of water. Do not allow to enter drainage system, surface or ground water.

6.3 Methods and material for containment and cleaning up

Dyke to collect large liquid spills. Absorb with liquid-binding material (sand, diatomite, universal binders). Do not place spilled materials back into the original container. Collect in closed and suitable containers for disposal.

6.4 Reference to other sections

For personal protective equipment see subsection 8.2. For disposal considerations see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Measures to prevent fire and explosions:

No special precautions required.

Measures required to protect the environment:

For environmental exposure controls see subsection 8.2.

Advices on general occupational hygiene:

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not mix with other products unless adviced by Diversey. Wash hands before breaks and at the end of workday. Use only with adequate ventilation. See chapter 8.2, Exposure controls / Personal protection.

7.2 Conditions for safe storage, including any incompatibilities

Store in accordance with local and national regulations. Store in a closed container. Keep only in original packaging.

For conditions to avoid see subsection 10.4. For incompatible materials see subsection 10.5.

7.3 Specific end use(s)

No specific advice for end use available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters Workplace exposure limits

Air limit values, if available:

Biological limit values, if available:

Recommended monitoring procedures, if available:

Additional exposure limits under the conditions of use, if available:

DNEL/DMEL and PNEC values

Human exposure

DNEL/DMEL oral exposure - Consumer (mg/kg bw)

Ingredient(s)	Short term - Local effects	Short term - Systemic effects	Long term - Local effects	Long term - Systemic effects
potassium carbonate	-	-	-	-

DNEL/DMEL dermal exposure - Worker

Ingredient(s)	Short term - Local effects	Short term - Systemic effects (mg/kg bw)	Long term - Local effects	Long term - Systemic effects (mg/kg bw)
potassium carbonate	No data available	-	16 mg/cm ² skin	-

DNEL/DMEL dermal exposure - Consumer

Ingredient(s)	Short term - Local effects	Short term - Systemic effects (mg/kg bw)	Long term - Local effects	Long term - Systemic effects (mg/kg bw)
potassium carbonate	No data available	-	8 mg/cm ² skin	-

DNEL/DMEL inhalatory exposure - Worker (mg/m³)

7 - 1				
Ingredient(s)	Short term - Local	Short term - Systemic	Long term - Local	Long term - Systemic
	effects	effects	effects	effects

DNEL/DMEL inhalatory exposure - Consumer (mg/m³)

BITEL/BITIEL IIII diatory expectate Container (ing/iii)				
Ingredient(s)	Short term - Local effects	Short term - Systemic effects	Long term - Local effects	Long term - Systemic effects
potassium carbonate	-	-	10	-

Environmental exposure

Environmental exposure - PNEC

Environmental expedite 11120				
Ingredient(s)	,	Surface water, marine	Intermittent (mg/l)	Sewage treatment
	(mg/l)	(mg/l)		plant (mg/l)
potassium carbonate	=	-	-	-

Environmental exposure - PNEC, continued

Ingredient(s)	Sediment, freshwater (mg/kg)	Sediment, marine (mg/kg)	Soil (mg/kg)	Air (mg/m³)
potassium carbonate	-	-	-	-

8.2 Exposure controls

The following information applies for the uses indicated in subsection 1.2 of the Safety Data Sheet. If available, please refer to the product information sheet for application and handling instructions. Normal use conditions are assumed for this section.

Recommended safety measures for handling the <u>undiluted</u> product:

Appropriate engineering controls: No special requirements under normal use conditions. Appropriate organisational controls: No special requirements under normal use conditions.

REACH use scenarios considered for the undiluted product:

SWFD - Sector-specific	LCS	PROC	Duration	FRC

	worker exposure			(min)	
	description				
Automatic transfer and dilution	AISE_SWED_PW_8b_2	PW	PROC 8b	60	ERC8b

Personal protective equipment

Eye / face protection: Safety glasses are not normally required. However, their use is recommended in those cases where

splashes may occur when handling the product (EN 16321 / EN 166).

Hand protection:No special requirements under normal use conditions.Body protection:No special requirements under normal use conditions.Respiratory protection:No special requirements under normal use conditions.

Environmental exposure controls: Should not reach sewage water or drainage ditch undiluted or unneutralised.

Recommended safety measures for handling the diluted product:

Recommended maximum concentration (% w/w): 0.3

Appropriate engineering controls: No special requirements under normal use conditions. Appropriate organisational controls: No special requirements under normal use conditions.

REACH use scenarios considered for the diluted product:

NEADIT use section to considered for the unuted pro	TEACH use section to sometime under product.						
	SWED	LCS	PROC	Duration	ERC		
				(min)			
Automatic application in a dedicated closed system	AISE_SWED_PW_1_1	PW	PROC 1	480	ERC8a		
Automatic application in a dedicated system	AISE SWED PW 4 1	PW	PROC 4	480	FRC8a		

Personal protective equipment

Eye / face protection:No special requirements under normal use conditions.Hand protection:No special requirements under normal use conditions.Body protection:No special requirements under normal use conditions.Respiratory protection:No special requirements under normal use conditions.

Environmental exposure controls: No special requirements under normal use conditions.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Information in this section refers to the product, unless it is specifically stated that substance data is listed

Method / remark

Physical state: Liquid

Colour: Clear , Pale , Yellow Odour: Product specific Odour threshold: Not applicable

Melting point/freezing point (°C): Not determined Not relevant to classification of this product

Initial boiling point and boiling range (°C): Not determined See substance data

Substance data, boiling point

Ingredient(s)	Value	Method	Atmospheric pressure
	(°C)		(hPa)
potassium carbonate	Not applicable to solids		1013
	or gases		

Method / remark

Flammability (solid, gas): Not applicable to liquids

Flammability (liquid): Not flammable.
Flash point (°C): Not applicable.
Sustained combustion: Not applicable.
(UN Manual of Tests and Criteria, section 32, L.2)

Lower and upper explosion limit/flammability limit (%): Not determined

Substance data, flammability or explosive limits, if available:

Method / remark

ISO 4316

ISO 4316

Autoignition temperature: Not determined Decomposition temperature: Not applicable.

pH: >= 11.5 (neat)
Dilution pH: ≈ 11 (0.3 %)

Kinematic viscosity: Not determined

Solubility in / Miscibility with water: Fully miscible

Substance data, solubility in water

Ingredient(s)	Value (g/l)	Method	Temperature (°C)
potassium carbonate	1100	Method not given	20

Substance data, partition coefficient n-octanol/water (log Kow): see subsection 12.3

Method / remark

See substance data

Vapour pressure: Not determined

Substance data, vapour pressure			
Ingredient(s)	Value	Method	Temperature
	(Pa)		(°C)
potassium carbonate	2300	Method not given	

Method / remark

OECD 109 (EU A.3)

Not relevant to classification of this product

Not applicable to liquids.

Relative density: ≈ 1.15 (20 °C) Relative vapour density: -.

Particle characteristics: No data available.

9.2 Other information

9.2.1 Information with regard to physical hazard classes

Explosive properties: Not explosive. Oxidising properties: Not oxidising. Corrosion to metals: Corrosive

9.2.2 Other safety characteristics

No other relevant information available.

SECTION 10: Stability and reactivity

10.1 Reactivity

No reactivity hazards known under normal storage and use conditions.

10.2 Chemical stability

Stable under normal storage and use conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known under normal storage and use conditions.

10.4 Conditions to avoid

None known under normal storage and use conditions.

10.5 Incompatible materials

May be corrosive to metals.

10.6 Hazardous decomposition products

None known under normal storage and use conditions.

SECTION 11: Toxicological information

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

Mixture data: .

Relevant calculated ATE(s):

ATE - Oral (mg/kg): >2000

Substance data, where relevant and available, are listed below:.

Acute toxicity

Acute oral toxicity

reate erai texiony						
Ingredient(s)	Endpoint	Value	Species	Method	Exposure	ATE Oral
		(mg/kg)			time (h)	(mg/kg)
potassium carbonate	LD 50	> 2000	Rat	Method not given		Not established

Acute dermal toxicity

Ingredient(s)	Endpoint	Value	Species	Method	Exposure	ATE Dermal

		(mg/kg)			time (h)	(mg/kg)
potassium carbonate	LD 50	> 2000	Rabbit	Method not given		Not established

Acute inhalative toxicity

Ingredient(s)	Endpoint	Value (mg/l)	Species	Method	Exposure time (h)
potassium carbonate	LC 50	No mortality observed		EPA OPP 81-3	

Acute inhalative toxicity, continued

Ingredient(s) ATE - inhalation, dust ATE - inhalation, mist ATE - inhalation,				ATE - inhalation, gas
	(mg/l)	(mg/l)	vapour (mg/l)	(mg/l)
potassium carbonate	Not established	Not established	Not established	Not established

Irritation and corrosivity

Skin irritation and corrosivity

Ingredient(s)	Result	Species	Method	Exposure time
potassium carbonate	Irritant		Weight of evidence	

Eye irritation and corrosivity

Lyo irritation and correctivity				
Ingredient(s)	Result	Species	Method	Exposure time
potassium carbonate	Irritant	Rabbit	OECD 405 (EU B.5)	

Respiratory tract irritation and corrosivity

 reophatory tract initiation and correctivity				
Ingredient(s)	Result	Species	Method	Exposure time
potassium carbonate	No data available			·

Sensitisation

Sensitisation by skin contact

Ingredient(s)	Result	Species	Method	Exposure time (h)
potassium carbonate	Not sensitising	Guinea pig	Method not given	

Sensitisation by inhalation

Ingredient(s)	Result	Species	Method	Exposure time
potassium carbonate	No data available			

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

| Ingredient(s) | Result (in-vitro) | Method (

Carcinogenicity

Carcinogenicity	
Ingredient(s)	Effect
potassium carbonate	No data available

Toxicity for reproduction

TOXICITY FOR TEPTODUCTION								
	Ingredient(s)	Endpoint	Specific effect	Value (mg/kg bw/d)	Species	Method	Exposure time	Remarks and other effects reported
	potassium carbonate	NOAEL	Teratogenic effects	180	Rat	Not known		

Repeated dose toxicity

Sub-acute or sub-chronic oral toxicity

Ingredient(s)	En	ndpoint	Value (mg/kg bw/d)	Species	Method	Exposure time (days)	Specific effects and organs affected
potassium carbona	ate N	NOAEL	6054	Rat	Method not given	28	

Sub-chronic dermal toxicity

Ingredient(s)	Endpoint	Value (mg/kg bw/d)	Species	Method	Exposure time (days)	Specific effects and organs affected
potassium carbonate		No data				
		available				

Sub-chronic inhalation toxicity

Ingredient(s)	Endpoint	Value	Species	Method	Exposure	Specific effects and organs
		(mg/kg bw/d)			time (days)	affected

potassium carbonate	NOAEL	0.06	Rat	Read across	21	
---------------------	-------	------	-----	-------------	----	--

Chronic toxicity

Ingredient(s)	Exposure route	Endpoint	Value (mg/kg bw/d)	Species	Method	Exposure time	Specific effects and organs affected	Remark
potassium carbonate	Oral	NOAEL	2667	Rat	Read	32 month(s)		
					across			

STOT-single exposure

Ingredient(s)	Affected organ(s)
potassium carbonate	No data available

STOT-repeated exposure

	Ingredient(s)	Affected organ(s)
Ī	potassium carbonate	No data available

Aspiration hazard

Substances with an aspiration hazard (H304), if any, are listed in section 3.

Potential adverse health effects and symptoms

Effects and symptoms related to the product, if any, are listed in subsection 4.2.

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

Endocrine disrupting properties - Human data, if available:

11.2.2 Other information

No other relevant information available.

SECTION 12: Ecological information

12.1 Toxicity

No data is available on the mixture.

Substance data, where relevant and available, are listed below:

Aquatic short-term toxicity Aquatic short-term toxicity - fish

Ingredient(s)	Endpoint	Value (mg/l)	Species	Method	Exposure time (h)
potassium carbonate	LC 50	68	Oncorhynchus	Method not given	96
			mykiss		

Aquatic short-term toxicity - crustacea

Aquatic short-term toxicity - crustacea					
Ingredient(s)	Endpoint	Value (mg/l)	Species	Method	Exposure time (h)
potassium carbonate	EC 50	200	Daphnia pulex	Method not given	48

Aquatic short-term toxicity - algae

Ingredient(s)	Endpoint	Value	Species	Method	Exposure
		(mg/l)			time (h)
potassium carbonate		No data			
		available			

Aquatic short-term toxicity - marine species

Ingredient(s)	Endpoint	Value (mg/l)	Species	Method	Exposure time (days)
potassium carbonate		No data			
		available			1

Impact on sewage plants - toxicity to bacteria

Ingredient(s)	Endpoint	Value (mg/l)	Inoculum	Method	Exposure time
potassium carbonate		No data			
		available	l	1	

Aquatic long-term toxicity

Aquatic long-term toxicity - rish									
Ingredient(s)	Endpoint	Value	Species	Method	Exposure	Effects observed			

	(mg/l)		time	
potassium carbonate	No data			
	available			

Aquatic long-term toxicity - crustacea

Ingredient(s)	Endpoint	Value (mg/l)	Species	Method	Exposure time	Effects observed
potassium carbonate		No data				
		available				

Aquatic toxicity to other aquatic benthic organisms, including sediment-dwelling organisms, if available:

Ingredient(s)	Endpoint	Value (mg/kg dw sediment)	Species	Method	Exposure time (days)	Effects observed
potassium carbonate		No data available				

Terrestrial toxicity

Terrestrial toxicity - soil invertebrates, including earthworms, if available:

Terrestrial toxicity - plants, if available:

Terrestrial toxicity - birds, if available:

Terrestrial toxicity - beneficial insects, if available:

Terrestrial toxicity - soil bacteria, if available:

12.2 Persistence and degradability

Abiotic degradation

Abiotic degradation - photodegradation in air, if available:

Abiotic degradation - hydrolysis, if available:

Abiotic degradation - other processes, if available:

Biodegradation

Ready biodegradability - aerobic conditions

Ingredient(s)	Inoculum	Analytical method	DT 50	Method	Evaluation
potassium carbonate					Not applicable (inorganic substance)

Ready biodegradability - anaerobic and marine conditions, if available:

 $\label{lem:decompartments} \textbf{Degradation in relevant environmental compartments, if available:}$

12.3 Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

Ingredient(s)	Value	Method	Evaluation	Remark	
potassium carbonate	No data available		No bioaccumulation expected		

Bioconcentration factor (BCF)

Ingredient(s)	Value	Species	Method	Evaluation	Remark
potassium carbonate	No data available				

12.4 Mobility in soil

Adsorption/Desorption to soil or sediment

Adsorption/Desorption to soil or sealment								
	Ingredient(s)	Adsorption coefficient	Desorption coefficient	Method	Soil/sediment	Evaluation		
					type			
		Log Koc	Log Koc(des)					
	potassium carbonate	No data available				Potential for mobility in soil,		
						soluble in water		

12.5 Results of PBT and vPvB assessment

Substances that fulfill the criteria for PBT/vPvB, if any, are listed in section 3.

12.6 Endocrine disrupting properties

Endocrine disrupting properties - Environmental effects, if available:

12.7 Other adverse effects

No other adverse effects known.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Waste from residues / unused products:

The concentrated contents or contaminated packaging should be disposed of by a certified handler or according to the site permit. Release of waste to sewers is discouraged. The cleaned packaging material is suitable for energy recovery or recycling in line with local legislation.

Empty packaging

Recommendation: Dispose of observing national or local regulations.

Suitable cleaning agents: Water, if necessary with cleaning agent.

SECTION 14: Transport information



Land transport (ADR/RID), Sea transport (IMDG), Air transport (ICAO-TI / IATA-DGR)

14.1 UN number or ID number: 3267 14.2 UN proper shipping name:

Corrosive liquid, basic, organic, n.o.s. (trisodium methylglycinediacetate) Corrosive liquid, basic, organic, n.o.s. (trisodium methylglycinediacetate)

14.3 Transport hazard class(es):

Transport hazard class (and subsidiary risks): 8

14.4 Packing group: III
14.5 Environmental hazards:
Environmentally hazardous: No

Marine pollutant: No

14.6 Special precautions for user: None known.

14.7 Maritime transport in bulk according to IMO instruments: The product is not transported in bulk tankers.

Other relevant information:

ADR

Classification code: C7
Tunnel restriction code: (E)
Hazard identification number: 80

IMO/IMDG

EmS: F-A, S-B

The product has been classified, labelled and packaged in accordance with the requirements of ADR and the provisions of the IMDG Code Transport regulations include special provisions for certain classes of dangerous goods packed in limited quantities.

SECTION 15: Regulatory information

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

EU regulations:

- Regulation (EC) No. 1907/2006 REACH
- Regulation (EC) No 1272/2008 CLP
- Regulation (EC) No. 648/2004 Detergents regulation
- Regulation (EU) 2017/745 on medical devices
- substances identified as having endocrine disrupting properties in accordance with the criteria set out in Delegated Regulation (EU) 2017/2100 or Regulation (EU) 2018/605

Page 9/10

- Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)
- International Maritime Dangerous Goods (IMDG) Code

Authorisations or restrictions (Regulation (EC) No 1907/2006, Title VII respectively Title VIII): Not applicable.

Ingredients according to EC Detergents Regulation 648/2004

phosphates

< 5 %

Seveso - Classification: Not classified

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out on the mixture

SECTION 16: Other information

The information in this document is based on our best present knowledge. However, it does not constitute a guarantee for any specific product features and does not establish a legally binding contract

SDS code: MSDS4536 Version: 06.3 Revision: 2024-08-07

Reason for revision:

This data sheet contains changes from the previous version in section(s):, 3, 9, 11, 12, 16

Classification procedure

The classification of the mixture is in general based on calculation methods using substance data, as required by Regulation (EC) No 1272/2008. If for certain classifications data on the mixture is available or for example bridging principles or weight of evidence can be used for classification, this will be indicated in the relevant sections of the Safety Data Sheet. See section 9 for physical chemical properties, section 11 for toxicological information and section 12 for ecological information.

Abbreviations and acronyms:

- · AISE The international Association for Soaps, Detergents and Maintenance Products
- ATE Acute Toxicity Estimate
- DNEL Derived No Effect Limit
- EC50 effective concentration, 50%
 ERC Environmental release categories
- EUH CLP Specific hazard statement
- LC50 Lethal Concentration, 50% / Median Lethal Concentration
- LCS Life cycle stage LD50 Lethal Dose, 50% / Median Lethal dose
- · NOAEL No observed adverse effect level
- NOEL No observed effect level
 OECD Organisation for Economic Cooperation and Development
- PBT Persistent, Bioaccumulative and Toxic
- PNEC Predicted No Effect Concentration
- PROC Process categories
- REACH number REACH registration number, without supplier specific part
- vPvB very Persistent and very Bioaccumulative
- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.

End of Safety Data Sheet