

Safety Data Sheet

According to Regulation (EC) No 1907/2006

Suma Med Neutral

Revision: 2018-01-25 Version: 02.2

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

1.1 Product identifier

Trade name: Suma Med Neutral

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

Identified uses:

For professional use only.

AISE-P1101 - Medical devices. Semi-automatic process

Cleaning only

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

1.3 Details of the supplier of the safety data sheet

Diversey Europe Operations BV, De Boelelaan 32, 1083HJ Amsterdam, The Netherlands

Contact details

Diversey Ltd

Weston Favell Centre, Northampton NN3 8PD, United Kingdom

Tel: 01604 405311, Fax: 01604 406809

Regulatory Email: customerservice.uk@diversey.com

1.4 Emergency telephone number

For medical or environmental emergency only:

call 0800 052 0185

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Eye Irrit. 2 (H319) Met. Corr. 1 (H290)

2.2 Label elements



Signal word: Warning.

Hazard statements:

H319 - Causes serious eye irritation. H290 - May be corrosive to metals.

2.3 Other hazards

No other hazards known

The product does not meet the criteria for PBT or vPvB in accordance with Regulation (EC) No 1907/2006, Annex XIII

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Ingredient(s)	EC number	CAS number	REACH number	Classification	Notes	Weight percent
citric acid monohydrate	201-069-1	5949-29-1	01-2119457026-42	Eye Irrit. 2 (H319)		30-50

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

Workplace exposure limit(s), if available, are listed in subsection 8.1.
[1] Exempted: ionic mixture. See Regulation (EC) No 1907/2006, Annex V, paragraph 3 and 4. This salt is potentially present, based on calculation, and included [2] Exempted: included in Annex IV of Regulation (EC) No 1907/2006.

^[3] Exempted: Annex V of Regulation (EC) No 1907/2006.

[4] Exempted: polymer. See Article 2(9) of Regulation (EC) No 1907/2006.

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: Immediately rinse eyes cautiously with lukewarm water for several minutes. Remove contact lenses,

if present and easy to do. Continue rinsing. If irritation occurs and persists, get medical attention.

Ingestion: Immediately drink 1 glass of water. 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:Causes severe irritation.

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

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

6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material (sand, diatomite, universal binders, sawdust).

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. Wash face, hands and any exposed skin thoroughly after handling. Take off immediately all contaminated clothing. Use personal protective equipment as required. Use only with adequate ventilation.

7.2 Conditions for safe storage, including any incompatibilities

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

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 oral exposure - Consumer (mg/kg bw)

Ingredient(s)	Short term - Local effects	Short term - Systemic effects	Long term - Local effects	Long term - Systemic effects
citric acid monohydrate		_	_	_

DNEL 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)
citric acid monohydrate	-	-	-	-

DNFL 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)
citric acid monohydrate	No data available	-	No data available	-

DNEL inhalatory exposure - Worker (mg/m³)

Ingredient(s)	Short term - Local effects	Short term - Systemic effects	Long term - Local effects	Long term - Systemic effects
citric acid monohydrate	-	-	-	-

DNEL inhalatory exposure - Consumer (mg/m³)

Ingredient(s)	Short term - Local effects	Short term - Systemic effects	Long term - Local effects	Long term - Systemic effects
citric acid monohydrate	-	-	-	-

Environmental exposure

Environmental exposure - PNEC

Ingredient(s)	Surface water, fresh (mg/l)	Surface water, marine (mg/l)	Intermittent (mg/l)	Sewage treatment plant (mg/l)
citric acid monohydrate	0.44	0.044	-	1000

Environmental exposure - PNEC, continued

Ingredient(s)	Sediment, freshwater (mg/kg)	Sediment, marine (mg/kg)	Soil (mg/kg)	Air (mg/m³)
citric acid monohydrate	34.6	3.46	33.1	-

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 undiluted product:

Covering activities such as filling and transfer of product to application equipment, flasks or buckets

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

Appropriate organisational controls: Avoid direct contact and/or splashes where possible. Train personnel.

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 166). **Hand 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: Should not reach sewage water or drainage ditch undiluted or unneutralised.

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

Recommended maximum concentration (%): 1

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

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, Colourless
Odour: Product specific
Odour threshold: Not applicable

pH: ≈ 2 (neat)

Melting point/freezing point (°C): Not determined

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

Not relevant to classification of this product

Substance data, boiling point

Ingredient(s)	Value (°C)	Method	Atmospheric pressure (hPa)
citric acid monohydrate	175	Method not given	1013

Method / remark

Flash point (°C): Not applicable. Sustained combustion: Not applicable. (UN Manual of Tests and Criteria, section 32, L.2) Evaporation rate: Not determined

Flammability (solid, gas): Not determined

Upper/lower flammability limit (%): Not determined

Substance data, flammability or explosive limits, if available:

Method / remark

Vapour pressure: Not determined

Substance data, vapour pressure

Ingredient(s)	Value (Pa)	Method	Temperature (°C)
citric acid monohydrate	No data available		

Method / remark

Vapour density: Not determined Relative density: ≈ 1.17 (20 °C)

Solubility in / Miscibility with Water: Fully miscible

Substance data, solubility in water

Ingredient(s)	Value (g/l)	Method	Temperature (°C)
citric acid monohydrate	880	Method not given	20

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

Method / remark

Autoignition temperature: Not determined Decomposition temperature: Not applicable.

Viscosity: Not determined

Explosive properties: Not explosive. **Oxidising properties:** Not oxidising.

9.2 Other information

Surface tension (N/m): Not determined Not relevant to classification of this product

Corrosion to metals: Corrosive Weight of evidence

Substance data, dissociation constant, if 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

Reacts with alkali and metals. Keep away from products containing chlorine-based bleaching agents or sulphites.

10.6 Hazardous decomposition products

None known under normal storage and use conditions.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

No data is available on the mixture.

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

Acute toxicity

Acute oral	toxicity
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Ingredient(s)	Endpoint	Value (mg/kg)	Species	Method	Exposure time (h)
citric acid monohydrate	LD 50	5400	Mouse	OECD 401 (EU B.1)	

Acute dermal toxicity

Ingredient(s)	Endpoint	Value (mg/kg)	Species	Method	Exposure time (h)
citric acid monohydrate	LD 50	> 2000	Rat	OECD 402 (EU B.3)	

Acute inhalative toxicity

Ingredient(s)	Endpoint	Value (mg/l)	Species	Method	Exposure time (h)
citric acid monohydrate		No data			
		available			

Irritation and corrosivity

Skin irritation and corrosivity

Ingredient(s)	Result	Species	Method	Exposure time
citric acid monohydrate	Not irritant	Rabbit	OECD 404 (EU B.4)	

Eye irritation and corrosivity

Ingredient(s)	Result	Species	Method	Exposure time
citric acid monohydrate	Irritant	Rabbit	OECD 405 (EU B.5)	

Respiratory tract irritation and corrosivity

Ingredient(s)	Result	Species	Method	Exposure time
citric acid monohydrate	No data available			

Sensitisation

Sensitisation by skin contact

Ingredient(s)	Result	Species	Method	Exposure time (h)
citric acid monohydrate	Not sensitising	Guinea pig	Method not given	

Sensitisation by inhalation

Ingredient(s)	Result	Species	Method	Exposure time
citric acid monohydrate	Not sensitising		Weight of evidence	

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Mutagenicity			

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

citric acid monohydrate	No evidence for mutagenicity, negative	Method not	No evidence of genotoxicity, negative	Method not
	test results	given	test results	given

Carcinogenicity

Ingredient(s)	Effect
citric acid monohydrate	No evidence for carcinogenicity, negative test results

Toxicity for reproduction

Ingredient(s)	Endpoint	Specific effect	Value (mg/kg bw/d)	Species	Method	Exposure time	Remarks and other effects reported
citric acid monohydrate			No data				No evidence for reproductive
			available				toxicity

Repeated dose toxicity

Sub-acute or sub-chronic oral toxicity

Ingredient(s)	Endpoint	Value (mg/kg bw/d)	Species	Method	Exposure time (days)	Specific effects and organs affected
citric acid monohydrate	NOAEL	4000	Rat	Method not given	5	

Sub-chronic dermal toxicity

Sub-critoric definal toxicity						
Ingredient(s)	Endpoint	Value	Species	Method		Specific effects and organs
		(mg/kg bw/d)			time (days)	affected
citric acid monohydrate		No data				
		available				

Sub-chronic inhalation toxicity

oub childric initialation toxicity						
Ingredient(s)	Endpoint	Value	Species	Method	Exposure	Specific effects and organs
		(mg/kg bw/d)			time (days)	affected
citric acid monohydrate		No data				
		available				

Chronic toxicity

Childric toxicity								
Ingredient(s)	Exposure	Endpoint	Value	Species	Method	Exposure	Specific effects and	Remark
	route		(mg/kg bw/d)			time	organs affected	
citric acid monohydrate	Oral		2000	Rat	Method not	90 day(s)	No effects observed	
					given			

STOT-single exposure

Ingredient(s)	Affected organ(s)
citric acid monohydrate	Not applicable

STOT-repeated exposure

Ingredient(s)	Affected organ(s)
citric acid monohydrate	Not applicable

Aspiration hazard

Substances with an aspiration hazard (H304), if any, are listed in section 3. If relevant, see section 9 for dynamic viscosity and relative density of the product.

Potential adverse health effects and symptoms

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

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)
citric acid monohydrate	LC 50	440	Leuciscus idus	OECD 203 (EU C.1)	48

Aquatic short-term toxicity - crustacea

Aquatic short-term toxicity - crustacea					
Ingredient(s)	Endpoint	Value	Species	Method	Exposure
		(mg/l)			time (h)
citric acid monohydrate	LC 50	1535	Daphnia	Method not given	24
			magna Straus	-	

Aquatic short-term toxicity - algae

Ingredient(s)	Endpoint	Value (mg/l)	Species	Method	Exposure time (h)
citric acid monohydrate	LC 50	425	Scenedesmus	Method not given	168

						quadri	cauda			
quatic short-term toxicity - marine species										
Ingredient(s) citric acid monohydrate			Endpoint	(mg	Value (mg/l) No data available		Species		Method	
npact on sewage plants - toxicity to bacteria				•	•					•
Ingredient(s)			Endpoint	-	Value (mg/l)		lum	Method		Exposure
citric acid monohydrate			EC o		0000	Pseudomonas Met		Meth	nod not given	16 hour(s
Aquatic long-term toxicity										
quatic long-term toxicity - fish Ingredient(s)	Endpoint	Valu		pecies	Me	thod	Expo		Effects ob	served
citric acid monohydrate		(mg/ No da availa	ata				tim	e		
							•	'		
quatic long-term toxicity - crustacea Ingredient(s)	Endpoint	Valu		pecies	Me	thod	Expo	sure	Effects ob	served
citric acid monohydrate		(mg/ No da availa	ata				tim	е		
							1			
quatic toxicity to other aquatic benthic organisms, inclu Ingredient(s)	ding sediment Endpoint	Valu	ie S	if available pecies		thod	Expo		Effects ob	served
		(mg/kg sedime	ent)				time (c	lays)		
citric acid monohydrate		No da availa					_			
errestrial toxicity										
errestrial toxicity - soil invertebrates, including earthwor Ingredient(s)	ms, if availabl	e: Valu	ıe S	pecies	Me	thod	Expo	SUITA	Effects ob	served
ingredient(s)	Liiupoiiit	(mg/kg soil	j dw	peoles		illou	time (c		Life of S	SCI VCU
citric acid monohydrate		No da availa					-			
errestrial toxicity - plants, if available:										
Ingredient(s)	Endpoint	Valu (mg/kg	dw	pecies	Me	thod	Expos time (c		Effects ob	served
citric acid monohydrate		Soil No da availa	ata				-			
orrestrial toxicity, birds, if available:	•	•	•		•		•			
errestrial toxicity - birds, if available: Ingredient(s)	Endpoint	Valu	e S	pecies	Me	thod	Expo		Effects ob	served
citric acid monohydrate		No da availa					time (c			
		avalla	bie				1			
errestrial toxicity - beneficial insects, if available: Ingredient(s)	Endpoint	Valu		pecies	Me	thod	Expo		Effects ob	served
citric acid monohydrate		(mg/kg soil)				time (c	• /		
citic acid monoriyurate		No da availa					_			
errestrial toxicity - soil bacteria, if available:										
Ingredient(s)	Endpoint	Valu (mg/kg soil	j dw	pecies	Me	thod	Expo		Effects ob	served
citric acid monohydrate		No da availa	ata				-			
2.2 Persistence and degradability biotic degradation biotic degradation - photodegradation in air, if available biotic degradation - hydrolysis, if available:	e:		ļ		•		•	•		
biotic degradation - other processes, if available:										
iodegradation eady biodegradability - aerobic conditions			A		DT		No. ci	-1		-4:
Ingredient(s)	Inoculum		Analytical		DT 50		Metho	a	Evalua	ation

	method			
citric acid monohydrate	Method not given	97 % in 28 day(s)	Method not given	Readily biodegradable

Ready biodegradability - anaerobic and marine conditions, if available:

Degradation in relevant environmental compartments, if available:

12.3 Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

Ingredient(s)	Value	Method	Evaluation	Remark
citric acid monohydrate	-1.72	Method not given	No bioaccumulation expected	

Bioconcentration factor (BCF)

_ 5	bloconcentration factor (bot)										
	Ingredient(s)	Value	Species	Method	Evaluation	Remark					
- [citric acid monohydrate	No data available									

12.4 Mobility in soil

Adsorption/Desorption to soil or sediment

Ingredient(s)	Adsorption coefficient Log Koc	Desorption coefficient Log Koc(des)	Method	Soil/sediment type	Evaluation
citric acid monohydrate	-				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 Other adverse effects

No other adverse effects known.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Waste from residues / unused

European Waste Catalogue:

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. 16 03 05* - organic wastes containing dangerous substances.

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: 3265

14.2 UN proper shipping name:

Corrosive liquid, acidic, organic, n.o.s. (citric acid)

14.3 Transport hazard class(es):

Class: 8 Label(s): 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 Transport in bulk according to Annex II of MARPOL and the IBC Code: The product is not transported in bulk tankers.

Other relevant information:

ADR

Classification code: C3
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:

- Directive 93/42/EEC on medical devices
- Regulation (EC) No 1272/2008 CLP
- Regulation (EC) No. 1907/2006 REACH

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

Ingredients according to EC Detergents Regulation 648/2004

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: MSDS4535 Version: 02.2 Revision: 2018-01-25

Reason for revision:

This data sheet contains changes from the previous version in section(s):, 2, 3, 16

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.

Full text of the H and EUH phrases mentioned in section 3:

• H319 - Causes serious eye irritation.

Abbreviations and acronyms:

- · AISE The international Association for Soaps, Detergents and Maintenance Products
- DNEL Derived No Effect Limit
- EUH CLP Specific hazard statement
- PBT Persistent, Bioaccumulative and Toxic
- PNEC Predicted No Effect Concentration
 REACH number REACH registration number, without supplier specific part
- vPvB very Persistent and very Bioaccumulative
- ATE Acute Toxicity Estimate

End of Safety Data Sheet