

according to Regulation (EC) No. 1907/2006

Revision Date 10.09.2018

Version 6.2

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

1.1 Product identifier

Catalogue No. 115525

Product name RINGER tablets for the preparation of RINGER'S solution

REACH Registration Number This product is a mixture. REACH Registration Number see section 3.

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

Identified uses Reagent for analysis

For additional information on uses please refer to the Merck Chemicals

portal (www.merckgroup.com).

1.3 Details of the supplier of the safety data sheet

Merck KGaA * 64271 Darmstadt * Germany * Phone:+49 6151 72-0 Company

Responsible Department LS-QHC * e-mail: prodsafe@merckgroup.com

1.4 Emergency telephone

number

Please contact the regional company representation in your country.

SECTION 2. Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Eye irritation, Category 2, H319

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

according to Regulation (EC) No. 1907/2006

Catalogue No. 115525

Product name RINGER tablets for the preparation of RINGER'S solution

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



Signal word

Warning

Hazard statements

H319 Causes serious eye irritation.

Precautionary statements

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.

Reduced labelling (≤125 ml)

Hazard pictograms



Signal word
Warning

2.3 Other hazards

None known.

SECTION 3. Composition/information on ingredients

Chemical nature

Mixture of inorganic compounds

3.1 Substance

Not applicable

according to Regulation (EC) No. 1907/2006

Catalogue No. 115525

Product name RINGER tablets for the preparation of RINGER'S solution

3.2 Mixture

Hazardous components (REGULATION (EC) No 1272/2008)

Chemical name (Concentration)

CAS-No. Registration number Classification

ammonium chloride (>= 20 % - < 25 %)

Substance does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

12125-02-9 01-2119489385-24-

XXXX Acute toxicity, Category 4, H302

Eye irritation, Category 2, H319

calcium chloride (>= 1 % - < 3 %)

PBT/vPvB: Not applicable for inorganic substances

10043-52-4 01-2119494219-28- Eye irritation, Category 2, H319

XXXX

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

After inhalation: fresh air.

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/shower.

After eye contact: rinse out with plenty of water. Call in ophthalmologist. Remove contact lenses.

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

irritant effects

according to Regulation (EC) No. 1907/2006

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Product name RINGER tablets for the preparation of RINGER'S solution

The following applies to ammonium salts in general: after swallowing: local irritation symptoms, nausea, vomiting, diarrhoea. Systemic effect: after the uptake of very large quantities: drop in blood pressure, collapse, CNS disorders, spasms, narcotic conditions, respiratory paralysis, haemolysis.

4.3 Indication of any immediate medical attention and special treatment needed

No information available.

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

For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

Not combustible.

Ambient fire may liberate hazardous vapours.

Fire may cause evolution of:

Hydrogen chloride gas, nitrogen oxides

5.3 Advice for firefighters

Special protective equipment for firefighters

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

Further information

Suppress (knock down) gases/vapours/mists with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground water system.

SECTION 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Avoid inhalation of dusts. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.

according to Regulation (EC) No. 1907/2006

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Product name RINGER tablets for the preparation of RINGER'S solution

Advice for emergency responders:

Protective equipment see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up dry. Dispose of properly. Clean up affected area. Avoid generation of dusts.

6.4 Reference to other sections

Indications about waste treatment see section 13.

SECTION 7. Handling and storage

7.1 Precautions for safe handling

Advice on safe handling

Observe label precautions.

Hygiene measures

Change contaminated clothing. Wash hands after working with substance.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Tightly closed. Dry.

Recommended storage temperature see product label.

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

SECTION 8. Exposure controls/personal protection

8.1 Control parameters

according to Regulation (EC) No. 1907/2006

Catalogue No. 115525

Product name RINGER tablets for the preparation of RINGER'S solution

Derived No Effect Level (DNEL)

ammonium chloride (12125-02-9)

Worker DNEL, Systemic effects inhalation 43,97 mg/m³

longterm

Worker DNEL, Systemic effects dermal 128,9 mg/kg Body weight

longterm

Consumer DNEL, Systemic effects inhalation 9,4 mg/m³

longterm

Consumer DNEL, Systemic effects dermal 55,2 mg/kg Body weight

longterm

Consumer DNEL, Systemic effects oral 55,2 mg/kg Body weight

longterm

calcium chloride (10043-52-4)

Worker DNEL, Local effects inhalation 5 mg/m³

longterm

Worker DNEL, acute Local effects inhalation 10 mg/m³

Consumer DNEL, Local effects inhalation 2,5 mg/m³

longterm

Consumer DNEL, Local effects inhalation 5 mg/m³

acute

Predicted No Effect Concentration (PNEC)

ammonium chloride (12125-02-9)

PNEC Fresh water 0,25 mg/l

PNEC Fresh water sediment 0,9 mg/kg

PNEC Marine water 0,025 mg/l

PNEC Marine sediment 0,09 mg/kg

PNEC Aquatic intermittent release 0,43 mg/l

PNEC Soil 50,7 mg/kg

PNEC Sewage treatment plant 13,1 mg/l

8.2 Exposure controls

Engineering measures

according to Regulation (EC) No. 1907/2006

Catalogue No. 115525

Product name RINGER tablets for the preparation of RINGER'S solution

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

See section 7.1.

Individual protection measures

Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of the hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier.

Eye/face protection

Safety glasses

Hand protection

full contact:

Glove material: Nitrile rubber

Glove thickness: 0,11 mm

Break through time: > 480 min

splash contact:

Glove material: Nitrile rubber

Glove thickness: 0,11 mm

Break through time: > 480 min

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374, for example KCL 741 Dermatril® L (full contact), KCL 741 Dermatril® L (splash contact).

The breakthrough times stated above were determined by KCL in laboratory tests acc. to EN374 with samples of the recommended glove types.

This recommendation applies only to the product stated in the safety data sheet<(>,<)> supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).

Other protective equipment protective clothing

according to Regulation (EC) No. 1907/2006

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Product name RINGER tablets for the preparation of RINGER'S solution

Respiratory protection

required when dusts are generated.

Recommended Filter type: Filter P 1 (acc. to DIN 3181) for solid particles of inert substances. The entrepeneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.

Environmental exposure controls

Do not let product enter drains.

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form tablets

Colour white

Odour odourless

Odour Threshold Not applicable

pH ca. 7

at 2,5 g/l 20 °C

Melting point No information available.

Boiling point No information available.

Flash point Not applicable

Evaporation rate No information available.

according to Regulation (EC) No. 1907/2006

Catalogue No. 115525

Product name RINGER tablets for the preparation of RINGER'S solution

Flammability (solid, gas) The product is not flammable.

Lower explosion limit No information available.

Upper explosion limit No information available.

Vapour pressure No information available.

Relative vapour density No information available.

Density No information available.

Relative density No information available.

Water solubility at 20 °C

soluble

Partition coefficient: n-

octanol/water

No information available.

Auto-ignition temperature No information available.

Decomposition temperature No information available.

Viscosity, dynamic No information available.

Explosive properties Not classified as explosive.

Oxidizing properties none

9.2 Other data

none

SECTION 10. Stability and reactivity

10.1 Reactivity

See section 10.3

according to Regulation (EC) No. 1907/2006

Catalogue No. 115525

Product name RINGER tablets for the preparation of RINGER'S solution

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature) .

10.3 Possibility of hazardous reactions

no information available

10.4 Conditions to avoid

no information available

10.5 Incompatible materials

no information available

10.6 Hazardous decomposition products

in the event of fire: See section 5.

SECTION 11. Toxicological information

11.1 Information on toxicological effects

Mixture

Acute oral toxicity

Acute toxicity estimate: > 2.000 mg/kg

Calculation method

Acute inhalation toxicity

Symptoms: Possible damages:, mucosal irritations

Acute dermal toxicity

This information is not available.

Skin irritation

This information is not available.

Eye irritation

Mixture causes serious eye irritation.

Sensitisation

This information is not available.

according to Regulation (EC) No. 1907/2006

Catalogue No. 115525

Product name RINGER tablets for the preparation of RINGER'S solution

Germ cell mutagenicity

This information is not available.

Carcinogenicity

This information is not available.

Reproductive toxicity

This information is not available.

Teratogenicity

This information is not available.

Specific target organ toxicity - single exposure

This information is not available.

Specific target organ toxicity - repeated exposure

This information is not available.

Aspiration hazard

This information is not available.

11.2 Further information

The following applies to ammonium salts in general: after swallowing: local irritation symptoms, nausea, vomiting, diarrhoea. Systemic effect: after the uptake of very large quantities: drop in blood pressure, collapse, CNS disorders, spasms, narcotic conditions, respiratory paralysis, haemolysis.

Other dangerous properties can not be excluded.

Handle in accordance with good industrial hygiene and safety practice.

Components

ammonium chloride

Acute oral toxicity

LD50 Rat: 1.410 mg/kg

OECD Test Guideline 401

Acute dermal toxicity LD50 Rat: > 2.000 mg/kg (ECHA)

according to Regulation (EC) No. 1907/2006

Catalogue No. 115525

Product name RINGER tablets for the preparation of RINGER'S solution

Skin irritation

Rabbit

Result: No skin irritation

Draize Test

Eye irritation

Rabbit

Result: Eye irritation

OECD Test Guideline 405

Sensitisation

Maximisation Test Guinea pig

Result: negative

(ECHA)

Repeated dose toxicity

Rat

male and female

Oral

90 d

daily

NOAEL: 1.695,7 mg/kg OECD Test Guideline 408

Subchronic toxicity

Germ cell mutagenicity

Genotoxicity in vivo

Micronucleus test

Mouse

male

Intraperitoneal injection

Result: negative

Method: OECD Test Guideline 474

Genotoxicity in vitro

HGPRT (cell forward mutation assay)

Result: negative

Method: OECD Test Guideline 476

according to Regulation (EC) No. 1907/2006

Catalogue No. 115525

Product name RINGER tablets for the preparation of RINGER'S solution

Ames test

Escherichia coli/Salmonella typhimurium

Result: negative

Method: OECD Test Guideline 471

calcium chloride

Acute dermal toxicity

LD50 Rabbit: > 5.000 mg/kg

(ECHA)

Skin irritation

Rabbit

Result: No irritation

OECD Test Guideline 404

Eye irritation

Rabbit

Result: Eye irritation

OECD Test Guideline 405

Germ cell mutagenicity

Genotoxicity in vitro

Ames test

Result: negative

(Lit.)

SECTION 12. Ecological information

Mixture

12.1 Toxicity

No information available.

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

according to Regulation (EC) No. 1907/2006

Catalogue No. 115525

Product name RINGER tablets for the preparation of RINGER'S solution

Substance(s) in the mixture do(es) not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII, or a PBT/vPvB assessment was not conducted.

12.6 Other adverse effects

Discharge into the environment must be avoided.

Components

ammonium chloride

Toxicity to fish

LC50 Oncorhynchus mykiss (rainbow trout): 42,91 mg/l; 96 h

Analytical monitoring: yes

US-EPA

Toxicity to daphnia and other aquatic invertebrates

static test EC50 Daphnia magna (Water flea): > 100 mg/l; 48 h

Analytical monitoring: yes

(ECHA)

Toxicity to bacteria

static test EC50 activated sludge: 1.310 mg/l; 0,5 h

OECD Test Guideline 209

Toxicity to fish (Chronic toxicity)

flow-through test EC10 Lepomis macrochirus (Bluegill sunfish): 4,28 mg/l; 30 d

Analytical monitoring: yes

(ECHA)

Biodegradability

The methods for determining the biological degradability are not applicable to inorganic substances.

Partition coefficient: n-octanol/water

Not applicable for inorganic substances

Substance does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

calcium chloride

according to Regulation (EC) No. 1907/2006

Catalogue No. 115525

Product name RINGER tablets for the preparation of RINGER'S solution

Toxicity to fish

LC50 Lepomis macrochirus (Bluegill sunfish): 10.650 mg/l; 96 h

(IUCLID)

Toxicity to daphnia and other aquatic invertebrates EC50 Daphnia magna (Water flea): 144 mg/l; 48 h

(IUCLID)

Toxicity to algae

IC50 algae: 3.130 mg/l; 120 h

(IUCLID)

PBT/vPvB: Not applicable for inorganic substances

SECTION 13. Disposal considerations

Waste treatment methods

See www.retrologistik.com for processes regarding the return of chemicals and containers, or contact us there if you have further questions.

SECTION 14. Transport information

Land transport (ADR/RID)

14.1 - 14.6 Not classified as dangerous in the meaning of transport

regulations.

Inland waterway transport (ADN)

Not relevant

Air transport (IATA)

14.1 - 14.6 Not classified as dangerous in the meaning of transport

regulations.

Sea transport (IMDG)

according to Regulation (EC) No. 1907/2006

Catalogue No. 115525

Product name RINGER tablets for the preparation of RINGER'S solution

14.1 - 14.6 Not classified as dangerous in the meaning of transport

regulations.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not relevant

SECTION 15. Regulatory information

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

EU regulations

Major Accident Hazard SEVESO III

Legislation Not applicable

Occupational restrictions Take note of Dir 94/33/EC on the protection of young people at

work.

Regulation (EC) No 1005/2009 on substances that not regulated

deplete the ozone layer

Regulation (EC) No 850/2004 of the European not regulated

Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending

Directive 79/117/EEC

Substances of very high concern (SVHC)

This product does not contain substances

of very high concern according to

Regulation (EC) No 1907/2006 (REACH), Article 57 above the respective regulatory concentration limit of \geq 0.1 % (w/w).

National legislation

Storage class 10 - 13

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out.

according to Regulation (EC) No. 1907/2006

Catalogue No. 115525

Product name RINGER tablets for the preparation of RINGER'S solution

SECTION 16. Other information

Full text of H-Statements referred to under sections 2 and 3.

H302 Harmful if swallowed.

H319 Causes serious eye irritation.

Training advice

Provide adequate information, instruction and training for operators.

Labelling

Hazard pictograms



Signal word

Warning

Hazard statements

H319 Causes serious eye irritation.

Precautionary statements

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.

Key or legend to abbreviations and acronyms used in the safety data sheet

Used abbreviations and acronyms can be looked up at www.wikipedia.org.

Regional representation

according to Regulation (EC) No. 1907/2006

Catalogue No. 115525

Product name RINGER tablets for the preparation of RINGER'S solution

This information is given on the authorised Safety Data Sheet for your country.

The information contained herein is based on the present state of our knowledge. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product.