

according to Regulation (EC) No. 1907/2006

Revision Date 11.01.2016

Version 5.3

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

1.1 Product identifier

Catalogue No.

100924

Product name

Ammonium chloride extra pure Ph Eur, BP, USP

REACH Registration Number 01-2119487950-27-XXXX

CAS-No.

12125-02-9

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

Identified uses

Pharmaceutical production, Cosmetic raw material

In compliance with the conditions described in the annex to this safety

data sheet.

1.3 Details of the supplier of the safety data sheet

Company

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

Responsible Department

EQ-RS * 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)

Acute toxicity, Category 4, Oral, H302 Eye irritation, Category 2, H319

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

Classification (67/548/EEC or 1999/45/EC)

Xn

Harmful

R22

Χi Irritant R36

For the full text of the R-phrases mentioned in this Section, see Section 16.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



Signal word Warning

Hazard statements H302 Harmful if swallowed. H319 Causes serious eye irritation.

according to Regulation (EC) No. 1907/2006

Catalogue No.

Product name

Ammonium chloride extra pure Ph Eur, BP, USP

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

Index-No.

017-014-00-8

2.3 Other hazards

None known.

SECTION 3. Composition/information on ingredients

3.1 Substance

Formula

NH₄CI

H₄CIN (Hill)

Index-No.

017-014-00-8

EC-No.

235-186-4

Molar mass

53,49 g/mol

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

Chemical Name (Concentration)

CAS-No.

Registration number

Classification

ammonium chloride (<= 100 %)

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

12125-02-9

01-2119487950-27-

XXXX

Acute toxicity, Category 4, H302 Eye irritation, Category 2, H319

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

Hazardous components (1999/45/EC)

Chemical Name (Concentration)

CAS-No.

Classification

ammonium chloride (<= 100 %)

12125-02-9

Xn, Harmful; R22

Xi, Irritant; R36

For the full text of the R-phrases mentioned in this Section, see Section 16.

3.2 Mixture

Not applicable

according to Regulation (EC) No. 1907/2006

Catalogue No.

100924

Product name

Ammonium chloride extra pure Ph Eur, BP, USP

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.

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

The following applies to ammonium salts in general: after swallowing: local irritation symptoms, nausea, vomiting, diarrhoea. Systemic effect: after the uptake of very large qantities: 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:

nitrogen oxides, Hydrogen chloride gas

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.

Advice for emergency responders: Protective equipment see section 8.

6.2 Environmental precautions

according to Regulation (EC) No. 1907/2006

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100924

Product name

Ammonium chloride extra pure Ph Eur, BP, USP

Do not empty into 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. Preventive skin protection recommended. 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)

See exposure scenario in the Annex to this MSDS.

SECTION 8. Exposure controls/personal protection

8.1 Control parameters

Derived No Effect Level (DNEL)

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

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

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

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

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

Predicted No Effect Concentration (PNEC)

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

according to Regulation (EC) No. 1907/2006

Catalogue No.

100924

Product name

Ammonium chloride extra pure Ph Eur, BP, USP

Engineering measures

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

Respiratory protection

required when dusts are generated.

Recommended Filter type: Filter P 2 (acc. to DIN 3181) for solid and liquid particles of harmful 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 empty into drains.

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form

Crystalline powder

Colour

white

according to Regulation (EC) No. 1907/2006

Catalogue No.

100924

Product name

Ammonium chloride extra pure Ph Eur, BP, USP

Odour

odourless

Odour Threshold

Not applicable

рΗ

ca. 4,7 at 200 g/l 25 °C

(External MSDS)

Melting point

338 °C

(sublimed), (External MSDS)

Boiling point/boiling range

Not applicable

Flash point

Not applicable

Evaporation rate

No information available.

Flammability (solid, gas)

The product is not flammable.

Lower explosion limit

No information available.

Upper explosion limit

No information available.

Vapour pressure

66 hPa at 250 °C (External MSDS)

1,3 hPa at 30 °C

Relative vapour density

No information available.

Density

1,53 g/cm3 at 25 °C

Relative density

No information available.

Water solubility

372 g/l at 20 °C

(External MSDS)

Partition coefficient: n-

octanol/water

log Pow: -3,2 (25 °C)

(experimental)

(ECHA) Bioaccumulation is not expected.

Auto-ignition temperature

No information available.

Decomposition temperature

Not applicable

Viscosity, dynamic

No information available.

Explosive properties

Not classified as explosive.

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Product name

Ammonium chloride extra pure Ph Eur, BP, USP

Oxidizing properties

none

9.2 Other data

Ignition temperature

> 400 °C

Bulk density

ca.600 - 900 kg/m3

Particle size

Mean particle size

0,116 mm

SECTION 10. Stability and reactivity

10.1 Reactivity

See section 10.3

10.2 Chemical stability

sublimable

10.3 Possibility of hazardous reactions

Violent reactions possible with:

alkali hydroxides, acids

Risk of ignition or formation of inflammable gases or vapours with:

halogen-halogen compounds, alkalines, alkaline substances

Risk of explosion with:

nitrates, chlorates, Heavy metal salts, nitrites, Hydrogen cyanide (hydrocyanic acid), Chlorine, silver salt, Strong oxidizing agents

10.4 Conditions to avoid

no information available

10.5 Incompatible materials

Aluminium, Lead, Iron, Copper, copper compounds

10.6 Hazardous decomposition products

in the event of fire: See section 5.

SECTION 11. Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity
LD50 Rat: 1.410 mg/kg
OECD Test Guideline 401

Symptoms: Irritations of mucous membranes in the mouth, pharynx, oesophagus and gastrointestinal tract.

absorption

Acute inhalation toxicity

Symptoms: Possible damages:, mucosal irritations

Acute dermal toxicity

This information is not available.

according to Regulation (EC) No. 1907/2006

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Product name

Ammonium chloride extra pure Ph Eur, BP, USP

Skin irritation

Rabbit

Result: No skin irritation

Draize Test

Eye irritation

Rabbit

Result: Eye irritation OECD Test Guideline 405 Causes serious eye irritation.

Sensitisation

Maximisation Test (GPMT) Guinea pig

Result: negative

(ECHA)

Germ cell mutagenicity Genotoxicity in vivo Micronucleus test

Mouse

male

Intraperitoneal injection

Bone marrow Result: negative

Method: OECD Test Guideline 474

Genotoxicity in vitro

HGPRT (cell forward mutation assay)

Result: negative

Method: OECD Test Guideline 476

Ames test

Escherichia coli/Salmonella typhimurium

Result: negative

Method: OECD Test Guideline 471

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.

Repeated dose toxicity

Rat

male and female

Oral 90 d

daily

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

Subchronic toxicity

according to Regulation (EC) No. 1907/2006

Catalogue No.

100924

Product name

Ammonium chloride extra pure Ph Eur, BP, USP

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 qantities: 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.

SECTION 12. Ecological information

12.1 Toxicity

Toxicity to fish

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

Analytical monitoring: yes

(ECHA)

Toxicity to daphnia and other aquatic invertebrates

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

Analytical monitoring: yes

(ECHA)

Toxicity to algae

static test EC50 Chlorella vulgaris (Fresh water algae): 1.300 mg/l; 5 d

(ECHA) (in analogy to similar products)

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)

12.2 Persistence and degradability

Biodegradability

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

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water

log Pow: -3,2 (25 °C)

(experimental)

(ECHA) Bioaccumulation is not expected.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

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

12.6 Other adverse effects

Discharge into the environment must be avoided.

according to Regulation (EC) No. 1907/2006

Catalogue No

100924

Product name

Ammonium chloride extra pure Ph Eur, BP, USP

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)

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.

Observe work restrictions regarding maternity protection in

accordance to Dir 92/85/EEC or stricter national regulations where

applicable.

Regulation (EC) No 1005/2009 on substances that

not regulated

deplete the ozone layer

Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending

not regulated

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).

according to Regulation (EC) No. 1907/2006

Catalogue No.

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Product name

Ammonium chloride extra pure Ph Eur, BP, USP

National legislation

Storage class

10 - 13

15.2 Chemical Safety Assessment

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

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.

Full text of R-phrases referred to under sections 2 and 3

R22

Harmful if swallowed.

R36

Irritating to eyes.

Training advice

Provide adequate information, instruction and training for operators.

Labelling

Hazard pictograms



Signal word

Warning

Hazard statements

H302 Harmful if swallowed.

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.

Labelling (67/548/EEC or 1999/45/EC)

Symbol(s)

Xn

Harmful

R-phrase(s)

22-36

Harmful if swallowed. Irritating to eyes.

S-phrase(s)

22

Do not breathe dust.

EC-No.

235-186-4

EC Label

Reduced labelling (≤125 ml)

Symbol(s)

Xn

Harmful

R-phrase(s) 22

Harmful if swallowed.

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

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

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Product name

Ammonium chloride extra pure Ph Eur, BP, USP

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

Regional representation

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.

Catalogue No.

100924

Product name

Ammonium chloride extra pure Ph Eur, BP, USP

EXPOSURE SCENARIO 1 (Industrial use)

1. industrial use (Pharmaceutical production, Cosmetic raw material)

Sectors of end-use

SU3

Industrial uses: Uses of substances as such or in preparations at industrial sites

SU 10

Formulation [mixing] of preparations and/ or re-packaging (excluding alloys)

Chemical product category

PC19

Intermediate

PC39

Cosmetics, personal care products

Process categories

PROC1

Use in closed process, no likelihood of exposure

PROC2

Use in closed, continuous process with occasional controlled exposure

PROC3

Use in closed batch process (synthesis or formulation)

PROC4

Use in batch and other process (synthesis) where opportunity for exposure arises Mixing or blending in batch processes for formulation of preparations and articles

PROC5

(multistage and/ or significant contact)

Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at non-dedicated facilities

PROC8a PROC8b

Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large

containers at dedicated facilities

PROC9

Transfer of substance or preparation into small containers (dedicated filling line, including

weighing)

PROC14

Production of preparations or articles by tabletting, compression, extrusion, pelletisation

PROC15 Use as laboratory reagent

Environmental Release Categories

ERC1

Manufacture of substances

ERC2

Formulation of preparations

ERC4

Industrial use of processing aids in processes and products, not becoming part of articles

ERC6a

Industrial use resulting in manufacture of another substance (use of intermediates)

ERC6b Industrial use of reactive processing aids

Contributing scenarios: Operational conditions and risk management measures

2.1 Contributing scenario controlling worker exposure for: PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC14, PROC15

Product characteristics

Mixture/Article

Concentration of the Substance in

Covers the percentage of the substance in the product up to

100 %.

Physical Form (at time of use)

Solid, medium dustiness

Frequency and duration of use

Frequency of use

5 days/week

Frequency of use

8 hours/day

Other operational conditions affecting workers exposure

Outdoor / Indoor

Indoor without local exhaust ventilation (LEV)

Organisational measures to prevent /limit releases, dispersion and exposure

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

Catalogue No. Product name

100924

Ammonium chloride extra pure Ph Eur, BP, USP

Covers daily exposures up to 8 hours.

Conditions and measures related to personal protection, hygiene and health evaluation Use suitable eye protection.

3. Exposure estimation and reference to its source

Environment

A chemical safety assessment was performed according REACH Article 14(3), Annex I, sections 3 (Environmental Hazard Assessment) and 4 (PBT/vPvB Assessment). As no hazard was identified, an exposure assessment and risk characterisation is not necessary (REACH Annex I section 5.0).

Workers

CS	Use descriptor	Exposure duration, route, effect	RCR	Exposure Assessment Method
2.1	PROC1	longterm, inhalative, systemic	< 0,02	ECETOC TRA
		longterm, dermal, systemic	< 0,003	ECETOC TRA
		longterm, combined, systemic	< 0,02	
2.1	PROC2	longterm, inhalative, systemic	0,01	ECETOC TRA
		longterm, dermal, systemic	0,01	ECETOC TRA
		longterm, combined, systemic	0,02	
2.1	PROC3	longterm, inhalative, systemic	0,02	ECETOC TRA
		longterm, dermal, systemic	0,003	ECETOC TRA
		longterm, combined, systemic	0,023	
2.1	PROC4	longterm, inhalative, systemic	0,11	ECETOC TRA
		longterm, dermal, systemic	0,05	ECETOC TRA
		longterm, combined, systemic	0,16	
2.1	PROC5	longterm, inhalative, systemic	0,11	ECETOC TRA
		longterm, dermal, systemic	0,11	ECETOC TRA
		longterm, combined, systemic	0,22	
2.1	PROC8a	longterm, inhalative, systemic	0,11	ECETOC TRA
		longterm, dermal, systemic	0,11	ECETOC TRA
		longterm, combined, systemic	0,22	
2.1	PROC8b	longterm, inhalative, systemic	0,11	ECETOC TRA
		longterm, dermal, systemic	0,05	ECETOC TRA
		longterm, combined, systemic	0,16	
2.1	PROC9	longterm, inhalative, systemic	0,11	ECETOC TRA
		longterm, dermal, systemic	0,05	ECETOC TRA
		longterm, combined, systemic	0,16	
2.1	PROC14	longterm, inhalative, systemic	0,02	ECETOC TRA
		longterm, dermal, systemic	0,03	ECETOC TRA
		longterm, combined, systemic	0,05	
2.1	PROC15	longterm, inhalative, systemic	0,01	ECETOC TRA
		longterm, dermal, systemic	0,003	ECETOC TRA
		longterm, combined, systemic	0,013	

The default parameters and -efficiencies of the applied exposure assessment model were used for the calculation (unless stated differently).

For (other) local effects risk management measures are based on qualitative risk characterisation.

4. Guidance to Downstream User to evaluate whether he works inside the boundaries set by the Exposure Scenario

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

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Product name

Ammonium chloride extra pure Ph Eur, BP, USP

Please refer to the following documents: ECHA Guidance on information requirements and chemical safety assessment Chapter R.12: Use descriptor system; ECHA Guidance for downstream users; ECHA Guidance on information requirements and chemical safety assessment Part D: Exposure Scenario Building, Part E: Risk Characterisation and Part G: Extending the SDS; VCI/Cefic REACH Practical Guides on Exposure Assessment and Communications in the Supply Chain; CEFIC Guidance Specific Environmental Release Categories (SPERCs).

For scaling of worker exposure assessments performed with ECETOC TRA, please consult the Merck tool ScIDeEx® at www.merckmillipore.com/scideex.

SAFETY DATA SHEET - Annex

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Product name

Ammonium chloride extra pure Ph Eur, BP, USP

EXPOSURE SCENARIO 2 (Professional use)

1. Professional use (Pharmaceutical production, Cosmetic raw material)

Sectors of end-use

SU 22

Professional uses: Public domain (administration, education, entertainment, services,

craftsmen)

Chemical product category

PC39

Cosmetics, personal care products

Environmental Release Categories

ERC8a

Wide dispersive indoor use of processing aids in open systems

ERC8d Wide dispersive outdoor use of processing aids in open systems

2. Contributing scenarios: Operational conditions and risk management measures

3. Exposure estimation and reference to its source

Environment

A chemical safety assessment was performed according REACH Article 14(3), Annex I, sections 3 (Environmental Hazard Assessment) and 4 (PBT/vPvB Assessment). As no hazard was identified, an exposure assessment and risk characterisation is not necessary (REACH Annex I section 5.0).

In accordance with REACH Article 14(5b), exposure estimations and risk characterizations for human health do not need to be performed for uses of substances in cosmetic products which are under the scope of Directive 76/768/EEC.

4. Guidance to Downstream User to evaluate whether he works inside the boundaries set by the Exposure Scenario

Please refer to the following documents: ECHA Guidance on information requirements and chemical safety assessment Chapter R.12: Use descriptor system; ECHA Guidance for downstream users; ECHA Guidance on information requirements and chemical safety assessment Part D: Exposure Scenario Building, Part E: Risk Characterisation and Part G: Extending the SDS; VCI/Cefic REACH Practical Guides on Exposure Assessment and Communications in the Supply Chain; CEFIC Guidance Specific Environmental Release Categories (SPERCs).

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

Catalogue No.

100924

Product name

Ammonium chloride extra pure Ph Eur, BP, USP

EXPOSURE SCENARIO 3 (Consumer use)

1. Consumer use (Pharmaceutical production, Cosmetic raw material)

Sectors of end-use

SU 21

Consumer uses: Private households (= general public = consumers)

Chemical product category

PC39

Cosmetics, personal care products

Environmental Release Categories

ERC8a

Wide dispersive indoor use of processing aids in open systems

ERC8d

Wide dispersive outdoor use of processing aids in open systems

2. Contributing scenarios: Operational conditions and risk management measures

3. Exposure estimation and reference to its source

Environment

A chemical safety assessment was performed according REACH Article 14(3), Annex I, sections 3 (Environmental Hazard Assessment) and 4 (PBT/vPvB Assessment). As no hazard was identified, an exposure assessment and risk characterisation is not necessary (REACH Annex I section 5.0).

In accordance with REACH Article 14(5b), exposure estimations and risk characterizations for human health do not need to be performed for uses of substances in cosmetic products which are under the scope of Directive 76/768/EEC.

Guidance to Downstream User to evaluate whether he works inside the boundaries set by the Exposure Scenario

Please refer to the following documents: ECHA Guidance on information requirements and chemical safety assessment Chapter R.12: Use descriptor system; ECHA Guidance for downstream users; ECHA Guidance on information requirements and chemical safety assessment Part D: Exposure Scenario Building, Part E: Risk Characterisation and Part G: Extending the SDS; VCI/Cefic REACH Practical Guides on Exposure Assessment and Communications in the Supply Chain; CEFIC Guidance Specific Environmental Release Categories (SPERCs).