SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Revision Date 26.05.2017 Version 9.3

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

1.1 Product identifier

Catalogue No.	101131
Product name	Ammonium hydrogen carbonate EMPROVE® ESSENTIAL Ph Eur,BP,E 503
REACH Registration Number	01-2119486970-26-XXXX
CAS-No.	1066-33-7

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	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)

Acute toxicity, Category 4, Oral, H302

For the full text of the H-Statements 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.

Reduced labelling (≤125 ml)

Hazard pictograms

Signal word

Warning

CAS-No. 1066-33-7

2.3 Other hazards

None known.

SECTION 3. Composition/information on ingredients

3.1 Substance

Formula	$(NH_4)HCO_3$	CH_5NO_3 (Hill)
EC-No.	213-911-5	
Molar mass	79,06 g/mol	

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

Chemical name (Concentration)

CAS-No. Registration number Classification

ammonium hydrogen carbonate *(<= 100 %)*

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

1066-33-7 01-2119486970-26-XXXX Acute toxicity, Category 4, H302

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

3.2 Mixture

Not applicable

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.

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, Nausea, Vomiting

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

5.3 Advice for firefighters

Special protective equipment for firefighters

In the event of fire, wear self-contained breathing apparatus.

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

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. 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, acute	Systemic effects	inhalation	160,7 mg/m³
Worker DNEL, acute	Local effects	inhalation	160,7 mg/m³
Worker DNEL, longterm	Systemic effects	inhalation	62,5 mg/m³
Worker DNEL, longterm	Local effects	inhalation	62,5 mg/m³
Worker DNEL, longterm	Systemic effects	dermal	57 mg/kg Body weight
Consumer DNEL, acute	Systemic effects	inhalation	143,91 mg/m³
Consumer DNEL, acute	Systemic effects	oral	34,05 mg/kg Body weight
Consumer DNEL, acute	Local effects	inhalation	143,91 mg/m³
Consumer DNEL, longterm	Systemic effects	dermal	34,2 mg/kg Body weight
Consumer DNEL, longterm	Systemic effects	inhalation	13,33 mg/m³
Consumer DNEL, longterm	Systemic effects	oral	17,1 mg/kg Body weight
Consumer DNEL, longterm	Local effects	inhalation	13,33 mg/m³

Predicted No Effect Concentration (PNEC)

PNEC Fresh water	0,37 mg/l
PNEC Fresh water sediment	0,1332 mg/kg
PNEC Marine water	0,037 mg/l
PNEC Marine sediment	0,01332 mg/kg
PNEC Aquatic intermittent release	0,63 mg/l
PNEC Soil	74,9 mg/kg
PNEC Sewage treatment plant	1347 mg/l

8.2 Exposure controls

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 let product enter drains.

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form	solid
Colour	colourless
Odour	ammoniacal
Odour Threshold	No information available.
pH	ca. 8 at 50 g/l 20 °C
Melting point	106 °C
Boiling point/boiling range	Not applicable
Flash point	does not flash
Evaporation rate	No information available.

Flammability (solid, gas)	The product is not flammable.
Lower explosion limit	Not applicable
Upper explosion limit	Not applicable
Vapour pressure	67 hPa at 20 °C
Relative vapour density	No information available.
Density	No information available.
Relative density	No information available.
Water solubility	220 g/l at 20 °C
Partition coefficient: n-octanol/water	log Pow: -2,4 (25 °C) OECD Test Guideline 107 Bioaccumulation is not expected. (IUCLID)
Auto-ignition temperature	No information available.
Decomposition temperature	ca.60 °C
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	none

9.2 Other data

Ignition temperature	Not applicable

SECTION 10. Stability and reactivity

10.1 Reactivity

See section 10.3

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

Violent reactions possible with:

nitrates, nitrites, Acids, alkalines

10.4 Conditions to avoid

Heating (decomposition).

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

Acute oral toxicity

LD50 Rat: 1.576 mg/kg

OECD Test Guideline 401

Symptoms: Nausea, Vomiting

absorption

Acute inhalation toxicity

This information is not available.

Acute dermal toxicity

This information is not available.

Skin irritation

This information is not available.

Eye irritation

Possible damages: slight irritation

Sensitisation

This information is not available.

Germ cell mutagenicity

Genotoxicity in vitro

Ames test

Salmonella typhimurium

Result: negative

Method: OECD Test Guideline 471

Mutagenicity (mammal cell test):

Result: negative

(External MSDS)

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 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): 173 mg/l; 96 h

(ECOTOX Database)

Toxicity to bacteria

EC50 Pseudomonas putida: 1.895 mg/l; 16 h

OECD Test Guideline 209

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water

log Pow: -2,4 (25 °C)

OECD Test Guideline 107

Bioaccumulation is not expected. (IUCLID)

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

Additional ecological information

Discharge into the environment must be avoided.

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 deplete the ozone layer	not regulated
Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC	not regulated
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 ≥ 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.

SECTION 16. Other information

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

H302 Harmful if swallowed.

Training advice

Provide adequate information, instruction and training for operators.

Labelling

Hazard pictograms

Signal word

Warning

Hazard statements

H302 Harmful if swallowed.

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

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.

EXPOSURE SCENARIO 1 (Industrial use)

1. Industrial use Pharmaceutical production, Cosmetic raw material)

Sectors of end-use

SU 3	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
PROC5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/ or significant contact)
PROC8a	Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at non-dedicated facilities
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

2. Contributing scenarios: Operational conditions and risk management measures

2.1 Contributing scenario controlling worker exposure for: PROC1, PROC2, PROC3, PROC14

Product characteristics

Concentration of the Substance in Mixture/Article	Covers the percentage of the substance in the product up to 100 %.
Physical Form (at time of use)	Solid, high dustiness

Frequency and duration of use

Frequency of use	8 hours/day
Frequency of use	5 days/week

Other operational conditions affecting workers exposure

Outdoor / Indoor	Indoor

Organisational measures to prevent /limit releases, dispersion and exposure

Covers daily exposures up to 8 hours.

2.2 Contributing scenario controlling worker exposure for: PROC4, PROC5, PROC8b, PROC9, PROC15

Product characteristics

Concentration of the Substance in Mixture/Article	Covers the percentage of the substance in the product up to 100 %.
Physical Form (at time of use)	Solid, high dustiness

Frequency and duration of use

Frequency of use	8 hours/day
Frequency of use	5 days/week

Other operational conditions affecting workers exposure

Outdoor / Indoor	Indoor

Organisational measures to prevent /limit releases, dispersion and exposure

Covers daily exposures up to 8 hours.

Conditions and measures related to personal protection, hygiene and health evaluation

Wear suitable gloves tested to EN374. Effectiveness (of a measure): 90 %

2.3 Contributing scenario controlling worker exposure for: PROC8a

Product characteristics

Concentration of the Substance in Mixture/Article	Covers the percentage of the substance in the product up to 100 %.
Physical Form (at time of use)	Solid, high dustiness

Frequency and duration of use

Frequency of use	8 hours/day
Frequency of use	5 days/week

Other operational conditions affecting workers exposure

Outdoor / Indoor	Indoor with local exhaust ventilation (LEV)

Organisational measures to prevent /limit releases, dispersion and exposure

Covers daily exposures up to 8 hours.

Conditions and measures related to personal protection, hygiene and health evaluation

Wear suitable gloves tested to EN374.

---

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, local	< 0,02	ECETOC TRA
		longterm, inhalative, systemic	< 0,02	ECETOC TRA
		longterm, dermal, systemic	< 0,02	ECETOC TRA
		longterm, combined, systemic	< 0,04	ECETOC TRA
2.1	PROC2	longterm, inhalative, local	0,02	ECETOC TRA
		longterm, inhalative, systemic	0,02	ECETOC TRA
		longterm, dermal, systemic	0,02	ECETOC TRA
		longterm, combined, systemic	0,04	ECETOC TRA
2.1	PROC3	longterm, inhalative, local	0,02	ECETOC TRA
		longterm, inhalative, systemic	0,02	ECETOC TRA
		longterm, dermal, systemic	0,01	ECETOC TRA
		longterm, combined, systemic	0,03	ECETOC TRA
2.1	PROC14	longterm, inhalative, local	0,16	ECETOC TRA
		longterm, inhalative, systemic	0,16	ECETOC TRA
		longterm, dermal, systemic	0,06	ECETOC TRA
		longterm, combined, systemic	0,22	ECETOC TRA

2.2	PROC4	longterm, inhalative, local	0,4	ECETOC TRA, modified
		longterm, inhalative, systemic	0,4	ECETOC TRA, modified
		longterm, dermal, systemic	0,12	ECETOC TRA, modified
		longterm, combined, systemic	0,52	ECETOC TRA, modified
2.2	PROC5	longterm, inhalative, local	0,4	ECETOC TRA, modified
		longterm, inhalative, systemic	0,4	ECETOC TRA, modified
		longterm, dermal, systemic	0,24	ECETOC TRA, modified
		longterm, combined, systemic	0,64	ECETOC TRA, modified
2.2	PROC8b	longterm, inhalative, local	0,4	ECETOC TRA, modified
		longterm, inhalative, systemic	0,4	ECETOC TRA, modified
		longterm, dermal, systemic	0,12	ECETOC TRA, modified
		longterm, combined, systemic	0,52	ECETOC TRA, modified
2.2	PROC9	longterm, inhalative, local	0,32	ECETOC TRA, modified
		longterm, inhalative, systemic	0,32	ECETOC TRA, modified
		longterm, dermal, systemic	0,12	ECETOC TRA, modified
		longterm, combined, systemic	0,44	ECETOC TRA, modified
2.2	PROC15	longterm, inhalative, local	0,08	ECETOC TRA, modified
		longterm, inhalative, systemic	0,08	ECETOC TRA, modified
		longterm, dermal, systemic	0,01	ECETOC TRA, modified
		longterm, combined, systemic	0,09	ECETOC TRA, modified
2.3	PROC8a	longterm, inhalative, local	< 0,4	ECETOC TRA, modified
		longterm, inhalative, systemic	< 0,4	ECETOC TRA, modified
		longterm, dermal, systemic	<= 0,24	ECETOC TRA, modified
		longterm, combined, systemic	<= 0,64	ECETOC TRA, modified

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

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).

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

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).

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.

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).