

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Revision Date 06.06.2013

Version 18.0

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

1.1 Product identifier

Catalogue No. 106482

Product name Sodium hydroxide pellets suitable for use as excipient EMPROVE®
exp Ph Eur,BP,FCC,JP,NF,E 524

REACH Registration Number 01-2119457892-27-XXXX

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)

Skin corrosion, Category 1A, H314

Corrosive to metals, Category 1, H290

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

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

C Corrosive R35

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

Danger

Hazard statements

H290 May be corrosive to metals.

H314 Causes severe skin burns and eye damage.

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Precautionary statements

Prevention

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response

P301 + P330 + P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P309 + P310 IF exposed or if you feel unwell: Immediately call a POISON CENTER or doctor/physician.

Reduced labelling (≤125 ml)

Hazard pictograms



Signal word

Danger

Hazard statements

H314 Causes severe skin burns and eye damage.

Precautionary statements

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

P301 + P330 + P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P309 + P310 IF exposed or if you feel unwell: Immediately call a POISON CENTER or doctor/physician.

Index-No. 011-002-00-6

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

Symbol(s)	C	Corrosive
R-phrases(s)	35	Causes severe burns.
S-phrases(s)	26-37/39-45	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear suitable gloves and eye/face protection. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
EC-No.	215-185-5	EC Label

2.3 Other hazards

PBT/vPvB: Not applicable for inorganic substances

SECTION 3. Composition/information on ingredients

3.1 Substance

Formula	NaOH	HNaO (Hill)
CAS-No.	1310-73-2	
Index-No.	011-002-00-6	
EC-No.	215-185-5	

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Molar mass 40,00 g/mol

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

Chemical Name (Concentration)

CAS-No.	Registration number	Classification
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sodium hydroxide ($\leq 100\%$)

PBT/vPvB: Not applicable for inorganic substances

1310-73-2	01-2119457892-27-XXXX	Skin corrosion, Category 1A, H314 Corrosive to metals, Category 1, H290
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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
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sodium hydroxide ($\leq 100\%$)

1310-73-2 C, Corrosive; R35

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

3.2 Mixture

not applicable

SECTION 4. First aid measures

4.1 Description of first aid measures

General advice

First aider needs to protect himself.

After inhalation: fresh air. Get medical attention.

After skin contact: wash off with plenty of water. Remove contaminated clothing. Call a physician immediately.

After eye contact: rinse out with plenty of water. Immediately call in ophthalmologist.

After swallowing: make victim drink water (two glasses at most), avoid vomiting (risk of perforation). Call a physician immediately. Do not attempt to neutralise.

4.2 Most important symptoms and effects, both acute and delayed

Irritation and corrosion, Cough, Shortness of breath, collapse, death

Risk of blindness!

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

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Not combustible.
Ambient fire may liberate hazardous vapours.

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

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 substance contact. Avoid inhalation of dusts. 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 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

Immediately change contaminated clothing. Apply preventive skin protection. Wash hands and face after working with substance.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

No aluminium, tin, or zinc containers.

Storage conditions

Tightly closed. Dry.

Store at +5°C to +30°C.

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

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Derived No Effect Level (DNEL)

Worker DNEL, longterm	Local effects	inhalation	1 mg/m ³
Consumer DNEL, longterm	Local effects	inhalation	1 mg/m ³

Predicted No Effect Concentration (PNEC)

PNEC no data available

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

Tightly fitting safety goggles

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 entrepreneur 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.

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Environmental exposure controls

Do not empty into drains.

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form	solid
Colour	colourless
Odour	odourless
Odour Threshold	not applicable
pH	ca. 14 at 50 g/l 20 °C
Melting point	323 °C
Boiling point/boiling range	1.390 °C at 1.013 hPa
Flash point	not applicable
Evapouration rate	No information available.
Flammability (solid, gas)	The product is not flammable.
Lower explosion limit	not applicable
Upper explosion limit	not applicable
Vapour pressure	at 20 °C not applicable
Relative vapour density	No information available.
Relative density	2,13 g/cm ³ at 20 °C
Water solubility	1.090 g/l at 20 °C
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.

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Oxidizing properties	none
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9.2 Other data

Ignition temperature	not applicable
Corrosion	May be corrosive to metals.

SECTION 10. Stability and reactivity

10.1 Reactivity

See section 10.3

10.2 Chemical stability

hygroscopic

10.3 Possibility of hazardous reactions

Risk of explosion/exothermic reaction with:

Acetone, Nitriles, phosphides, halogens, halogen-halogen compounds, chlorinated solvents, Ethylene oxide, Hydrazine hydrate, hydroxylamine, anhydrides, Peroxides, Acrolein, Acid chlorides, Acids, sulphuric acid, silver salt, hydrogen peroxide, organic nitro compounds, Water
Metals, Light metals

Possible formation of:

Hydrogen

Violent reactions possible with:

ammonium compounds, organic combustible substances, phenols

Generates dangerous gases or fumes in contact with:

persulfates, Sodium borohydride, Oxides of phosphorus

10.4 Conditions to avoid

Exposure to moisture.

10.5 Incompatible materials

Aluminium, brass, Metals, metal alloys, Zinc, Tin

10.6 Hazardous decomposition products

no information available

SECTION 11. Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity

Symptoms: If ingested, severe burns of the mouth and throat, as well as a danger of perforation of the oesophagus and the stomach.

Acute inhalation toxicity

Symptoms: burns of mucous membranes, Cough, Shortness of breath, Possible damages:, damage of respiratory tract

Acute dermal toxicity

This information is not available.

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Skin irritation

rabbit

Result: Causes burns.

(RTECS)

Causes severe burns.

Eye irritation

rabbit

Result: Causes burns.

(RTECS)

Causes serious eye damage. Risk of blindness!

Sensitisation

This information is not available.

Germ cell mutagenicity

Genotoxicity in vitro

Mutagenicity (mammal cell test): micronucleus.

Result: negative

(Lit.)

Ames test

Result: negative

(IUCLID)

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

Systemic effects:

collapse, death

Handle in accordance with good industrial hygiene and safety practice.

SECTION 12. Ecological information

12.1 Toxicity

Toxicity to fish

LC50 *Gambusia affinis* (Mosquito fish): 125 mg/l; 96 h (External MSDS)

Toxicity to daphnia and other aquatic invertebrates

EC50 *Daphnia magna* (Water flea): 76 mg/l; 24 h (External MSDS)

Toxicity to bacteria

EC50 *Photobacterium phosphoreum*: 22 mg/l; 15 min (External MSDS)

12.2 Persistence and degradability

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Biodegradability

The methods for determining biodegradability are not applicable to inorganic substances.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB: Not applicable for inorganic substances

12.6 Other adverse effects

Additional ecological information

Harmful effect due to pH shift.

Forms corrosive mixtures with water even if diluted.

Neutralisation possible in waste water treatment plants.

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 UN number	UN 1823
14.2 Proper shipping name	SODIUM HYDROXIDE, SOLID
14.3 Class	8
14.4 Packing group	II
14.5 Environmentally hazardous	--
14.6 Special precautions for user	yes
Tunnel restriction code	E

Inland waterway transport (ADN)

Not relevant

Air transport (IATA)

14.1 UN number	UN 1823
14.2 Proper shipping name	SODIUM HYDROXIDE, SOLID
14.3 Class	8
14.4 Packing group	II
14.5 Environmentally hazardous	--
14.6 Special precautions for user	no

Sea transport (IMDG)

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14.1 UN number	UN 1823
14.2 Proper shipping name	SODIUM HYDROXIDE, SOLID
14.3 Class	8
14.4 Packing group	II
14.5 Environmentally hazardous	--
14.6 Special precautions for user	yes
EmS	F-A S-B

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	96/82/EC
Legislation	Directive 96/82/EC does not apply
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 deplete the ozone layer	not regulated
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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
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Regulation (EC) No 689/2008 concerning the export and import of dangerous chemicals	not regulated
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Substances of very high concern (SVHC)	This product does not contain substances of very high concern above the respective regulatory limit (> 0.1 % (w/w) Regulation (EC) No 1907/2006 (REACH), Article 57).
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National legislation

Storage class	8B
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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.

H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.

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

R35	Causes severe burns.
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Training advice

Provide adequate information, instruction and training for operators.

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.

SAFETY DATA SHEET – Annex
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Catalogue No.	106482
Product name	Sodium hydroxide pellets suitable for use as excipient EMPROVE® exp Ph Eur,BP,FCC,JP,NF,E 524

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)
PROC10 Roller application or brushing
PROC14 Production of preparations or articles by tableting, 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 environmental exposure for: ERC1, ERC2, ERC4, ERC6a, ERC6b

Technical conditions and measures / Organizational measures

Water	Solutions with high pH-value must be neutralized before discharge.
Remarks	Do not allow uncontrolled discharge of product into the environment.

2.2 Contributing scenario controlling worker exposure for: PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC10, PROC14, PROC15

Product characteristics

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

Frequency and duration of use

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

Covers daily exposures up to 8 hours.

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

Wear suitable gloves (tested to EN374), coverall and eye protection.

3. Exposure estimation and reference to its source

Workers

CS	Use descriptor	Exposure duration, route, effect	RCR	Exposure Assessment Method
2.2	PROC1	longterm, inhalative, local	0,01	ECETOC TRA 3
2.2	PROC2	longterm, inhalative, local	0,01	ECETOC TRA 3
2.2	PROC3	longterm, inhalative, local	0,10	ECETOC TRA 3
2.2	PROC4	longterm, inhalative, local	0,50	ECETOC TRA 3
2.2	PROC5	longterm, inhalative, local	0,50	ECETOC TRA 3
2.2	PROC8a	longterm, inhalative, local	0,50	ECETOC TRA 3
2.2	PROC8b	longterm, inhalative, local	0,10	ECETOC TRA 3
2.2	PROC9	longterm, inhalative, local	0,10	ECETOC TRA 3
2.2	PROC10	longterm, inhalative, local	0,50	ECETOC TRA 3
2.2	PROC14	longterm, inhalative, local	0,10	ECETOC TRA 3
2.2	PROC15	longterm, inhalative, local	0,10	ECETOC TRA 3

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

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.merck-chemicals.com.

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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

2.1 Contributing scenario controlling environmental exposure for: ERC8a, ERC8d

Technical conditions and measures / Organizational measures

Water	Solutions with high pH-value must be neutralized before discharge.
Remarks	Do not allow uncontrolled discharge of product into the environment.

3. Exposure estimation and reference to its source

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).

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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

2.1 Contributing scenario controlling environmental exposure for: ERC8a, ERC8d: Wide dispersive indoor use of processing aids in open systems, Wide dispersive outdoor use of processing aids in open systems

3. Exposure estimation and reference to its source

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).