Safety data sheet

according to 1907/2006/EC, Article 31 Commission regulation (EU) 2020/878

Printing date 18.05.2023 *Version number 4.0 (replaces version 3.0)* *Revision: 18.05.2023*

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

· ***1.1 Product identifier***

· ***Trade name:*** Potassium hydroxide, pellets, Pharmpur®, Ph Eur, BP, NF

· ***Article number:*** PO0266
· ***CAS Number:***
1310-58-3
· ***EC number:***
215-181-3
· ***Index number:***
019-002-00-8
· ***1.2 Relevant identified uses of the substance or mixture and uses advised against***
No further relevant information available.
· ***Application of the substance / the preparation:*** Laboratory reagent

· ***1.3 Details of the supplier of the safety data sheet***
· ***Manufacturer/Supplier:***
Scharlab, S.L.
C/Gato Pérez, 33. Pol.Ind. Mas d'en Cisa
08181 Sentmenat (Barcelona) SPAIN
Tel: (+34) 93 745 64 00 - FAX: (+34) 93 715 27 65
email: scharlab@scharlab.com
Internet Web Site: www.scharlab.com
· ***Regional representation:***
Scharlab, S.L.
C/Gato Pérez, 33. Pol.Ind. Mas d'en Cisa
08181 Sentmenat (Barcelona) SPAIN
Tel: (+34) 93 745 64 00 - FAX: (+34) 93 715 27 65
email: scharlab@scharlab.com
Internet Web Site: www.scharlab.com

· ***Further information obtainable from:*** Technical Department
· ***1.4 Emergency telephone number:***
Please contact the regional Scharlab distributor/dealer in your country
During normal opening times: Scharlab, S.L. (+34) 93 715 18 11

SECTION 2: Hazards identification

· ***2.1 Classification of the substance or mixture***
· ***Classification according to Regulation (EC) No 1272/2008***

corrosion

Skin Corr. 1A H314 Causes severe skin burns and eye damage.

Acute Tox. 4 H302 Harmful if swallowed.

· ***2.2 Label elements***
· ***Labelling according to Regulation (EC) No 1272/2008***
The substance is classified and labelled according to the GB CLP regulation.

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31 Commission regulation (EU) 2020/878

Printing date 18.05.2023 *Version number 4.0 (replaces version 3.0)* *Revision: 18.05.2023*

Trade name: Potassium hydroxide, pellets, Pharmpur®, Ph Eur, BP, NF

(Contd. of page 1)

· ***Hazard pictograms***

GHS05 GHS07

· ***Signal word*** Danger
· ***Hazard statements***
H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
· ***Precautionary statements***

P260	Do not breathe dusts or mists.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

· ***2.3 Other hazards***
· ***Results of PBT and vPvB assessment***
· ***PBT:*** Not applicable.
· ***vPvB:*** Not applicable.

SECTION 3: Composition/information on ingredients

· ***3.1 Substances***
· ***CAS No. Description***
1310-58-3 potassium hydroxide
· ***Identification number(s)***
· ***EC number:*** 215-181-3
· ***Index number:*** 019-002-00-8

SECTION 4: First aid measures

· ***4.1 Description of first aid measures***
· ***General information:***
Immediately remove any clothing soiled by the product.
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
Take affected persons out into the fresh air.
· ***After inhalation:***
In case of unconsciousness place patient stably in side position for transportation.
In case of asphyxia, apply oxygen therapy.
In case of respiratory arrest, administer artificial respiration.
· ***After skin contact:***
Immediately wash with water and soap and rinse thoroughly.
May cause delayed burns.
· ***After eye contact:***
Rinse opened eye for several minutes under running water. Then consult a doctor.
If the casualty wears contact lenses, they should be removed as long as they are not stuck to the eyes, otherwise additional damage may occur.

(Contd. on page 3)

Safety data sheet
according to 1907/2006/EC, Article 31 Commission regulation (EU) 2020/878

Printing date 18.05.2023 *Version number 4.0 (replaces version 3.0)* *Revision: 18.05.2023*

Trade name: Potassium hydroxide, pellets, Pharmpur®, Ph Eur, BP, NF

(Contd. of page 2)

· ***After swallowing:***
Call for a doctor immediately.
Rinse out mouth and then drink plenty of water.
· ***4.2 Most important symptoms and effects, both acute and delayed***
The main symptoms are described for the different cases of contact: skin, eyes, inhalation and ingestion.
· ***4.3 Indication of any immediate medical attention and special treatment needed***
Treat symptomatically.

SECTION 5: Firefighting measures

· ***5.1 Extinguishing media***
· ***Suitable extinguishing agents:***
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire extinguishing methods suitable to surrounding conditions.
· ***5.2 Special hazards arising from the substance or mixture***
During heating or in case of fire poisonous gases are produced.
· ***5.3 Advice for firefighters***
· ***Protective equipment:***
Respiratory protection and full chemical protective clothing must be provided for extinguishing work.
Cool exposed containers by water spray or water mist.
Do not inhale explosion gases or combustion gases.
· ***Additional information***
Collect contaminated fire fighting water separately. It must not enter the sewage system.
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

· ***6.1 Personal precautions, protective equipment and emergency procedures***
Avoid contact with skin, eyes and clothing.
Use respiratory protective device against the effects of fumes/dust/aerosol.
Ensure adequate ventilation
Wear protective equipment. Keep unprotected persons away.
· ***6.2 Environmental precautions:***
Do not allow to penetrate the ground/soil.
Do not allow to enter sewers/ surface or ground water.
· ***6.3 Methods and material for containment and cleaning up:***
Send for recovery or disposal in suitable receptacles.
Use neutralising agent.
Dispose contaminated material as waste according to section 13.
Ensure adequate ventilation.
· ***6.4 Reference to other sections***
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

· ***7.1 Precautions for safe handling***
Provide suction extractors if dust is formed.
Store in cool, dry place in tightly closed receptacles.
Keep receptacles tightly sealed.

(Contd. on page 4)

Safety data sheet
according to 1907/2006/EC, Article 31 Commission regulation (EU) 2020/878

Printing date 18.05.2023 *Version number 4.0 (replaces version 3.0)* *Revision: 18.05.2023*

Trade name: Potassium hydroxide, pellets, Pharmpur®, Ph Eur, BP, NF

(Contd. of page 3)

Thorough dedusting.
Do not eat, drink or smoke during use.
Wash hands after handling.
· ***Information about fire - and explosion protection:*** No special measures required.

· ***7.2 Conditions for safe storage, including any incompatibilities***
· ***Storage:***
· ***Requirements to be met by storerooms and receptacles:***
Store in a cool, dry and well-ventilated place.
Store only in unopened original receptacles.
· ***Information about storage in one common storage facility:*** Store away from foodstuffs.
· ***Further information about storage conditions:***
Protect from humidity and water.
Keep container tightly sealed.
See product label for storage temperature.
· ***7.3 Specific end use(s)*** No further relevant information available.

SECTION 8: Exposure controls/personal protection

· ***8.1 Control parameters***
· ***Ingredients with limit values that require monitoring at the workplace:***

1310-58-3 potassium hydroxide
WEL Short-term value: 2 mg/m³
· ***DNELs***
DNEL consumer, acute. Local effects: Inhalative - 1 mg/m3
DNEL consumer, prolonged. Local effects: Inhalative - 1 mg/m3
DNEL worker, acute. Local effects: Inhalative - 1 mg/m3
DNEL worker, cronic. Local effects: Inhalative - 1 mg/m3
· ***Additional information:*** The lists valid during the making were used as basis.

· ***8.2 Exposure controls***
· ***Appropriate engineering controls*** No further data; see section 7.
· ***Individual protection measures, such as personal protective equipment***
· ***General protective and hygienic measures:***
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
· ***Respiratory protection:*** Not required.
· ***Hand protection***


Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
· ***Material of gloves***
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

(Contd. on page 5)

Safety data sheet

according to 1907/2006/EC, Article 31 Commission regulation (EU) 2020/878

Printing date 18.05.2023 *Version number 4.0 (replaces version 3.0)* *Revision: 18.05.2023*

Trade name: Potassium hydroxide, pellets, Pharmpur®, Ph Eur, BP, NF

(Contd. of page 4)

· ***Penetration time of glove material***
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· ***Eye/face protection***

Tightly sealed goggles

SECTION 9: Physical and chemical properties

· ***9.1 Information on basic physical and chemical properties***
· ***General Information***

· ***Physical state***	Solid
· ***Colour:***	White
· ***Odour:***	Odourless
· ***Odour threshold:***	Not determined.
· ***Melting point/freezing point:***	406 °C
· ***Boiling point or initial boiling point and boiling range***	1,327 °C
· ***Flammability***	Product is not flammable.
· ***Lower and upper explosion limit***	
· ***Lower:***	Not determined.
· ***Upper:***	Not determined.
· ***Flash point:***	Not applicable.
· ***Decomposition temperature:***	Not determined.
· ***pH***	13.5
· ***Viscosity:***	
· ***Kinematic viscosity***	Not applicable.
· ***Dynamic:***	Not applicable.
· ***Solubility***	
· ***water at 20 °C:***	1120 g/l
· ***Partition coefficient n-octanol/water (log value)***	Not determined.
· ***Vapour pressure at 20 °C:***	0 hPa
· ***Density and/or relative density***	
· ***Density at 20 °C:***	2.04 g/cm³
· ***Relative density***	Not determined.
· ***Vapour density***	Not applicable.

· ***9.2 Other information***

· ***Appearance:***	
· ***Form:***	Solid
· ***Important information on protection of health and environment, and on safety.***	
· ***Ignition temperature:***	Not determined.
· ***Explosive properties:***	Product does not present an explosion hazard.
· ***Molecular weight***	56.1 g/mol
· ***Change in condition***	
· ***Evaporation rate***	Not applicable.

· ***Information with regard to physical hazard classes***

· ***Explosives***	Void
· ***Flammable gases***	Void

(Contd. on page 6)

Safety data sheet
according to 1907/2006/EC, Article 31 Commission regulation (EU) 2020/878

Printing date 18.05.2023 *Version number 4.0 (replaces version 3.0)* *Revision: 18.05.2023*

Trade name: Potassium hydroxide, pellets, Pharmpur®, Ph Eur, BP, NF

(Contd. of page 5)

· ***Aerosols***	Void
· ***Oxidising gases***	Void
· ***Gases under pressure***	Void
· ***Flammable liquids***	Void
· ***Flammable solids***	Void
· ***Self-reactive substances and mixtures***	Void
· ***Pyrophoric liquids***	Void
· ***Pyrophoric solids***	Void
· ***Self-heating substances and mixtures***	Void
· ***Substances and mixtures, which emit flammable gases in contact with water***	Void
· ***Oxidising liquids***	Void
· ***Oxidising solids***	Void
· ***Organic peroxides***	Void
· ***Corrosive to metals***	Void
· ***Desensitised explosives***	Void

SECTION 10: Stability and reactivity

· ***10.1 Reactivity*** Stable under normal conditions. No decomposition if used according to regulations.
· ***10.2 Chemical stability***
· ***Thermal decomposition / conditions to be avoided:***
No decomposition if used according to specifications.
Stable at environment temperature.
· ***10.3 Possibility of hazardous reactions***
Heating occurs when water is added.
Reacts with strong acids and oxidising agents.
Reacts with water and acids.
If a reaction with strong reducing agents such as metal hydrides or alkali metals occurs, hydrogen gas is generated, which creates a risk of explosion.
· ***10.4 Conditions to avoid*** No further relevant information available.
· ***10.5 Incompatible materials:***
Organic materials
Aluminium
Zinc
Potassium
Copper, tin.
Ether
· ***10.6 Hazardous decomposition products:***
Carbon oxides
In case of fire: see section 5.

SECTION 11: Toxicological information

· ***11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008***
· ***Acute toxicity*** Harmful if swallowed.
· ***LD/LC50 values relevant for classification:***
Oral LD50 333 mg/kg (rat)
· ***Skin corrosion/irritation***
Fur - Rabbit
Causes severe skin burns and eye damage.
· ***Serious eye damage/irritation*** Eyes - Rabbit

(Contd. on page 7)

Safety data sheet

according to 1907/2006/EC, Article 31 Commission regulation (EU) 2020/878

Printing date 18.05.2023 *Version number 4.0 (replaces version 3.0)* *Revision: 18.05.2023*

Trade name: Potassium hydroxide, pellets, Pharmpur®, Ph Eur, BP, NF

(Contd. of page 6)

· ***Respiratory or skin sensitisation***
Sensitisation test - Guinea pig
Result: negative
· ***Germ cell mutagenicity***
Ames test
Salmonella typhimurium
Result: negative
In vitro mammalian cell gene mutation assay
Mouse lymphoma test
Result: negative
· ***Carcinogenicity***
IARC: No component of this product is identified as a probable, possible or confirmed human carcinogen at levels greater than or equal to 0.1% by the International Agency for Research on Carcinogens (IARC).
· ***STOT-single exposure***
Acute oral toxicity - If swallowed, severe burns to mouth and neck, plus danger of perforation of oesophagus and stomach.
Acute inhalation toxicity: mucous membrane burns, coughing, shortness of breath and possible respiratory tract damage.
· ***11.2 Information on other hazards***
· ***Endocrine disrupting properties*** Substance is not listed.

SECTION 12: Ecological information

· ***12.1 Toxicity***
· ***Aquatic toxicity:***
Toxicity to fish
LC50 - Gambusia affinis (Mosquito fish) - 80 mg/l - 96 h
· ***12.2 Persistence and degradability***
Methods for the determination of biological degradability are not applicable for inorganic substances.
· ***12.3 Bioaccumulative potential*** No further relevant information available.
· ***12.4 Mobility in soil*** No further relevant information available.
· ***12.5 Results of PBT and vPvB assessment***
· ***PBT:*** Not applicable.
· ***vPvB:*** Not applicable.
· ***12.6 Endocrine disrupting properties***
The product does not contain substances with endocrine disrupting properties.
· ***12.7 Other adverse effects***
· ***Additional ecological information:***
· ***General notes:***
Water hazard class 1 (German Regulation) (Assessment by list): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
Must not reach sewage water or drainage ditch undiluted or unneutralised.
Rinse off of bigger amounts into drains or the aquatic environment may lead to increased pH-values. A high pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably reduced, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

(Contd. on page 8)

Safety data sheet
according to 1907/2006/EC, Article 31 Commission regulation (EU) 2020/878

Printing date 18.05.2023 *Version number 4.0 (replaces version 3.0)* *Revision: 18.05.2023*

Trade name: Potassium hydroxide, pellets, Pharmpur®, Ph Eur, BP, NF

(Contd. of page 7)

SECTION 13: Disposal considerations

· ***13.1 Waste treatment methods***
· ***Recommendation***
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· ***Uncleaned packaging:***
· ***Recommendation:*** Disposal must be made according to official regulations.
· ***Recommended cleansing agents:*** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

· ***14.1 UN number or ID number***
· ***ADR, IMDG, IATA*** UN1813
· ***14.2 UN proper shipping name***
· ***ADR*** 1813 POTASSIUM HYDROXIDE, SOLID
· ***IMDG, IATA*** POTASSIUM HYDROXIDE, SOLID
· ***14.3 Transport hazard class(es)***

· ***ADR, IMDG, IATA***

· ***Class*** 8 Corrosive substances.
· ***Label*** 8
· ***14.4 Packing group***
· ***ADR, IMDG, IATA*** II
· ***14.5 Environmental hazards:***
· ***Marine pollutant:*** No
· ***14.6 Special precautions for user*** Warning: Corrosive substances.
· ***Hazard identification number (Kemler code):*** 80
· ***EMS Number:*** F-A,S-B
· ***Segregation groups*** (SGG18) Alkalis
· ***Stowage Category*** A
· ***Segregation Code*** SG35 Stow "separated from" SGG1-acids
· ***14.7 Maritime transport in bulk according to IMO instruments*** Not applicable.

· ***Transport/Additional information:***

· ***ADR***
· ***Limited quantities (LQ)*** 1 kg
· ***Transport category*** 2
· ***Tunnel restriction code*** E
· ***UN "Model Regulation":*** UN 1813 POTASSIUM HYDROXIDE, SOLID, 8, II

SECTION 15: Regulatory information

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

· ***Directive 2012/18/EU***
· ***Named dangerous substances - ANNEX I*** -

(Contd. on page 9)

Safety data sheet

according to 1907/2006/EC, Article 31 Commission regulation (EU) 2020/878

Printing date 18.05.2023 *Version number 4.0 (replaces version 3.0)* *Revision: 18.05.2023*

Trade name: Potassium hydroxide, pellets, Pharmpur®, Ph Eur, BP, NF

(Contd. of page 8)

· ***15.2 Chemical safety assessment:*** A Chemical Safety Assessment has been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· ***Department issuing SDS:*** Product Safety Department
· ***Contact:*** msds@scharlab.com
· ***Abbreviations and acronyms:***
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
ICAO: International Civil Aviation Organisation
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
DNEL: Derived No-Effect Level (UK REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 4: Acute toxicity – Category 4
Skin Corr. 1A: Skin corrosion/irritation – Category 1A

(Contd. on page 10)

Safety data sheet

according to 1907/2006/EC, Article 31 Commission regulation (EU) 2020/878

Printing date 18.05.2023 *Version number 4.0 (replaces version 3.0)* *Revision: 18.05.2023*

Trade name: Potassium hydroxide, pellets, Pharmpur®, Ph Eur, BP, NF

(Contd. of page 9)

Annex: Exposure scenario 1

· ***1 - Short title of the exposure scenario*** Industrial use
· ***Sector of Use***
SU3 Industrial uses: Uses of substances as such or in preparations at industrial sites
· ***Process category***
PROC1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions.
PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
PROC3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition
PROC4 Chemical production where opportunity for exposure arises
PROC5 Mixing or blending in batch processes
PROC7 Industrial spraying
PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities
PROC9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
PROC10 Roller application or brushing
PROC13 Treatment of articles by dipping and pouring
PROC14 Tabletting, compression, extrusion, pelletisation, granulation
PROC15 Use as laboratory reagent
PROC19 Manual activities involving hand contact
PROC23 Open processing and transfer operations at substantially elevated temperature
PROC24 High (mechanical) energy work-up of substances bound in /on materials and/or articles
PROC26 Handling of solid inorganic substances at ambient temperature
· ***Environmental release category***
ERC2 Formulation into mixture
ERC4 Use of non-reactive processing aid at industrial site (no inclusion into or onto article)
ERC5 Use at industrial site leading to inclusion into/onto article
ERC6a Use of intermediate
ERC6b Use of reactive processing aid at industrial site (no inclusion into or onto article)
ERC7 Use of functional fluid at industrial site
· ***Description of the activities / processes covered in the Exposure Scenario***
See section 1 of the annex to the Safety Data Sheet.
· ***2 - Conditions of use***
· ***Duration and frequency*** Days of issuance (days/year): 200
· ***Worker***
Days of issuance (days/year): 200
Regular use with exposure up to 8 hrs. per workday.
· ***Environment***
Wastewater must be treated by a municipal STP. Municipal STP discharge rate <2E3 m3/d.
· ***Physical parameters*** The substance is rapidly hydrolysed
· ***Physical state***
Solid
Fluid
· ***Concentration of the substance in the mixture***
Raw material.
Covers a percentage of substance in the product up to 100 %.
· ***Other operational conditions***
· ***Other operational conditions affecting worker exposure***
Indoor application.
Keep container dry.
Avoid contact with eyes.

(Contd. on page 11)

Safety data sheet
according to 1907/2006/EC, Article 31 Commission regulation (EU) 2020/878

Printing date 18.05.2023 *Version number 4.0 (replaces version 3.0)* *Revision: 18.05.2023*

Trade name: Potassium hydroxide, pellets, Pharmpur®, Ph Eur, BP, NF

(Contd. of page 10)

Avoid contact with the skin.

· ***Other operational conditions affecting consumer exposure during the use of the product***
Not applicable.

· ***Risk management measures***
The objective is to prevent the passage of NaOH solutions into municipal wastewater or surface water. If such discharges are expected to cause significant pH changes, regular pH monitoring is required during introduction to open water. In general, discharges shall be made in such a way as to minimise pH variations at the surface of the receiving waters.

Most aquatic organisms can tolerate pH values of 6 to 9. This is also reflected in the description of standard OECD tests with aquatic organisms.

· ***Worker protection***

· ***Organisational protective measures***
Clean up spills immediately.
The employer must also check that the required personal protective equipment is available and used as instructed.
Ensure good ventilation. This can be achieved by using a local exhaustion or general exhaust system. If these measures are insufficient to keep the solvent vapour concentration below the workplace limit, wear an adequate respiratory protective device.
Keep good industrial hygiene.
Make sure that the workplace is well-lit and organised.
Ensure that operators are trained to minimise exposure.
Clean equipment and workplace on a daily basis.
Handle the substance within a closed system.
The automatic process must be supervised by specialists or authorised personnel.
Workers in the identified processes/risk areas must be trained to:
a) Avoid working without respiratory protection
(b) Understand the corrosive properties of the substance being worked with
(c) Observe the safest procedures, as specified by the employer

· ***Technical protective measures***
Ensure good ventilation/exhaustion at the workplace.
Replace, if possible, manual processes with automatic and/or closed processes. This would avoid irritating mists, sprays and splashes.
Only handle and refill product in closed systems.
Put lid on container immediately after use.
The use of tongs, claws with long handles for manual use to avoid direct contact and splash exposure.
Ensure good interior ventilation, especially at floor level. (Fumes are heavier than air).

· ***Personal protective measures***
Respiratory protection: In case of dust or aerosol formation (e.g. when spraying) wear respiratory protection with approved filter (P2).
Rubber or plastic boots.
Tightly sealed goggles
Protective work clothing
Protective gloves
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· ***Measures for consumer protection***
Ensure adequate labelling.
Keep locked up and out of the reach of children.

· ***Environmental protection measures***
The environmental risk assessment is only applicable for the aquatic environment, where applicable, including waste water treatment plants (WWTP)/waste water treatment plants (WWTP),

(Contd. on page 12)

Safety data sheet
according to 1907/2006/EC, Article 31 Commission regulation (EU) 2020/878

(Contd. of page 11)

as NaOH emissions in the different life cycle stages (production and use) apply mainly to water (waste).

· ***Air*** No significant emissions to air are expected due to the very low vapour pressure of NaOH.

· ***Water***

The high solubility in water and the very low vapour pressure indicate that NaOH is predominantly found in water. The exposure assessment for the aquatic environment will only address possible pH changes in PTS effluent and surface water related to locally released OH-.

Generally, prior to the introduction of wastewater into wastewater treatment plants a neutralisation is required.

· ***Soil*** No significant emissions to the terrestrial environment are expected.

· ***Disposal measures*** Disposal must be made according to official regulations.

· ***Disposal procedures*** Chemical treatment of contaminated water.

· ***Waste type***

Partially emptied and uncleaned packaging

Aqueous solution

· ***3 - Exposure estimation***

· ***Worker (oral)*** No significant oral exposure

· ***Worker (dermal)*** No significant dermal exposure

· ***Worker (inhalation)***

PROC: 1. 8 hours average 0.019 mg / m3. Risk characterization ratio: <0.001
PROC: 2. 8 hours average 9.6 mg / m3. Risk characterization ratio: 0.01
PROC: 3. 8 hours average 19 mg / m3. Risk characterization ratio: 0.02
PROC: 4. 8 hours average 38 mg / m3. Risk characterization ratio: 0.04
PROC: 5. 8 hours average 96 mg / m3. Risk characterization ratio: 0.101
PROC: 7. 8 hours average 140 mg / m3. Risk characterization ratio: 0.151
PROC: 8a. 8 hours average 96 mg / m3. Risk characterization ratio: 0.101
PROC: 8b. 8 hours average 48 mg / m3. Risk characterization ratio: 0.05
PROC: 10. 8 hours average 96 mg / m3. Risk characterization ratio: 0.101
PROC: 13. 8 hours average 96 mg / m3. Risk characterization ratio: 0.101
PROC: 15. 8 hours average 19 mg / m3. Risk characterization ratio: 0.02

· ***Environment***

Soil: No exposure

Humans via environment: No exposure

· ***Consumer*** Not relevant for this Exposure Scenario.

· ***4 - Guidance for downstream users***

Environment and Health: ECETOC TRA model used. If other measures are taken to manage risk/ operating conditions, then users should ensure that these risks are at least at equivalent levels.

(Contd. on page 13)

Safety data sheet

according to 1907/2006/EC, Article 31 Commission regulation (EU) 2020/878

Printing date 18.05.2023 *Version number 4.0 (replaces version 3.0)* *Revision: 18.05.2023*

Trade name: Potassium hydroxide, pellets, Pharmpur®, Ph Eur, BP, NF

(Contd. of page 12)

Annex: Exposure scenario 2

· ***1 - Short title of the exposure scenario*** Laboratory use
· ***Sector of Use***
SU22 Professional uses: Public domain (administration, education, entertainment, services, craftsmen)
· ***Process category***
PROC1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions.
PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
PROC3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition
PROC4 Chemical production where opportunity for exposure arises
PROC5 Mixing or blending in batch processes
PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities
PROC9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
PROC10 Roller application or brushing
PROC11 Non industrial spraying
PROC13 Treatment of articles by dipping and pouring
PROC14 Tabletting, compression, extrusion, pelletisation, granulation
PROC15 Use as laboratory reagent
PROC19 Manual activities involving hand contact
PROC23 Open processing and transfer operations at substantially elevated temperature
PROC24 High (mechanical) energy work-up of substances bound in /on materials and/or articles
PROC26 Handling of solid inorganic substances at ambient temperature
· ***Environmental release category***
ERC8a Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor)
ERC8b Widespread use of reactive processing aid (no inclusion into or onto article, indoor)
ERC8c Widespread use leading to inclusion into/onto article (indoor)
ERC8d Widespread use of non-reactive processing aid (no inclusion into or onto article, outdoor)
ERC8e Widespread use of reactive processing aid (no inclusion into or onto article, outdoor)
ERC8f Widespread use leading to inclusion into/onto article (outdoor)
· ***Description of the activities / processes covered in the Exposure Scenario***
See section 1 of the annex to the Safety Data Sheet.
· ***2 - Conditions of use***
· ***Duration and frequency*** Days of issuance (days/year): 200
· ***Worker***
Days of issuance (days/year): 200
Regular use with exposure up to 8 hrs. per workday.
· ***Environment***
Wastewater must be treated by a municipal STP. Municipal STP discharge rate <2E3 m3/d.
· ***Physical parameters***
· ***Physical state***
Solid
Fluid
· ***Concentration of the substance in the mixture***
Raw material.
Covers a percentage of substance in the product up to 100 %.
· ***Used amount per time or activity*** Smaller than 0.6 kg per application.
· ***Other operational conditions***
· ***Other operational conditions affecting worker exposure***
Indoor application.

(Contd. on page 14)

Safety data sheet
according to 1907/2006/EC, Article 31 Commission regulation (EU) 2020/878

Printing date 18.05.2023 *Version number 4.0 (replaces version 3.0)* *Revision: 18.05.2023*

Trade name: Potassium hydroxide, pellets, Pharmpur®, Ph Eur, BP, NF

(Contd. of page 13)

Keep container dry.
Avoid contact with eyes.
Avoid contact with the skin.

· ***Other operational conditions affecting consumer exposure during the use of the product***
Not applicable.

· ***Risk management measures***
The objective is to prevent the passage of NaOH solutions into municipal wastewater or surface water. If such discharges are expected to cause significant pH changes, regular pH monitoring is required during introduction to open water. In general, discharges shall be made in such a way as to minimise pH variations at the surface of the receiving waters.

Most aquatic organisms can tolerate pH values of 6 to 9. This is also reflected in the description of standard OECD tests with aquatic organisms.

· ***Worker protection***

· ***Organisational protective measures***
Clean up spills immediately.
The employer must also check that the required personal protective equipment is available and used as instructed.
Ensure good ventilation. This can be achieved by using a local exhaustion or general exhaust system. If these measures are insufficient to keep the solvent vapour concentration below the workplace limit, wear an adequate respiratory protective device.
Keep good industrial hygiene.
Make sure that the workplace is well-lit and organised.
Ensure that operators are trained to minimise exposure.
Clean equipment and workplace on a daily basis.
Handle the substance within a closed system.
The automatic process must be supervised by specialists or authorised personnel.
Workers in the identified processes/risk areas must be trained to:
a) Avoid working without respiratory protection
(b) Understand the corrosive properties of the substance being worked with
(c) Observe the safest procedures, as specified by the employer

· ***Technical protective measures***
Ensure good ventilation/exhaustion at the workplace.
Replace, if possible, manual processes with automatic and/or closed processes. This would avoid irritating mists, sprays and splashes.
Only handle and refill product in closed systems.
Put lid on container immediately after use.
The use of tongs, claws with long handles for manual use to avoid direct contact and splash exposure.

· ***Personal protective measures***
Respiratory protection: In case of dust or aerosol formation (e.g. when spraying) wear respiratory protection with approved filter (P2).
Rubber or plastic boots.
Tightly sealed goggles
Face protection
Protective work clothing
Wear suitable protective gloves tested in accordance with EN374.

· ***Measures for consumer protection***
Ensure adequate labelling.
Keep locked up and out of the reach of children.

· ***Environmental protection measures***

· ***Air*** No significant emissions to air are expected due to the very low vapour pressure of NaOH.

· ***Water***
The high solubility in water and the very low vapour pressure indicate that NaOH is predominantly found in water. The exposure assessment for the aquatic environment will only address possible pH changes in PTS effluent and surface water related to locally released OH-.

(Contd. on page 15)

Safety data sheet

according to 1907/2006/EC, Article 31 Commission regulation (EU) 2020/878

Printing date 18.05.2023 *Version number 4.0 (replaces version 3.0)* *Revision: 18.05.2023*

Trade name: Potassium hydroxide, pellets, Pharmpur®, Ph Eur, BP, NF

(Contd. of page 14)

Generally, prior to the introduction of wastewater into wastewater treatment plants a neutralisation is required.

· ***Soil*** No significant emissions to the terrestrial environment are expected.
· ***Disposal measures*** Disposal must be made according to official regulations.
· ***Disposal procedures*** Chemical treatment of contaminated water.
· ***Waste type***
Partially emptied and uncleaned packaging
Aqueous solution
· ***3 - Exposure estimation***
· ***Worker (oral)*** No significant oral exposure
· ***Worker (dermal)*** No significant dermal exposure
· ***Worker (inhalation)***
PROC: 1. 8 hours average 0.019 mg / m3. Risk characterization ratio: <0.001
PROC: 2. 8 hours average 9.6 mg / m3. Risk characterization ratio: 0.01
PROC: 3. 8 hours average 19 mg / m3. Risk characterization ratio: 0.02
PROC: 4. 8 hours average 38 mg / m3. Risk characterization ratio: 0.04
PROC: 5. 8 hours average 96 mg / m3. Risk characterization ratio: 0.101
PROC: 7. 8 hours average 140 mg / m3. Risk characterization ratio: 0.151
PROC: 8a. 8 hours average 96 mg / m3. Risk characterization ratio: 0.101
PROC: 8b. 8 hours average 48 mg / m3. Risk characterization ratio: 0.05
PROC: 10. 8 hours average 96 mg / m3. Risk characterization ratio: 0.101
PROC: 13. 8 hours average 96 mg / m3. Risk characterization ratio: 0.101
PROC: 15. 8 hours average 19 mg / m3. Risk characterization ratio: 0.02
· ***Environment***
Soil: No exposure
Humans via environment: No exposure
· ***Consumer*** Not relevant for this Exposure Scenario.
· ***4 - Guidance for downstream users***
Environment and Health: ECETOC TRA model used. If other measures are taken to manage risk/ operating conditions, then users should ensure that these risks are at least at equivalent levels.