

PYRIDOSTIGMINE BROMIDE

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Revision date:

Version: 1.0

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

1.1. Product identifier

Product form : Substance
Substance name : PYRIDOSTIGMINE BROMIDE
Chemical name : 3-(Dimethylcarbamoyloxy)-1-methyl-pyridinium bromide
EC no : 202-929-9
CAS No : 101-26-8
Product code : 868078
Synonyms : Pyridostigmine bromide

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : Industrial
For professional use only

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

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2031BH Haarlem - Netherlands
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info@duchefa.com - www.duchefa.com

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number
UNITED KINGDOM	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	0870 243 2241

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute Tox. 2 (Oral) H300
Acute Tox. 2 (Inhalation) H330
Resp. Sens. 1 H334
Lact H362
STOT SE 1 H370

Full text of H-phrases: see section 16

Classification according to Directive 67/548/EEC or 1999/45/EC

T+; R26/27/28

R43

Full text of R-phrases: see section 16

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Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



Signal word (CLP)

: Danger

Hazard statements (CLP)

: H300+H330 - Fatal if swallowed or if inhaled
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H362 - May cause harm to breast-fed children
H370 - Causes damage to organs

Precautionary statements (CLP)

: P302+P352 - IF ON SKIN: Wash with plenty of soap and water
P263 - Avoid contact during pregnancy/while nursing
P301+P310 - IF SWALLOWED: immediately call a POISON CENTER or doctor/physician
P309+P311 - IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician
P403+P233 - Store in a well-ventilated place. Keep container tightly closed

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substance

Name	Product identifier	%	Classification according to Directive 67/548/EEC
PYRIDOSTIGMINE BROMIDE (Main constituent)	(CAS No) 101-26-8 (EC no) 202-929-9	100	T+; R26/27/28 R43

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
PYRIDOSTIGMINE BROMIDE (Main constituent)	(CAS No) 101-26-8 (EC no) 202-929-9	100	Acute Tox. 2 (Oral), H300 Acute Tox. 2 (Inhalation), H330 Resp. Sens. 1, H334 Lact, H362 STOT SE 1, H370

Full text of R- and H-phrases: see section 16

3.2. Mixture

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation : Assure fresh air breathing. Allow the victim to rest. If not breathing, give artificial respiration. Immediately call a POISON CENTER or doctor/physician.

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- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Immediately call a POISON CENTER or doctor/physician. Wash contaminated clothing before reuse.
- First-aid measures after eye contact : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
- First-aid measures after ingestion : Rinse mouth. Induce vomiting (ONLY IN CONSCIOUS PERSONS!). Fatal if swallowed. Immediately call a POISON CENTER or doctor/physician. Give water to drink.

4.2. Most important symptoms and effects, both acute and delayed

- Symptoms/injuries : Nausea. Vomiting. Dizziness. Sleepiness. Gastrointestinal complaints. Cramps. Unconsciousness. Profuse sweating. May cause irritation or asthma-like symptoms. Blood pressure drop.
- Symptoms/injuries after skin contact : Fatal in contact with skin.
- Symptoms/injuries after ingestion : Fatal if swallowed.

4.3. Indication of any immediate medical attention and special treatment needed

Doctor: gastric lavage. Activated carbon. Antidote : Atropinsulfate intravenous.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.

5.2. Special hazards arising from the substance or mixture

- Hazardous decomposition products in case of fire : On burning: release of harmful gases/vapours. Carbon monoxide. Carbon dioxide. Nitrogen oxides. Hydrogen bromide.

5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection.
- Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Store away from other materials. Sweep up dry powder and dispose properly. Recover the product by vacuuming, shovelling or sweeping.

6.4. Reference to other sections

Reference to other sections (8, 13).

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Additional hazards when processed : Minimize generation of dust. Risk of dust explosion. Take precautionary measures against static discharges. Handle and open container with care.

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Precautions for safe handling	: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Do not get in eyes, on skin, or on clothing.
Hygiene measures	: Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Keep container closed when not in use. Keep only in the original container in a cool, well-ventilated place. Hygroscopic product. Keep away from food, drink and animal feedingstuffs.
Incompatible products	: Strong bases. Strong acids.
Incompatible materials	: Sources of ignition. Direct sunlight. Moisture. Water.
Storage temperature	: < 30 °C

7.3. Specific end use(s)

Pharmaceutical industry.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Personal protective equipment	: Avoid all unnecessary exposure.
Hand protection	: Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed. Wear gloves to EN374 to protect against skin effects from powders. Minimum thickness: 0.35 mm Break through time: 480 min.
Eye protection	: Chemical goggles or safety glasses.
Skin and body protection	: Wear suitable protective clothing.
Respiratory protection	: Respiratory protection according to European standard EN 14387 or equivalent. Dust production: dust mask with filter type P3.
Other information	: Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Crystalline powder.
Colour	: white.
Odour	: odourless.
Odour threshold	: No data available
pH	: 4,5
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 152 - 154 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable

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Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Soluble in water.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: not explosive. Potential dust explosion hazard from airborne release.
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

Other properties	: Bulk density: 490 kg/m3.
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SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Not established.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

fume. Carbon monoxide. Carbon dioxide. Nitrogen oxides. Hydrogen bromide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Fatal if swallowed. Fatal if inhaled.
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PYRIDOSTIGMINE BROMIDE (101-26-8)	
LD50 oral rat	37,5 mg/kg
ATE CLP (oral)	37,500 mg/kg bodyweight
ATE CLP (gases)	100,000 ppmv/4h
ATE CLP (vapours)	0,500 mg/l/4h
ATE CLP (dust,mist)	0,050 mg/l/4h
LD 50 oral (Mouse)	16, mg/kg
	LD50 intraperitoneal 2.7 mg/kg (rat); LD50 subcutaneous 3.1 mg/kg (rat)

Skin corrosion/irritation	: Not classified Based on available data, the classification criteria are not met pH: 4,5
Serious eye damage/irritation	: Not classified Based on available data, the classification criteria are not met pH: 4,5
Respiratory or skin sensitisation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled. Based on available data, the classification criteria are not met

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Germ cell mutagenicity	: Not classified Mutagenicity : Ames test : negative
Carcinogenicity	: Not classified Based on available data, the classification criteria are not met

PYRIDOSTIGMINE BROMIDE (101-26-8)	
	CMR
	Lact

Reproductive toxicity	: May cause harm to breast-fed children. Based on available data, the classification criteria are not met
Specific target organ toxicity (single exposure)	: Causes damage to organs. Based on available data, the classification criteria are not met
Specific target organ toxicity (repeated exposure)	: Not classified Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified Based on available data, the classification criteria are not met
Potential Adverse human health effects and symptoms	: Fatal if swallowed. Fatal in contact with skin.

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

PYRIDOSTIGMINE BROMIDE (101-26-8)	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

PYRIDOSTIGMINE BROMIDE (101-26-8)	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

: Avoid release to the environment

13.1. Waste treatment methods

Waste disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations. Dispose of this material and its container at hazardous or special waste collection point.
Ecology - waste materials	: Avoid release to the environment. Hazardous waste due to toxicity.

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

UN-No. : 2811

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UN-No.(IATA) : 2811
UN-No. (IMDG) : 2811
UN-No.(ADN) : 2811

14.2. UN proper shipping name

Proper Shipping Name : TOXIC SOLID, ORGANIC, N.O.S.
Transport document description : UN 2811 TOXIC SOLID, ORGANIC, N.O.S., 6.1, II, (D/E)

14.3. Transport hazard class(es)

Class (UN) : 6.1
Classification code (UN) : T2
Class (IATA) : 6.1
Class (IMDG) : 6.1
Class (ADN) : 6.1
Hazard labels (UN) : 6.1



14.4. Packing group

Packing group (UN) : II

14.5. Environmental hazards

Dangerous for the environment : No
Marine pollutant : No
Other information : No supplementary information available.

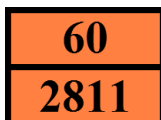
14.6. Special precautions for user

14.6.1. Overland transport

Hazard identification number (Kemler No.) : 60

Classification code (UN) : T2

Orange plates :



Special provision (ADR) : 274, 614

Transport category (ADR) : 2

Tunnel restriction code : D/E

Limited quantities (ADR) : 500g

Excepted quantities (ADR) : E4

EAC code : 2X

14.6.2. Transport by sea

No additional information available

14.6.3. Air transport

No additional information available

14.6.4. Inland waterway transport

Carriage prohibited (ADN) : No

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

Not applicable

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

15.1.1. EU-Regulations

No REACH Annex XVII restrictions

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : DISCLAIMER OF LIABILITY The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. REACH Disclaimer:
This information is based on current knowledge. Consistency of data in the SDS with CSR is considered, as far as the information is available at the time of compilation (cfr Revision date and Version number).

Full text of R-, H- and EUH-phrases:

Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Lact	Reproductive toxicity, Additional category, Effects on or via lactation
Resp. Sens. 1	Sensitisation — Respiratory, category 1
STOT SE 1	Specific target organ toxicity — single exposure, Category 1
H300	Fatal if swallowed
H330	Fatal if inhaled
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H362	May cause harm to breast-fed children
H370	Causes damage to organs
R26/27/28	Very toxic by inhalation, in contact with skin and if swallowed
R43	May cause sensitisation by skin contact
T+	Very toxic

SDS EU (REACH Annex II) Duchefa

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product