

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date Not Applicable

Revision Number N/A

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

1.1. Product identifier

Product Code(s) MM0683.00-0250

Product Name Hyoscine Butylbromide

NOTE [8] - No registration number is given for this substance because it is under the threshold in REACH Article 6(1) and not subject to the registration requirements according to REACH Title II

EC No 205-744-1

CAS No 149-64-4

Chemical name N-Butylhyoscinium bromide

Pure substance/mixture Substance

Formula C21 H30 Br N O4

Molecular weight 440.43

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

Recommended use Laboratory use

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Supplier

Will be updated as per company.

Will be updated as per company.

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date Not Applicable

Revision Number N/A

MM0683.00-0250 - Hyoscine Butylbromide

1.4. Emergency telephone number

Emergency Telephone Will be updated as per company.

| Emergency Telephone - §45 - (EC)1272/2008 | |
|--|---|
| Europe | 112 |
| Austria | No information available |
| Bulgaria | |
| Croatia | |
| Cyprus | |
| Czech Republic | |
| Denmark | |
| France | |
| Hungary | |
| Ireland | |
| Italy | |
| Lithuania | |
| Luxembourg | (+352) 8002 5500 Free telephone number with a 24/7 access in French, Dutch and English. |
| Netherlands | |
| Norway | |
| Portugal | |
| Romania | |
| Slovakia | |
| Slovenia | |
| Spain | |
| Sweden | |
| Switzerland | |

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Acute toxicity - Oral

Category 4 - (H302)

2.2. Label elements

205-744-1

Contains N-Butylhyoscinium bromide

Will be updated as per company.

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date Not Applicable

Revision Number N/A

MM0683.00-0250 - Hyoscine Butylbromide



Signal word
Warning

Hazard statements

H302 - Harmful if swallowed

Precautionary Statements - EU (§28, 1272/2008)

P264 - Wash face, hands and any exposed skin thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell

P330 - Rinse mouth

P501 - Dispose of contents/ container to an approved waste disposal plant

2.3. Other hazards

No information available.

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

| Chemical name | EU - REACH (1907/2006) - Article 59(1) - Candidate List of Substances of Very High Concern (SVHC) for Authorisation | EU - REACH (1907/2006) - Endocrine Disruptor Assessment List of Substances |
|---------------------------|--|--|
| N-Butylhyoscinium bromide | - | - |

SECTION 3: Composition/information on ingredients

3.1 Substances

| Chemical name | Weight-% | REACH registration number | EC No | Classification according to Regulation (EC) No. 1272/2008 [CLP] | Specific concentration limit (SCL) | M-Factor | M-Factor (long-term) |
|---------------------------------------|----------|---------------------------|-----------|---|------------------------------------|----------|----------------------|
| N-Butylhyoscinium bromide 149-64-4 | 100 | - | 205-744-1 | Acute Tox. 4 (H302) | | | |

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

Will be updated as per company.

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date Not Applicable

Revision Number N/A

MM0683.00-0250 - Hyoscine Butylbromide

Acute Toxicity Estimate

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

| Chemical name | Oral LD50 mg/kg | Dermal LD50 mg/kg | Inhalation LC50 - 4 hour - dust/mist - mg/L | Inhalation LC50 - 4 hour - vapour - mg/L | Inhalation LC50 - 4 hour - gas - ppm |
|---------------------------------------|-----------------|-------------------|---|--|--------------------------------------|
| N-Butylhyoscinium bromide 149-64-4 | 1040 | No data available | No data available | No data available | No data available |

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

General advice Show this safety data sheet to the doctor in attendance.

Inhalation Remove to fresh air.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a doctor.

Skin contact In the case of skin irritation or allergic reactions see a doctor. Wash skin with soap and water.

Ingestion Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Call a doctor.

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

Symptoms No information available.

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

Note to doctors Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the

Will be updated as per company.

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date Not Applicable

Revision Number N/A

MM0683.00-0250 - Hyoscine Butylbromide

surrounding environment.

Large Fire

CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing media

Do not scatter spilled material with high pressure water streams.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical

No information available.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.
Use personal protection equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions

Ensure adequate ventilation.

For emergency responders

Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions

See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

Methods for containment

Prevent further leakage or spillage if safe to do so.

Methods for cleaning up

Take up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards

Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections

See section 8 for more information. See section 13 for more information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Ensure adequate ventilation.

Will be updated as per company.

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date Not Applicable

Revision Number N/A

MM0683.00-0250 - Hyoscine Butylbromide

General hygiene considerations

Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions#

Please refer to the manufacturer's certificate for specific storage and transport temperature conditions. Store only in the original receptacle unless other advice is given on the CoA. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children.

7.3. Specific end use(s)

Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Derived No Effect Level (DNEL) Predicted No Effect Concentration (PNEC)

No information available.
No information available.

8.2. Exposure controls

Personal protective equipment

Eye/face protection

Avoid contact with eyes. Wear safety glasses with side shields (or goggles).

Hand protection

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374. Wear protective butyl rubber gloves.

Will be updated as per company.

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date Not Applicable

Revision Number N/A

MM0683.00-0250 - Hyoscine Butylbromide

| | |
|--|---|
| Skin and body protection | Wear suitable protective clothing. |
| Respiratory protection | No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required. |
| General hygiene considerations | Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection. |
| Environmental exposure controls | Do not allow into any sewer, on the ground or into any body of water. |

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | | |
|--|----------------------------|-------------------------|
| Physical state | Solid | Remarks • Method |
| Appearance | Crystalline powder | |
| Colour | white | |
| Odour | No information available. | |
| Odour threshold | No information available | |
| Property | Values | |
| Melting point / freezing point | 142 - 144 °C | |
| Initial boiling point and boiling range | No data available | |
| Flammability | No data available | |
| Flammability Limit in Air | | |
| Upper flammability or explosive limits | No data available | |
| Lower flammability or explosive limits | No data available | |
| Flash point | No data available | |
| Autoignition temperature | No data available | |
| Decomposition temperature | No data available | |
| pH | No data available | |
| pH (as aqueous solution) | No data available | |
| Kinematic viscosity | No data available | |
| Dynamic viscosity | No data available | |
| Water solubility | 50 g/l | |
| Solubility(ies) | slightly soluble, Methanol | |
| Partition coefficient | No data available | |
| Vapour pressure | No data available | |
| Relative density | No data available | |
| Bulk density | No data available | |
| Liquid Density | No data available | |
| Relative vapour density | No data available | |
| Particle characteristics | | |
| Particle Size | No information available | |

Will be updated as per company.

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date Not Applicable

Revision Number N/A

MM0683.00-0250 - Hyoscine Butylbromide

| | |
|---|--|
| Particle Size Distribution | No information available |
| 9.2. Other information | |
| Molecular weight | 440.43 |
| Molecular formula | C ₂₁ H ₃₀ BrN O ₄ |
| 9.2.1. Information with regards to physical hazard classes | |
| Not applicable | |
| 9.2.2. Other safety characteristics | |
| No information available | |
| SECTION 10: Stability and reactivity | |
| 10.1. Reactivity | |
| Reactivity | No information available. |
| 10.2. Chemical stability | |
| Stability | Stable under normal conditions. |
| Explosion data | |
| Sensitivity to mechanical impact | None. |
| Sensitivity to static discharge | None. |
| 10.3. Possibility of hazardous reactions | |
| Possibility of hazardous reactions | None under normal processing. |
| 10.4. Conditions to avoid | |
| Conditions to avoid | None known based on information supplied. |
| 10.5. Incompatible materials | |
| Incompatible materials | None known based on information supplied. |
| Hazardous decomposition products | |
| None known based on information supplied. | |

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure

Product Information

Will be updated as per company.

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date Not Applicable

Revision Number N/A

MM0683.00-0250 - **Hyoscine Butylbromide**

| | |
|---------------------|--|
| Inhalation | Specific test data for the substance or mixture is not available. |
| Eye contact | Specific test data for the substance or mixture is not available. |
| Skin contact | Specific test data for the substance or mixture is not available. |
| Ingestion | Specific test data for the substance or mixture is not available. Harmful if swallowed. (based on components). |

Symptoms related to the physical, chemical and toxicological characteristics

| | |
|-----------------|---------------------------|
| Symptoms | No information available. |
|-----------------|---------------------------|

Numerical measures of toxicity

Acute toxicity

Component Information

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|---------------------------|----------------------|-------------|-----------------|
| N-Butylhyoscinium bromide | = 1040 mg/kg (Rat) | | |

Delayed and immediate effects as well as chronic effects from short and long-term exposure

| | |
|----------------------------------|---|
| Skin corrosion/irritation | Based on available data, the classification criteria are not met. |
|----------------------------------|---|

| | |
|--|---------------------------|
| Serious eye damage/eye irritation | No information available. |
|--|---------------------------|

| | |
|--|---------------------------|
| Respiratory or skin sensitisation | No information available. |
|--|---------------------------|

| | |
|-------------------------------|---------------------------|
| Germ cell mutagenicity | No information available. |
|-------------------------------|---------------------------|

| | |
|------------------------|---------------------------|
| Carcinogenicity | No information available. |
|------------------------|---------------------------|

| | |
|------------------------------|---------------------------|
| Reproductive toxicity | No information available. |
|------------------------------|---------------------------|

Will be updated as per company.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity The environmental impact of this product has not been fully investigated.

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment The product does not contain any substance(s) classified as PBT or vPvB.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

| | |
|--|---|
| Waste from residues/unused products | Dispose of waste in accordance with environmental legislation. Dispose of in accordance with local regulations. |
| Contaminated packaging | Do not reuse empty containers. |

SECTION 14: Transport information

IATA

| | |
|---|----------------|
| 14.1 UN number or ID number | Not regulated |
| 14.2 UN proper shipping name | Not regulated |
| 14.3 Transport hazard class(es) | Not regulated |
| 14.4 Packing group | Not regulated |
| 14.5 Environmental hazards | Not applicable |
| 14.6 Special precautions for user Special Provisions | None |

IMDG

| | |
|---|-------------------------------|
| 14.1 UN number or ID number | Not regulated |
| 14.2 UN proper shipping name | Not regulated |
| 14.3 Transport hazard class(es) | Not regulated |
| 14.4 Packing group | Not regulated |
| 14.5 Marine pollutant | Not applicable |
| 14.6 Special precautions for user Special Provisions | None No information available |
| 14.7 Maritime transport in bulk according to IMO instruments | No information available |

RID

| | |
|---|----------------|
| 14.1 UN number or ID number | Not regulated |
| 14.2 UN proper shipping name | Not regulated |
| 14.3 Transport hazard class(es) | Not regulated |
| 14.4 Packing group | Not regulated |
| 14.5 Environmental hazards | Not applicable |
| 14.6 Special precautions for user Special Provisions | None |

ADR

| | |
|---|----------------|
| 14.1 UN number or ID number | Not regulated |
| 14.2 UN proper shipping name | Not regulated |
| 14.3 Transport hazard class(es) | Not regulated |
| 14.4 Packing group | Not regulated |
| 14.5 Environmental hazards | Not applicable |
| 14.6 Special precautions for user Special Provisions | None |

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

| | |
|--------------------------|--|
| Water hazard class (WGK) | slightly hazardous to water (WGK 1) |
| Poland | <p>SDS created according to the following Polish regulation: Act of February 25, 2011 on chemical substances and their mixtures (Journal of Laws of 2018, item 143, as amended). Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency (EC) as amended. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, as amended. Regulation of the Minister of Health of 10 August 2012 on the criteria and method of classifying chemical substances and their mixtures (Journal of Laws of 2012, item 1018). Regulation of the Minister of Health of 20 April 2012 on labeling packaging of hazardous substances and mixtures and some mixtures (Journal of Laws of 2012, item 445). Regulation of the Minister of Family, Labor and Social Policy of 12 June 2018 on the maximum allowable concentrations and intensities of factors harmful to health in the work environment (Journal of Laws of 2018, item 1286). Announcement of the Minister of Economy, Labor and Social Policy of August 28, 2003 on the publication of the unified text of the Ordinance of the Minister of Labor and Social Policy on general health and safety at work regulations (Journal of Laws of 2003, No. 169, item 1650). Regulation of the Minister of Health of 30 December 2004 on occupational safety and health related to the presence of chemical agents in the workplace (Journal of Laws of 2005, No. 11, item 86). Act of December 14, 2012 on waste (Journal of Laws of 2013, item 21) Regulation of the Minister of Health of December 30, 2004 on occupational health and safety related to the presence of chemical agents in the workplace (Journal U. of 2005, No. 11, item 86). Waste Act of December 14, 2012 (Journal of Laws of 2013, item 21). Act of 13 June 2013 on the management of packaging and packaging waste, Journal of Laws 2013, item 888). Government statement of September 24, 2002 - European Agreement on the International Carriage of Dangerous Goods by Road (ADR) (Journal of Laws No. 194, item 1629 and Journal of Laws of 2003, No. 207, item 2013 and 2014).</p> |

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors

Not applicable

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

International Inventories

TSCA

Contact supplier for inventory compliance status

DSL/NDSL

Contact supplier for inventory compliance status

EINECS/ELINCS

Contact supplier for inventory compliance status

ENCS

Contact supplier for inventory compliance status

IECSC

Contact supplier for inventory compliance status

KECL

Contact supplier for inventory compliance status

PICCS

Contact supplier for inventory compliance status

AIIC

Contact supplier for inventory compliance status

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report

A Chemical Safety Assessment is not required for this substance

SECTION 16: Other information

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

Full text of H-Statements referred to under section 3

H302 - Harmful if swallowed

Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: Exposure controls/personal protection

| | | | |
|---------|-----------------------------|------|----------------------------------|
| TWA | TWA (time-weighted average) | STEL | STEL (Short Term Exposure Limit) |
| Ceiling | Maximum limit value | * | Skin designation |

| Classification procedure | Method Used |
|---|--------------------|
| Classification according to Regulation (EC) No. 1272/2008 [CLP] | Method Used |
| Acute oral toxicity | Calculation method |
| Acute dermal toxicity | Calculation method |
| Acute inhalation toxicity - gas | Calculation method |
| Acute inhalation toxicity - Vapour | Calculation method |
| Acute inhalation toxicity - dust/mist | Calculation method |
| Skin corrosion/irritation | Calculation method |
| Serious eye damage/eye irritation | Calculation method |
| Respiratory sensitisation | Calculation method |
| Skin sensitisation | Calculation method |
| Mutagenicity | Calculation method |
| Carcinogenicity | Calculation method |
| Reproductive toxicity | Calculation method |
| STOT - single exposure | Calculation method |
| STOT - repeated exposure | Calculation method |
| Acute aquatic toxicity | Calculation method |
| Chronic aquatic toxicity | Calculation method |
| Aspiration hazard | Calculation method |
| Ozone | Calculation method |

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Food Research Journal Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

NICET (National Institute for Occupational Safety and Health) and the National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's ChemID Plus (NLM CII)
National Library of Medicine's PubMed database (NLM PUBMED)

National Library of Medicine's PubChem
National Toxicology Program (NTP)

National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)

New Zealand's Chemical Classification and Information Database (CCID)
Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications

Organisation for Economic Co-operation and Development ENVIRONMENT, Health, and Safety Publications Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme

Organisation for Economic Co-operation and Development High Production Volume Chemicals Screening Information Data Set

Organisation for Economic World Health Organization

Revision date

N/A

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

This material is for informational purposes only.

Disclaimer
The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. Company makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

Disclaimer

The Final Document will be available at the time of consignment.

Can vary as per company.

End of Safety Data Sheet