Safety data sheet according to 1907/2006/EC, Article 31

Printing date 02.07.2013 Revision: 23 01 2012

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

1.1 Product identifier

Bupivacaine hydrochloride

Trade name Stock number: CAS Number: 18010-40-7 241-917-8

EC number: 241-917-8

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

S1124 Scientific research and developr SU24 Scientific research and development

1.3 Details of the supplier of the safety data sheet Manufacturer/Supplier:

Alfa Aesar GmbH & Co.KG A Johnson Matthey Company Zeppelinstr. 7b Zeppelinsti. 7b 76185 Karlsruhe / Germany Tel: +49 (0) 721 84007 280 Fax: +49 (0) 721 84007 300 Email: tech@alfa.com

Informing department:

www.alfa.com
www.alfa.com
product safety Tel + +049 (0) 7275 988687-0
Carechem 24: +44 (o) 1235 239 670 (Multi-language emergency number)
Poison Information Center Mainz
www.giftinfo.uni-mainz.de Telephone: +49(0)6131/19240 1.4 Emergency telephone number:

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

(2)

GHS06 skull and crossbones

Acute Tox. 2 H300 Fatal if swallowed. Acute Tox. 1 H310 Fatal in contact with skin.

Acute Tox. 1 H330 Fatal if inhaled.

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

💹 T+; Very toxic

R26/27/28: Very toxic by inhalation, in contact with skin and if swallowed.

Information concerning particular hazards

for human and environment: Other hazards that do not result in

classification No information known.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

Hazard pictograms Signal word Hazard statements

GHS06

Danger
H300 Fatal if swallowed.
H310 Fatal in contact with skin.
H330 Fatal if inhaled.

Precautionary statements

P360 Do not breathe dust/fume/gas/mist/vapours/spray.
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
P320 Specific treatment is urgent (see on this label).
P361 Remove/Take off immediately all contaminated clothing.

The substance is classified and labelled according to the CLP regulation.

Store locked up

P405 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3 Other hazards Results of PBT and vPvB assessment

PBT vPvR

Not applicable. Not applicable.

Not applicable

SECTION 3: Composition/information on ingredients

3.1 Substances CAS# Designation: Identification number(s):

18010-40-7 Bupivacaine hydrochloride

EC number: 241-917-8

SECTION 4: First aid measures

4.1 Description of first aid measures General information

Instantly remove any clothing soiled by the product.
Remove breathing apparatus only after soiled clothing has been completely removed.
In case of irregular breathing or respiratory arrest provide artificial respiration.
Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms

persist. Seek immediate medical advice.

Instantly wash with water and soap and rinse thoroughly. Seek immediate medical advice.

Do not induce vomiting; instantly call for medical help.

After skin contact After eye contact

After inhalation

Rinse opened eye for several minutes under running water. Then consult doctor.

After swallowing 4.2 Most important symptoms and effects,

both acute and delayed
4.3 Indication of any immediate medical
attention and special treatment needed

No further relevant information available

No further relevant information available

SECTION 5: Firefighting measures

5.1 Extinguishing media Suitable extinguishing agents 5.2 Special hazards arising from the

substance or mixture

CO2, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.

If this product is involved in a fire, the following can be released:

Carbon monoxide and carbon dioxide Nitrogen oxides (NOx) Hydrogen chloride (HCI) Possibly Hydrogen cyanide (HCN)

5.3 Advice for firefighters Protective equipment:

Wear self-contained breathing apparatus.

Wear full protective suit.

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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

6.2 Environmental precautions:

Wear protective equipment. Keep unprotected persons away.

Do not allow product to reach sewage system or water bodies.

Do not allow material to be released to the environment without proper governmental permits. Do not allow product to reach sewage system or water bodies.

Do not allow to enter the ground/soil.

6.3 Methods and material for containment

and cleaning up:

Dispose of contaminated material as waste according to item 13.

Ensure adequate ventilation.

No special measures required.

See Section 7 for information on safe handling

See section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Prevention of secondary hazards: 6.4 Reference to other sections

Keep containers tightly sealed. Store in cool, dry place in tightly closed containers. Ensure good ventilation/exhaustion at the workplace. Open and handle container with care.

Information about protection against

explosions and fires:

No information known.

7.2 Conditions for safe storage, including any incompatibilities

Storage Requirements to be met by storerooms and containers:

Information about storage in one common

storage facility: Further information about storage

conditions:

No special requirements.

Store away from oxidizing agents.

Keep container tightly sealed. Store in cool, dry conditions in well sealed containers. Store in a locked cabinet or with access restricted to technical experts or their assistants. No further relevant information available.

7.3 Specific end use(s)

SECTION 8: Exposure controls/personal protection

Additional information about design of

technical systems:

Properly operating chemical fume hood designed for hazardous chemicals and having an average face velocity of at least 100 feet per minute.

8.1 Control parameters Components with critical values that require

monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

No data

Additional information: 8.2 Exposure controls

Personal protective equipment General protective and hygienic measures

The usual precautionary measures should be adhered to in handling the chemicals. Keep away from foodstuffs, beverages and food.
Instantly remove any soiled and impregnated garments.
Wash hands during breaks and at the end of the work.
Store protective clothing separately.
Avoid contact with the eyes and skin.
Maintain an ergonomically appropriate working environment.
Use self-contained respiratory protective device in emergency situations.
Check protective gloves prior to each use for their proper condition.
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.

Breathing equipment: Protection of hands:

Impervious gloves

Material of gloves

Penetration time of glove material Eye protection: **Body protection:**

Not determined Safety glasses Protective work clothing.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information Appearance: Form: Colour: Crystalline powder White

Not determined Smell: Odour threshold: Not determined pH-value: Not applicable.

Change in condition
Melting point/Melting range:
Boiling point/Boiling range:
Sublimation temperature / start: 255-259 °C Not determined Not determined Inflammability (solid, gaseous)
Ignition temperature:
Decomposition temperature:
Self-inflammability:
Critical values for explosion: Not determined Not determined Not determined Not determined.

Lower:
Upper:
Steam pressure:
Density
Relative density Not determined Not determined Not applicable. Not determined Not determined. Vapour density
Evaporation rate
Solubility in / Miscibility with Not applicable. Not applicable.

Water: Not determined Partition coefficient (n-octanol/water): Not determined.

Viscosity: Not applicable. dvnamic: kinematic: Not applicable.

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Trade name *Bupivacaine hydrochloride* (Contd. of page 2) 9.2 Other information No further relevant information available

SECTION 10: Stability and reactivity

10.1 Reactivity 10.2 Chemical stability Thermal decomposition / conditions to be

10.3 Possibility of hazardous reactions 10.5 Incompatible materials: 10.6 Hazardous decomposition products:

No information known.

Stable under recommended storage conditions.

No decomposition if used and stored according to specifications.

No dangerous reactions known Oxidizing agents

Oxidizing agents
Carbon monoxide and carbon dioxide
Nitrogen oxides (NOx)
Hydrogen chloride (HCI)
Possibly Hydrogen cyanide (HCN)

SECTION 11: Toxicological information

11.1 Information on toxicological effects Acute toxicity:

Danger by skin resorption. Fatal if inhaled. Fatal in contact with skin.

Fatal if swallowed.
The Registry of Toxic Effects of Chemical Substances (RTECS) contains acute toxicity data for components in this product.

No classification data on carcinogenic properties of this material is available from the EPA, IARC, NTP, OSHA or ACGIH.

LD/LC50 values that are relevant for classification:

Oral LD50 18 mg/kg (rabbit)

Skin irritation or corrosion: Eye irritation or corrosion: Sensitization:

Germ cell mutagenicity: Carcinogenicity:

Reproductive toxicity:

Specific target organ system toxicity - repeated exposure:

exposure:

Specific target organ system toxicity - single

Aspiration hazard:

Additional toxicological information:

No effects known.

No effects known. No effects known.

No effects known.

May cause irritation

May cause irritation No sensitizing effect known. No effects known.

To the best of our knowledge the acute and chronic toxicity of this substance is not fully known.

SECTION 12: Ecological information

12.1 Toxicity
Aquatic toxicity:

12.2 Persistence and degradability 12.3 Bioaccumulative potential 12.4 Mobility in soil

Additional écological information:

General notes:

Do not allow product to reach ground water, water bodies or sewage system. Do not allow material to be released to the environment without proper governmental permits. Water hazard class 2 (Self-assessment): hazardous for water. Danger to drinking water if even small quantities leak into soil. Avoid transfer into the environment.

No further relevant information available.

No further relevant information available. No further relevant information available No further relevant information available.

12.5 Results of PBT and vPvB assessment PBT: vPvB:

SECTION 13: Disposal considerations

12.6 Other adverse effects

13.1 Waste treatment methods

Not applicable. Not applicable. No further relevant information available.

Hand over to disposers of hazardous waste. Must be specially treated under adherence to official regulations. Consult state, local or national regulations for proper disposal

Uncleaned packagings: Recommendation:

Recommendation

Disposal must be made according to official regulations.

SECTION 14: Transport information

UN-Number ADR, IMDG, IATA 14.2 UN proper shipping name

UN2811

2811 TOXIC SOLID, ORGANIC, N.O.S. (Bupivacaine hydrochloride) TOXIC SOLID, ORGANIC, N.O.S. (Bupivacaine hydrochloride)

14.3 Transport hazard class(es)

ADR

IMDG, IATA

6.1 (T2) Toxic substances. Class

IMDG, IATA

Class 6.1 Toxic substances. Label

Packing group ADR, IMDG, IATA

Ш 14.5 Environmental hazards: Not applicable.

14.6 Special precautions for user Warning: Toxic substances.

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14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

UN "Model Regulation": UN2811, TOXIC SOLID, ORGANIC, N.O.S. (Bupivacaine hydrochloride), 6.1, II

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture Australian Inventory of Chemical Substances Substance is not listed.

Standard for the Uniform Scheduling of Drugs and Poisons National regulations Information about limitation of use:

For use only by technically qualified individuals. Employment restrictions concerning young persons must be observed.

Water hazard class 2 (Self-assessment): hazardous for water.

Water hazard class:
Other regulations, limitations and prohibitive regulations
ELINCS (European List of Notified Chemical

Substances)

Substances of very high concern (SVHC) according to REACH, Article 57 REACH - Pre-registered substances

Substance is not listed.

Substance is not listed.

Substance is not listed. Substance is listed.

A Chemical Safety Assessment has not been carried out. 15.2 Chemical safety assessment:

SECTION 16: Other information

Employers should use this information only as a supplement to other information gathered by them, and should make independent judgement of suitability of this information to ensure proper use and protect the health and safety of employees. This information is furnished without warranty, and any use of the product not in conformance with this Material Safety Data Sheet, or in combination with any other product or process, is the responsibility of the user.

Department issuing data specification sheet:
Abbreviations and acronyms:

Health, Safety and Environmental Department.
RID: Regilement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Carriage of Dangerous Goods by Raid)
ICAO: International Civil Aviation Organization
ADR: Accord européen sur le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Carriage of Dangerous Goods by Raid)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Mar

DE/E