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

Printing date 02.07.2013 Revision: 10.09.2012

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

1.1 Product identifier

Amiodarone hydrochloride J60456

Trade name Stock number: CAS Number: 19774-82-4

EC number: 243-293-2

1.2 Relevant identified uses of the substance or mixture and uses advised against. Identified use: 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 Zeppelinst. 7b 76185 Karlsruhe / Germany Tel: +49 (0) 721 84007 280 Fax: +49 (0) 721 84007 300 Email: tech@alfa.com

Not applicable

Not applicable Not applicable Not applicable

Not applicable

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)

The substance is not classified as hazardous to health or the environment according to the CLP regulation. No 1272/2008

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

Information concerning particular hazards for human and environment:

Other hazards that do not result in classification

Not applicable

No information known.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008
Hazard pictograms

Signal word Hazard statements

2.3 Other hazards Results of PBT and vPvB assessment

PB₁

Not applicable. vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.1 Substances CAS# Designation: Identification number(s): 19774-82-4 Amiodarone hydrochloride

EC number: 243-293-2

SECTION 4: First aid measures

4.1 Description of first aid measures After inhalation

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist. Seek immediate medical advice.

After skin contact Instantly wash with water and soap and rinse thoroughly.

Seek immediate medical advice.
Rinse opened eye for several minutes under running water. Then consult doctor. After eve contact Seek medical treatment.

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 (HCl)

5.3 Advice for firefighters Protective equipment:

Wear self-contained breathing apparatus.

Wear full protective suit.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

Ensure adequate ventilation 6.2 Environmental precautions:

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: Prevention of secondary hazards:

6.4 Reference to other sections

Collect mechanically.

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 Information about protection against explosions and fires: Keep containers tightly sealed.

No information known.

(Contd. on page 2)

(Contd. of page 1)

Printing date 02.07.2013 Revision: 10.09.2012

Trade name Amiodarone hydrochloride

7.2 Cond Storage .2 Conditions for safe storage, including any incompatibilities

Requirements to be met by storerooms and

containers: Information about storage in one common

storage facility:

Further information about storage conditions:

Keep container tightly sealed.

Refrigerate

Refrigerate

Protect from heat. Store away from oxidizing agents.

7.3 Specific end use(s) No further relevant information available

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.

Additional information: No data

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. Maintain an ergonomically appropriate working environment. Use breathing protection with high concentrations. 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:

and varies from manufacturer to manufacturer.

Material of gloves Penetration time of glove material Impervious gloves Not determined Safety glasses Protective work clothing. Eve protection: Body protection:

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance: Form: Colour: Powder Smell: Not determined

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

Change in condition
Melting point/Melting range:
Boiling point/Boiling range:
Sublimation temperature / start:
Inflammability (solid, gaseous)
Ignition temperature:
Decomposition temperature:
Self-inflammability:
Critical yalues for explosion: 156-163 °C Not determined Not determined Not determined Not determined Not determined Not determined.

Critical values for explosion: Lower: Not determined Upper: Not determined Not applicable. Not determined Steam pressure: Density Relative density
Vapour density
Evaporation rate
Solubity in / Miscibility with Not determined. Not applicable. Not applicable. Not determined Not determined.

Partition coefficient (n-octanol/water): Viscosity: dynamic: lot applicable. kinematic

Not applicable. No further relevant information available. 9.2 Other information

SECTION 10: Stability and reactivity

10.1 Reactivity 10.2 Chemical stability

No information known.

Stable under recommended storage conditions.

Thermal decomposition / conditions to be avoided:

10.3 Possibility of hazardous reactions 10.5 Incompatible materials:

No decomposition if used and stored according to specifications.

Reacts with strong oxidizing agents Oxidizing agents

10.6 Hazardous decomposition products: Carbon monoxide and carbon dioxide Nitrogen oxides (NOx)

Hydrogen chloride (HCI)

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

LD/LC50 values that are relevant for classification: Oral LD50 >3000 mg/kg (rat)

Skin irritation or corrosion:

May cause irritation Eye irritation or corrosion: May cause irritation Sénsitization: No sensitizing effect known. Germ cell mutagenicity: No effects known.

(Contd. on page 3)

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

Printing date 02.07.2013 Revision: 10.09.2012

Trade name Amiodarone hydrochloride

(Contd. of page 2)
No classification data on carcinogenic properties of this material is available from the EPA, IARC, NTP, OSHA Carcinogenicity:

The Registry of Toxic Effects of Chemical Substances (RTECS) contains reproductive data for components in this product. Reproductive toxicity:

No effects known.

Specific target organ system toxicity -

repeated exposure: Specific target organ system toxicity - single

exposure:

Aspiration hazard: Additional toxicological information: No effects 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 ecological information:

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

General notes:

Do not allow material to be released to the environment without proper governmental permits. Water hazard class 1 (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system. Avoid transfer into the environment.

12.5 Results of PBT and vPvB assessment PBT:

12.6 Other adverse effects

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

SECTION 13: Disposal considerations

13.1 Waste treatment methods Recommendation

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

Disposal must be made according to official regulations.

SECTION 14: Transport information

UN-Number ADR, ADN, IMDG, IATA Not applicable 14.2 UN proper shipping name ADR, ADN, IMDG, IATA Not applicable

14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA

Class Not applicable

Packing group ADR, IMDG, IATA Not applicable 14.5 Environmental hazards: Not applicable 14.6 Special precautions for user Not applicable

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

Not applicable.

UN "Model Regulation":

SECTION 15: Regulatory information

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

Australian Inventory of Chemical Substances Standard for the Uniform Scheduling of Drugs and Poisons

Substance is listed. Substance is not listed.

National regulations

Information about limitation of use: For use only by technically qualified individuals.

Water hazard class:

Water hazard class 1 (Self-assessment): slightly hazardous for water.

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 15.2 Chemical safety assessment:

Substance is not listed.

Substance is not listed. Substance is listed.

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other informationEmployers 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:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
GHS: Globally Harmonized 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)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent