

Material Safety Data Sheet

Version 3.0 Revision Date: 28.01.2026

SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

1.1 Product identifier

Product name: Dronedarone Hydrochloride

Product Number: AS112502

CAS No.: 141625-93-6

REACH Registration No.: A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

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

IDENTIFIED USES: LABORATORY CHEMICALS, MANUFACTURE OF CHEMICAL PRODUCTS

1.3. Details of the supplier of the safety data sheet

Manufacturer: Activate Scientific GmbH, Am Mitterweg 12, D-83209 Prien, Germany

Telephone: +49-(0)8051-9651660

1.4. Emergency telephone number

Emergency Phone EU: +49-(0)551-383180

Emergency Phone UK: +44-(0)1747 833100

Transport Emergency US & CD: 800-451-8346 (or 1-800-CHEMCALL)

SECTION 2 - HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP]

Acute toxicity, oral Category 3 - H301

Acute toxicity, dermal Category 3 - H311

Acute toxicity, inhalation Category 3 - H331

2.2 Label elements

Labeling according to Regulation (EC) No 1272/2008



Signalword *Danger*

Hazard statement(s)

H301 Toxic if swallowed

H311 Toxic in contact with skin

H331 Toxic if inhaled.

Precautionary statement(s)

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P305 + P351 IF IN EYES: Rinse cautiously with water for several minutes.

P310 Immediately call a POISON CENTRE or doctor if you feel unwell.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1 % or higher.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

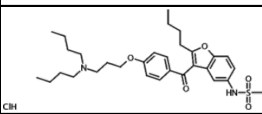
Product Number: AS112502

Substance Name: Dronedarone Hydrochloride

CAS: 141625-93-6

Formula: C31H45ClN2O5S

MW: 593.22

Component	Classification	Structure	Concentration
Dronedarone Hydrochloride	Acute toxicity, oral Category 3 - H301 Acute toxicity, dermal Category 3 - H311 Acute toxicity, inhalation Category 3 - H331		<= 100%

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4 - FIRST AID MEASURES

4.1 Description of first aid measures

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

If inhaled If breathed in- move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact Wash off with soap and plenty of water. Consult a physician.

In case of eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5 - FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture Carbon

Nitrogen oxides (NOx), Hydrogen Chloride Gas, Sulfur oxides

5.3 Advice for fire-fighters Wear self-contained breathing apparatus for fire fighting if necessary.

5.4 Further information No data available

SECTION 6 - ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

6.2 Environmental precautions Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed Containers for disposal.

6.4 Reference to other sections For disposal see section 13.

SECTION 7 - HANDLING AND STORAGE

7.1 Precautions for safe handling Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed. Storage Temperature:

2-7°C Refrigerate

7.3 Specific end uses No data available

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Appropriate engineering controls Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Body Protection impervious clothing, the type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator. For higher level protection use type OV/AG/P99 (US) or type ABEK-P2

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

- a) Appearance/Form: crystal - powder Colour: white - off white
- b) Odour: No data available
- c) Melting point/freezing point range: No data available
- d) Initial boiling point and boiling range: No data available
- e) Flash point: No data available
- f) Flammability (solid, gas): No data available
- g) Upper/lower flammability/ explosive limits: No data available
- h) Auto ignition temperature: No data available
- i) Explosive properties: No data available
- j) Oxidizing properties: No data available

9.2 Other safety information

No data available

SECTION 10 - STABILITY AND REACTIVITY

10.1 Reactivity No data available

10.2 Chemical stability No data available

10.3 Possibility of hazardous reactions No data available

10.4 Conditions to avoid No data available

10.5 Incompatible materials Strong oxidizing agents

10.6 Hazardous decomposition products Other decomposition products - No data available

SECTION 11 - TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity No data available

Skin corrosion/irritation No data available

Serious eye damage/eye irritation No data available

Respiratory or skin sensitization No data available

Germ cell mutagenicity No data available

Carcinogenicity IARC: No component of this product presents at levels greater than or equal to 0.1% is identified as Probable- possible or confirmed human carcinogen by IARC.

Reproductive toxicity No data available

Specific target organ toxicity - single exposure Inhalation - May cause respiratory irritation.

Specific target organ toxicity - repeated exposure No data available

Aspiration hazard No data available

Potential health effects

Inhalation: May be harmful if inhaled. Causes respiratory tract irritation.

Ingestion: May be harmful if swallowed.

Skin: May be harmful if absorbed through skin. Causes skin irritation.

Eyes: Causes serious eye irritation.

Signs and Symptoms of Exposure To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Additional Information RTECS: Not available

SECTION 12 - ECOLOGICAL INFORMATION

12.1 Toxicity No data available

12.2 Persistence and degradability No data available

12.3 Bio accumulative potential No data available

12.4 Mobility in soil No data available

12.5 Results of PBT and vPvB assessment No data available

12.6 Other adverse effects No data available

SECTION 14: Transport information

14.1. UN number or ID number

ADR/RID: IMDG: IATA:

14.2. UN proper shipping name

ADR/RID: IMDG: IATA:

14.3. Transport hazard class(es)

ADR/RID: IMDG: IATA:

14.4. Packing group

ADR/RID: IMDG: IATA:

14.5. Environmental hazards

ADR/RID: No IMDG Marine Pollutant : No IATA: No

14.6. Special precautions for user

No Data Available

SECTION 15 - REGULATORY INFORMATION

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

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

No data available

15.2 Chemical Safety Assessment

No data available

SECTION 16 - OTHER INFORMATION

DISCLAIMER FOR R&D USE ONLY- NOT FOR DRUG, HOUSEHOLD OR OTHER USES

Hazard statement(s)

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P310 Immediately call a POISON CENTRE or doctor if you feel unwell.

WARRANTY The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Activate Scientific GmbH, shall not be held liable for any damage resulting from handling or from contact with the above product. See reverse side of invoice or packing slip for additional terms and conditions of sale.