



TCI EUROPE N.V.

SAFETY DATA SHEET

According to 1907/2006/EC, Article 31

Revision number: 1

Revision date: 10/03/2018

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

1.1 Product identifiers

Product name: Dronedarone Hydrochloride
Product code: D4689

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

Identified uses: Reagents.

1.3 Details of the supplier of the safety data sheet

Supplier:

TCI EUROPE N.V.
Boerenveldseweg 6
Haven 1063
B-2070 Zwijndrecht
Telephone: +32(0)3 735 07 00
E-mail: sales-eu@tcichemicals.com

1.4 Emergency telephone number: +32(0)70 245 245

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Reproductive toxicity Category 2

2.2 Label elements

Pictograms or hazard symbols



Signal word

Hazard statements

Precautionary statements

Warning

H361D-Suspected of damaging fertility. Suspected of damaging the unborn child.

P201-Obtain special instructions before use.

P202-Do not handle until all safety precautions have been read and understood.

P280-Wear protective gloves, protective clothing, face protection.

P308+P313-IF exposed or concerned: Get medical advice or attention.

P405-Store locked up.

P501-Dispose of contents/container through a waste management company authorized by the local government.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable

vPvB: Not applicable

SECTION 3: Composition/information on ingredients

3.1 Substances

Components: Dronedarone Hydrochloride
Percent: >98.0%(HPLC)(T)
CAS RN: 141625-93-6
Synonyms: N-[2-Butyl-3-[4-[3-(dibutylamino)propoxy]benzoyl]-5-benzofuranyl]methanesulfonamide Hydrochloride
Chemical Formula: C₃₁H₄₄N₂O₅S · HCl

SECTION 4: First aid measures

4.1 Description of first aid measures

Inhalation:	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical advice/attention.
Skin contact:	Remove/Take off immediately all contaminated clothing. Gently wash with plenty of soap and water. Get medical advice/attention.
Eye contact:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Get medical advice/attention.
Ingestion:	Get medical advice/attention. Rinse mouth.
Protection of first-aiders:	A rescuer should wear personal protective equipment, such as rubber gloves and air-tight goggles.

4.2 Most important symptoms and effects, both acute and delayed

No data available

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: Dry chemical, foam, water spray, carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Take care as it may decompose upon combustion or in high temperatures to generate poisonous fume. Carbon dioxide, Carbon monoxide, Nitrogen oxides (NOx), Hydrogen chloride, Sulfur oxides

5.3 Advice for firefighters

Fire-extinguishing work is done from the windward and the suitable fire-extinguishing method according to the surrounding situation is used. Uninvolved persons should evacuate to a safe place. In case of fire in the surroundings: Remove movable containers if safe to do so. When extinguishing fire, be sure to wear personal protective equipment

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Keep people away from and upwind of spill/leak. Entry to non-involved personnel should be controlled around the leakage area by roping off, etc

6.2 Environmental precautions

Prevent product from entering drains

6.3 Methods and materials for containment and cleaning up

Sweep dust to collect it into an airtight container, taking care not to disperse it. Adhered or collected material should be promptly disposed of, in accordance with appropriate laws and regulations.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Handling is performed in a well ventilated place. Wear suitable protective equipment. Prevent dispersion of dust. Wash hands and face thoroughly after handling. Use a closed system if possible. Use a local exhaust if dust or aerosol will be generated. Avoid all contact!

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed. Store in a refrigerator. Store locked up. Store away from incompatible materials such as oxidizing agents.
Heat-sensitive

7.3 Specific end use(s)

No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

No data available

8.2 Exposure controls

Install a closed system or local exhaust. Also install safety shower and eye bath.

Respiratory protection:

Dust respirator, self-contained breathing apparatus(SCBA), supplied air respirator, etc. Use respirators approved under appropriate government standards and follow local and national regulations.

Hand protection:

Impervious gloves.

Eye protection:

Safety goggles. A face-shield, if the situation requires.

Skin and body protection:

Impervious protective clothing. Protective boots, if the situation requires.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state (20°C):	Solid
Form:	Crystal - Powder
Colour:	White - Almost white
Odour:	No data available
pH:	No data available
Melting point/freezing point:	144°C
Boiling point/range:	No data available
Flash point:	No data available
Evaporation rate(Butyl Acetate=1):	No data available
Flammability(solid, gas):	No data available
Flammability or explosive limits:	
Lower:	No data available
Upper:	No data available
Vapour pressure:	No data available.
Vapour density:	No data available
Relative density:	No data available
Solubility(ies):	
[Water]	No data available
[Other solvents]	No data available
Partition coefficient:	No data available
n-octanol/water:	
Autoignition temperature:	No data available
Decomposition temperature:	No data available
Dynamic Viscosity:	No data available
Kinematic viscosity:	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 Stable under proper conditions.

10.3 Possibility of hazardous reactions No special reactivity has been reported.

10.4 Conditions to avoid No data available

10.5 Incompatible materials Oxidizing agents

10.6 Hazardous decomposition products Carbon dioxide, Carbon monoxide, Nitrogen oxides (NOx), Hydrogen chloride, Sulfur oxides

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute Toxicity:	No data available
Skin corrosion/irritation:	No data available
Serious eye damage/irritation:	No data available
Respiratory or skin sensitization:	No data available
Germ cell mutagenicity:	No data available
Carcinogenicity:	
IARC =	No data available
NTP =	No data available
Reproductive toxicity:	No data available
STOT-single exposure:	No data available
STOT-repeated exposure:	No data available
Aspiration hazard:	No data available

SECTION 12: Ecological information

12.1 Toxicity	
Fish:	No data available
Crustacea:	No data available
Algae:	No data available
12.2 Persistence and degradability	No data available
12.3 Bioaccumulative potential	No data available
12.4 Mobility in soil	
Log Pow:	No data available
Soil adsorption (Koc):	No data available
Henry's Law (PaM³/mol):	No data available
12.5 Results of PBT and vPvB assessment	
PBT:	Not applicable
vPvB:	Not applicable
12.6 Other adverse effects	No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recycle to process, if possible. Consult your local regional authorities. You may be able to dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber system. Observe all federal, state and local regulations when disposing of the substance.

SECTION 14: Transport information

14.1 UN number	Not listed
14.2 UN proper shipping name	
ADR/RID	Not listed
IMDG/IMO	Not listed
ICAO/IATA	Not listed
14.3 Transport hazard class(es)	
ADR/RID	Does not correspond to the classification standard of the United Nations
IMDG/IMO	Does not correspond to the classification standard of the United Nations
ICAO/IATA	Does not correspond to the classification standard of the United Nations
14.4 Packaging group	
ADR/RID	-
IMDG/IMO	-
ICAO/IATA	-
14.5 Environmental hazards	
Marine pollutant	-
14.6 Special precautions for user	No data available

SECTION 15: Regulatory information

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

Substance of Very High Concern (SVHC) according to the REACH Regulations (EC) No.1907/2006 Not listed

15.2 Chemical safety assessment A chemical safety assessment has not been carried out.

SECTION 16: Other information

Prepared by: TCI EUROPE N.V.
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This SDS was prepared sincerely on the basis of the information we could obtain, however, any warranty shall not be given regarding the data contained and the assessment of hazards and toxicity. Prior to use, please investigate not only the hazards and toxicity information but also the laws and regulations of the organization, area and country where the products are to be used, which shall be given the first priority. The products are supposed to be used promptly after purchase in consideration of safety. Some new information or amendments may be added afterwards. If the products are to be used far behind the expected time of use or you have any questions, please feel free to contact us. The stated cautions are for normal handling only. In case of special handling, sufficient care should be taken, in addition to the safety measures suitable for the situation. All chemical products should be treated with the recognition of "having unknown hazards and toxicity", which differ greatly depending on the conditions and handling when in use and/or the conditions and duration of storage. The products must be handled only by those who are familiar with specialized knowledge and have experience or under the guidance of those specialists throughout use from opening to storage and disposal. Safe usage conditions shall be set up on each user's own responsibility.

End of Safety Data Sheet