

# SAFETY DATA SHEET

Creation Date 08-May-2013 Revision Date 07-February-2025 Revision Number 3

1. Identification

Product Name Ivabradine hydrochloride

Cat No.: AC466280000; AC466282500; AC466280010

CAS-No 148849-67-6

**Synonyms** 2H-3-benzazepin-2-one,

3\_3-(((3,4-dimethoxybicyclo(4,2,0)octa-1,3,5-trien-7-yl)methyl)methylamino)propyl)-1,3,4,5-t

etrahydro-7,8-dimethoxy-monohydrochloride

Recommended Use Laboratory chemicals.

**Uses advised against** Food, drug, pesticide or biocidal product use.

Details of the supplier of the safety data sheet

Company

Importer/Distributor

Fisher Scientific 112 Colonnade Road, Ottawa, ON K2E 7L6,

Canada

Tel: 1-800-234-7437

Manufacturer

Fisher Scientific Company One Reagent Lane Fair Lawn, NJ 07410 Tel: (201) 796-7100

**Emergency Telephone Number** 

For information **US** call: 001-800-227-6701 / **Europe** call: +32 14 57 52 11 Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99 **CHEMTREC** Tel. No. **US**:001-800-424-9300 / **Europe**:001-703-527-3887

# 2. Hazard(s) identification

Classification

WHMIS 2015 Classification Not classified under the Hazardous Products Regulations (SOR/2015-17)

Acros Organics

One Reagent Lane

Fair Lawn, NJ 07410

Based on available data, the classification criteria are not met

Label Elements

None required

**Other Hazards** 

Very toxic to aquatic organisms

# 3. Composition/Information on Ingredients

Component	CAS-No	Weight %
Chlorhydrate of 3-(3-{	148849-67-6	<=100
[((7S)-3,4-dimethoxybicyclo[4.2.0]octa-1,3,5-trien-7-yl)methyl]methylamino}		
propyl)-7,8-dimethoxy-1,3,4,5-tetrahydro-2H-3-benz		
azepin-2-one		

## 4. First-aid measures

**General Advice** If symptoms persist, call a physician.

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get

medical attention.

**Skin Contact** Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists,

call a physician.

**Inhalation** Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if

symptoms occur.

Ingestion Clean mouth with water and drink afterwards plenty of water. Get medical attention if

symptoms occur.

Most important symptoms/effects

**Notes to Physician** 

None reasonably foreseeable.

Treat symptomatically

## 5. Fire-fighting measures

Suitable Extinguishing Media Water spray, carbon dioxide (CO2), dry chemical, alcohol-resistant foam.

Unsuitable Extinguishing Media No information available

Flash Point No information available

Method - No information available

**Autoignition Temperature** 

**Explosion Limits** 

No information available

Upper No data available
Lower No data available
Sensitivity to Mechanical Impact No information available
Sensitivity to Static Discharge No information available

#### **Specific Hazards Arising from the Chemical**

Do not allow run-off from fire-fighting to enter drains or water courses.

### **Hazardous Combustion Products**

Carbon monoxide (CO). Carbon dioxide (CO<sub>2</sub>). Nitrogen oxides (NOx). Hydrogen halides.

## **Protective Equipment and Precautions for Firefighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

**NFPA** 

HealthFlammabilityInstabilityPhysical hazards010N/A

### 6. Accidental release measures

**Personal Precautions** 

Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust

**Environmental Precautions** 

Do not flush into surface water or sanitary sewer system. Do not allow material to contaminate ground water system. Prevent product from entering drains. Local authorities

should be advised if significant spillages cannot be contained.

Up

Methods for Containment and Clean Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed containers for disposal.

### 7. Handling and storage

Handling

Wear personal protective equipment/face protection. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation. Avoid dust formation.

Storage.

Keep container tightly closed in a dry and well-ventilated place. To maintain product quality: Keep refrigerated. Incompatible Materials. Strong oxidizing agents. Strong acids.

### 8. Exposure controls / personal protection

**Exposure Guidelines** 

This product does not contain any hazardous materials with occupational exposure limitsestablished by the region specific regulatory bodies.

**Engineering Measures** 

Ensure adequate ventilation, especially in confined areas.

Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control

hazardous materials at source

#### Personal protective equipment

**Eye Protection** 

Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard FN166.

**Hand Protection** 

Wear appropriate protective gloves and clothing to prevent skin exposure.

Glove material	Breakthrough time	Glove thickness	Glove comments
Nitrile rubber	See manufacturers	-	Splash protection only
Neoprene	recommendations		
Natural rubber			
PVC			

Inspect gloves before use, observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information) gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, gloves with care avoiding skin contamination.

#### **Respiratory Protection**

When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained properly Recommended Filter type: Particulates filter conforming to EN 143

When RPE is used a face piece Fit Test should be conducted

#### **Environmental exposure controls**

Prevent product from entering drains. Do not allow material to contaminate ground water system. Local authorities should be

advised if significant spillages cannot be contained.

#### **Hygiene Measures**

Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and chemical properties

Physical State Solid

Appearance White to off-white
Odor No information available
Odor Threshold No information available

pH No information available Melting Point/Range 140 °C / 284 °F

Melting Point/Range 140 °C / 284 °F
Boiling Point/Range No information available
Flash Point No information available
Evaporation Rate Not applicable

Flammability (solid,gas) No information available

Flammability or explosive limits

Upper No data available
Lower No data available
Vapor Pressure No information available
Vapor Density Not applicable
Specific Gravity No information available

Specific GravityNo information availableSolubilityNo information availablePartition coefficient; n-octanol/waterNo data available

Autoignition TemperatureNo information availableDecomposition TemperatureNo information available

ViscosityNot applicableMolecular FormulaC27 H36 N2 O5 . H Cl

Molecular Weight 505.05

## 10. Stability and reactivity

Reactive Hazard None known, based on information available

**Stability** Stable under recommended storage conditions.

Conditions to Avoid Incompatible products. Excess heat. Avoid dust formation.

Incompatible Materials Strong oxidizing agents, Strong acids

Hazardous Decomposition Products Carbon monoxide (CO), Carbon dioxide (CO2), Nitrogen oxides (NOx), Hydrogen halides

Hazardous Polymerization Hazardous polymerization does not occur.

**Hazardous Reactions** None under normal processing.

## 11. Toxicological information

**Acute Toxicity** 

Product Information The toxicological properties have not been fully investigated

Oral LD50

Based on ATE data, the classification criteria are not met. ATE > 2000 mg/kg.

Dermal LD50

Based on ATE data, the classification criteria are not met. ATE > 2000 mg/kg.

Mist LC50

Based on ATE data, the classification criteria are not met. ATE > 5 mg/l.

Component Information

Toxicologically Synergistic No information available

**Products** 

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

Irritation No information available

**Sensitization** No information available

**Carcinogenicity** The table below indicates whether each agency has listed any ingredient as a carcinogen.

Component	CAS-No	IARC	NTP	ACGIH	OSHA	Mexico
Chlorhydrate of 3-(3-{	148849-67-6	Not listed				
[((7S)-3,4-dimethoxybi						
cyclo[4.2.0]octa-1,3,5-t						
rien-7-yl)methyl]methyl						
amino}						
propyl)-7,8-dimethoxy-						
1,3,4,5-tetrahydro-2H-						
3-benzazepin-2-one						

Mutagenic Effects No information available

**Reproductive Effects** No information available.

**Developmental Effects** No information available.

**Teratogenicity** No information available.

STOT - single exposure None known STOT - repeated exposure None known

Aspiration hazard No information available

Symptoms / effects,both acute and No information available

delayed

Endocrine Disruptor Information No information available

Other Adverse Effects The toxicological properties have not been fully investigated.

## 12. Ecological information

**Ecotoxicity** 

Very toxic to aquatic organisms. The product contains following substances which are hazardous for the environment.

Persistence and Degradability

Bioaccumulation/ Accumulation

No information available.

No information available.

## 13. Disposal considerations

**Waste Disposal Methods** 

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

## 14. Transport information

DOT

UN-No UN3077

Proper Shipping Name Environmentally hazardous substances, solid, n.o.s.

Hazard Class 9
Packing Group III

TDG

UN-No UN3077

Proper Shipping Name Environmentally hazardous substances, solid, n.o.s.

Hazard Class 9
Packing Group III

#### Ivabradine hydrochloride

**IATA** 

UN-No UN3077

Proper Shipping Name Environmentally hazardous substances, solid, n.o.s.

Hazard Class 9
Packing Group

IMDG/IMO

UN-No UN3077

**Proper Shipping Name** Environmentally hazardous substances, solid, n.o.s.

Hazard Class 9
Packing Group III

## 15. Regulatory information

#### International Inventories

Component	CAS-No	DSL	NDSL	TSCA	TSCA Inventory notification - Active-Inactive	EINECS	ELINCS	NLP
Chlorhydrate of 3-(3-{ [((7S)-3,4-dimethoxybicyclo[4.2.0] octa-1,3,5-trien-7-yl)methyl]methyl amino} propyl)-7,8-dimethoxy-1,3,4,5-tetra hydro-2H-3-benzazepin-2-one		-	-	-	-	-	-	-

Component	CAS-No	IECSC	KECL	ENCS	ISHL	TCSI	AICS	NZIoC	PICCS
Chlorhydrate of 3-(3-{	148849-67-6	-	-	-	Х	-	-	-	-
[((7S)-3,4-dimethoxybicyclo[4.2.0]									
octa-1,3,5-trien-7-yl)methyl]methyl									
amino}									
propyl)-7,8-dimethoxy-1,3,4,5-tetra									
hydro-2H-3-benzazepin-2-one									

#### Legend:

X - Listed '-' - Not Listed

KECL - NIER number or KE number (http://ncis.nier.go.kr/en/main.do)

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

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

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

**IECSC** - Chinese Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

**ENCS** - Japanese Existing and New Chemical Substances

AICS - Australian Inventory of Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

#### Canada

SDS in compliance with provisions of information as set out in Canadian Standard - Part 4, Schedule 1 and 2 of the Hazardous Products Regulations (HPR) and meets the requirements of the HPR (Paragraph 13(1)(a) of the Hazardous Products Act (HPA)).

#### Other International Regulations

Authorisation/Restrictions according to EU REACH Not applicable

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

Component	CAS-No	OECD HPV	Persistent Organic Pollutant	Ozone Depletion Potential	Restriction of Hazardous Substances (RoHS)
Chlorhydrate of 3-(3-{ [((7S)-3,4-dimethoxybicyclo[4.	148849-67-6	Not applicable	Not applicable	Not applicable	Not applicable

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2.0]octa-1,3,5-trien-7-yl)methy			
Ilmethylamino}			
propyl)-7,8-dimethoxy-1,3,4,5-			
tetrahydro-2H-3-benzazepin-2			
-one			

Component	CAS-No	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report	Rotterdam Convention (PIC)	Basel Convention (Hazardous Waste)
		Notification	Requirements		
Chlorhydrate of 3-(3-{ [((7S)-3,4-dimethoxybicyclo[4. 2.0]octa-1,3,5-trien-7-yl)methy I]methylamino} propyl)-7,8-dimethoxy-1,3,4,5- tetrahydro-2H-3-benzazepin-2 -one		Not applicable	Not applicable	Not applicable	Not applicable

# 16. Other information

Prepared By Regulatory Affairs

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**Revision Summary**This document has been updated to comply with the requirements of WHMIS 2015 to align

with the Globally Harmonised System (GHS) for the Classification and Labelling of

Chemicals.

#### **Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

**End of SDS**