

# **SAFETY DATA SHEET**

Creation Date 08-May-2013 Revision Date 07-Feb-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

Fisher Scientific Company
One Reagent Lane
Fair Lawn, NJ 07410
Acros Organics
One Reagent Lane
Fair Lawn, NJ 07410
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

Classification under 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

### Label Elements

None required

### Hazards not otherwise classified (HNOC)

Very toxic to aquatic life

# 3. Composition/information on Ingredients

Component	CAS No	Weight %	
Ivabradine hydrochloride	148849-67-6	<=100	

### 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 and

effects

None reasonably foreseeable.

Notes to Physician 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 (CO2). 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

formation.

**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.

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.

**Personal Protective Equipment** 

**Eve/face Protection** Wear appropriate protective eveglasses or chemical safety goggles as described by

OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard

EN166.

Skin and body protection Wear appropriate protective gloves and clothing to prevent skin exposure.

**Respiratory Protection** 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.

No information available

**Recommended Filter type:** Particulates filter conforming to EN 143.

Handle in accordance with good industrial hygiene and safety practice. **Hygiene Measures** 

Physical and chemical properties

**Physical State** Solid

**Appearance** White to off-white

Odor No information available **Odor Threshold** No information available

No information available рH Melting Point/Range 140 °C / 284 °F **Boiling Point/Range** No information available

**Evaporation Rate** Not applicable

Flammability (solid,gas) No information available

Flammability or explosive limits

Flash Point

Upper No data available Lower No data available No information available **Vapor Pressure** 

Not applicable **Vapor Density** 

**Specific Gravity** No information available Solubility No information available

Partition coefficient; n-octanol/water No 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
lvabradine hvdrochloride	148849-67-6	Not listed				

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 No information available

**Bioaccumulation/ Accumulation** No information available.

**Mobility** 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

I<u>ATA</u>

UN-No UN3077

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

Hazard Class 9
Packing Group III

IMDG/IMO

UN-No UN3077

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

Hazard Class 9
Packing Group III

# 15. Regulatory Information

### **United States of America Inventory**

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	TSCA - EPA Regulatory Flags
Ivabradine hydrochloride	148849-67-6	-	-	-

#### Leaend:

TSCA US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

X - Listed

'-' - Not Listed

TSCA - Per 40 CFR 751, Regulation of Certain Chemical Substances & Mixtures, Under TSCA Section 6(h) (PBT)

Not applicable

Substances & Mixtures, Under 13CA Section 6(11) (FB

TSCA 12(b) - Notices of Export Not applicable

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#### **International Inventories**

Canada (DSL/NDSL), Europe (EINECS/ELINCS/NLP), Philippines (PICCS), Japan (ENCS), Japan (ISHL), Australia (AICS), China (IECSC), Korea (KECL).

Component	CAS No	DSL	NDSL	EINECS	PICCS	ENCS	ISHL	AICS	IECSC	KECL
Ivabradine hydrochloride	148849-67-6	-		-	•	•	Χ	•	-	-

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

### U.S. Federal Regulations

### **SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

#### SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act) Not applicable

Clean Air Act Not applicable

**OSHA** - Occupational Safety and

Health Administration

Not applicable

### **CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

**California Proposition 65**This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know

Regulations

Not applicable

### **U.S. Department of Transportation**

Reportable Quantity (RQ): N
DOT Marine Pollutant N
DOT Severe Marine Pollutant N

U.S. Department of Homeland

Security

This product does not contain any DHS chemicals.

Other International Regulations

Mexico - Grade No information available

### Authorisation/Restrictions according to EU REACH Not applicable

Component	CAS No	REACH (1907/2006) -	REACH (1907/2006) -	REACH Regulation (EC
		Annex XIV - Substances	Annex XVII - Restrictions	1907/2006) article 59 -
		Subject to Authorization	on Certain Dangerous	Candidate List of
			Substances	Substances of Very High
				Concern (SVHC)
Ivabradine hydrochloride	148849-67-6	-	-	_

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

Componer	it	CAS No	OECD HPV	Persistent Organic Pollutant	Ozone Depletion Potential	Restriction of Hazardous Substances (RoHS)
Ivabradine hydro	hloride	148849-67-6	Not applicable	Not applicable	Not applicable	Not applicable

Contains component(s) that meet a 'definition' of per & poly fluoroalkyl substance (PFAS)? Not applicable

### Other International Regulations

	Component	CAS No	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements	Rotterdam Convention (PIC)	Basel Convention (Hazardous Waste)
-	Ivabradine hydrochloride	148849-67-6	Not applicable	Not applicable	Not applicable	Not applicable

Prepared By Regulatory Affairs

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Revision Summary

This document has been updated to comply with the US OSHA HazCom 2012 Standard

replacing the current legislation under 29 CFR 1910.1200 to align with the Globally

Harmonized System of Classification and Labeling of Chemicals (GHS).

### **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**