

SAFETY DATA SHEET

Creation Date 17-Oct-2016

Revision Date 20-Dec-2025

Revision Number 5

This safety data sheet was created pursuant to the requirements of: US OSHA Hazard Communication Standard 2024 (29 CFR 1910.1200)

1. Identification

| | |
|---------------------|--|
| Product Name | Paroxetine hydrochloride hemihydrate |
| Cat No. : | AC462630000, AC462630010, AC462630050 |
| CAS No | 110429-35-1 |
| Synonyms | No information available |

Recommended Use
Uses advised against

Laboratory chemicals.
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
Tel: (201) 796-7100

Acros Organics
One Reagent Lane
Fair Lawn, NJ 07410

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

This chemical is considered hazardous according to [US] OSHA (29 CFR 1910.1200, 2024)

| | |
|-----------------------------------|------------|
| Acute oral toxicity | Category 4 |
| Skin Corrosion/Irritation | Category 2 |
| Serious Eye Damage/Eye Irritation | Category 2 |

Label Elements

Signal Word
Warning

Hazard Statements
Harmful if swallowed
Causes skin irritation

Causes serious eye irritation



Precautionary Statements

Prevention

Wash face, hands and any exposed skin thoroughly after handling

Do not eat, drink or smoke when using this product

Wear protective gloves/protective clothing/eye protection/face protection

Skin

IF ON SKIN: Wash with plenty of soap and water

If skin irritation occurs: Get medical advice/attention

Take off contaminated clothing

Eyes

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

If eye irritation persists: Get medical advice/attention

Ingestion

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell

Rinse mouth

Disposal

Dispose of contents/container to an approved waste disposal plant

Hazards not otherwise classified (HNOC)

None identified

Hazards classified under paragraph (d)(1)(ii) of 1910.1200

No information available

3. Composition/information on Ingredients

| Component | CAS No | Weight % |
|--------------------------------------|-------------|----------|
| Paroxetine hydrochloride hemihydrate | 110429-35-1 | >95 |
| Paroxetine hydrochloride | 78246-49-8 | - |

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 Method - No information available
No information available

Autoignition Temperature No information available
Explosion Limits

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

Keep product and empty container away from heat and sources of ignition.

Hazardous Combustion Products

Carbon monoxide (CO). Carbon dioxide (CO₂). Nitrogen oxides (NO_x). Hydrogen fluoride.

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 | Health | Flammability | Instability | Physical hazards |
|-------------|---------------|---------------------|--------------------|-------------------------|
| | 2 | 1 | 0 | N/A |

6. Accidental release measures

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

Environmental Precautions Should not be released into the environment.

Methods for Containment and Clean Up 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 containers tightly closed in a dry, cool and well-ventilated place. Incompatible Materials. Strong acids. Strong oxidizing agents.

8. Exposure controls / personal protection

Exposure Guidelines This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Engineering Measures Ensure that eyewash stations and safety showers are close to the workstation location.

Personal Protective Equipment

Eye/face 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 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.

Recommended Filter type: Particulates filter conforming to EN 143.

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

9. Physical and chemical properties

Appearance

Physical State Solid

Color

Odor

Odor Threshold

Property

Melting Point/Range

Softening Point

Boiling Point/Range

Flash Point

Flammability (liquid)

Flammability (solid,gas)

Explosion Limits

No information available

No information available

Values

No data available

No data available

No information available

No information available

Not applicable

No information available

No data available

Remarks

Method

Method - No information available

Solid

Autoignition Temperature

Decomposition Temperature

pH

Viscosity

Water Solubility

Solubility in other solvents

Partition Coefficient (n-octanol/water)

Component log Pow

Paroxetine hydrochloride hemihydrate 3.38

Vapor Pressure

No data available

Density / Specific Gravity

No data available

Bulk Density

No data available

Vapor Density

Not applicable

Solid

Particle characteristics

Other Information

Molecular Formula C19 H20 F N O3 . H Cl. 0.5 H2 O

Molecular Weight 374.83

Evaporation Rate Not applicable - Solid

10. Stability and reactivity

Reactive Hazard None known, based on information available

Stability No information available.

Conditions to Avoid Incompatible products.

Incompatible Materials Strong acids, Strong oxidizing agents

Hazardous Decomposition Products Carbon monoxide (CO), Carbon dioxide (CO₂), Nitrogen oxides (NO_x), Hydrogen fluoride

Hazardous Polymerization Hazardous polymerization does not occur.

Hazardous Reactions None under normal processing.

11. Toxicological information

Information on expected route of exposure

Inhalation Not an expected route of exposure.

Ingestion May be harmful if swallowed.

Eyes Avoid contact with eyes. Irritating to eyes.

Skin Avoid contact with skin. May cause irritation.

Toxicology data for the components

| Component | LD50 Oral | LD50 Dermal | LC50 Inhalation |
|--------------------------|------------------------|-------------|-----------------|
| Paroxetine hydrochloride | LD50 = 415 mg/kg (Rat) | - | - |

Toxicologically Synergistic Products No information available

(b) skin corrosion/irritation; Category 2

(c) serious eye damage/irritation; Category 2

(d) respiratory or skin sensitization;

Respiratory No data available
Skin No data available

(e) germ cell mutagenicity; No data available

(f) carcinogenicity;

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

| Component | CAS No | IARC | NTP | ACGIH | OSHA | Mexico |
|--------------------------------------|-------------|------------|------------|------------|------------|------------|
| Paroxetine hydrochloride hemihydrate | 110429-35-1 | Not listed |
| Paroxetine hydrochloride | 78246-49-8 | Not listed |

(g) reproductive toxicity; No data available

(h) STOT-single exposure; No data available

(i) STOT-repeated exposure; No data available

Target Organs No information available.

(j) aspiration hazard: Not applicable
Solid

Symptoms / effects, both acute and delayed No information available.

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

Endocrine Disrupting Properties This product does not contain any known or suspected endocrine disruptors.

12. Ecological information

Ecotoxicity

Do not empty into drains.

Persistence and Degradability Persistence is unlikely

Bioaccumulation/ Accumulation No information available.

Mobility No information available.

| Component | log Pow |
|--------------------------------------|---------|
| Paroxetine hydrochloride hemihydrate | 3.38 |

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 Not regulated

TDG Not regulated

IATA Not regulated

IMDG/IMO Not regulated

15. Regulatory Information

United States of America Inventory

| Component | CAS No | TSCA | TSCA Inventory notification - Active-Inactive | TSCA - EPA Regulatory Flags |
|--------------------------------------|-------------|------|---|-----------------------------|
| Paroxetine hydrochloride hemihydrate | 110429-35-1 | - | - | - |
| Paroxetine hydrochloride | 78246-49-8 | - | - | - |

Legend:

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

TSCA 12(b) - Notices of Export Not applicable

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 |
|--------------------------------------|-------------|-----|------|--------|-------|------|------|------|-------|------|
| Paroxetine hydrochloride hemihydrate | 110429-35-1 | - | - | - | - | - | - | - | - | - |
| Paroxetine hydrochloride | 78246-49-8 | - | - | - | - | - | - | - | - | - |

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) - Annex XIV - Substances Subject to Authorization | REACH (1907/2006) - Annex XVII - Restrictions on Certain Dangerous Substances | REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC) |
|--------------------------------------|-------------|---|---|---|
| Paroxetine hydrochloride hemihydrate | 110429-35-1 | - | - | - |
| Paroxetine hydrochloride | 78246-49-8 | - | - | - |

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) |
|--------------------------------------|-------------|----------------|------------------------------|---------------------------|--|
| Paroxetine hydrochloride hemihydrate | 110429-35-1 | Not applicable | Not applicable | Not applicable | Not applicable |
| Paroxetine hydrochloride | 78246-49-8 | 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) |
|--------------------------------------|-------------|---|--|----------------------------|------------------------------------|
| Paroxetine hydrochloride hemihydrate | 110429-35-1 | Not applicable | Not applicable | Not applicable | Not applicable |
| Paroxetine hydrochloride | 78246-49-8 | Not applicable | Not applicable | Not applicable | Not applicable |

16. Other Information**Prepared By**

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Revision Date

20-Dec-2025

Print Date

20-Dec-2025

Revision Summary

Updated to the U.S. Department of Labor's Occupational Safety and Health Administration (OSHA) which published its Final Rule in the Federal Register revising the Hazard Communication Standard (HCS/HazCom), 29 CFR 1910.1200 (2024) (HCS §1910.1200, 2024), May 20, 2024, effective July 19, 2024.

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