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

1.1 Product identifier

Paroxetine Hydrochloride Hemihydrate (1991)
Paroxetine Hydrochloride Hemihydrate ; CAS No. : 110429-35-1

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

Relevant identified uses

Product Categories [PC]

PC 29 - Pharmaceuticals

Uses advised against

This product should not be used for purposes other than the applications referred to above.

1.3 Details of the supplier of the safety data sheet

Supplier (manufacturer/importer/only representative/downstream user/distributor)

Ofipharma B.V.

Street : Heembadweg 5

Postal code/city : 9561 CZ Ter Apel

Telephone : +31 599 745 390

Telefax : +31 599 582 734

1.4 Emergency telephone number

+31 599 583 433
Telefoon voor professionele hulpverleners: NVIC + (0)30 - 274 88 88. Uitsluitend bestemd om professionele hulpverleners te informeren bij acute vergiftigingen.

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

Acute Tox. 4 ; H302 - Acute toxicity (oral) : Category 4 ; Harmful if swallowed.
Skin Irrit. 2 ; H315 - Skin corrosion/irritation : Category 2 ; Causes skin irritation.
Eye Irrit. 2 ; H319 - Serious eye damage/eye irritation : Category 2 ; Causes serious eye irritation.
STOT SE 3 ; H335 - STOT-single exposure : Category 3 ; May cause respiratory irritation.

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms

Exclamation mark (GHS07)

Signal word

Warning

Hazard statements

H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

Precautionary statements

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P310	Immediately call a POISON CENTER/doctor/....
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations

2.3 Other hazards
None

2.4 Additional information
This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII.

SECTION 3: Composition/information on ingredients

3.1 Substances
Substance name : Paroxetine Hydrochloride Hemihydrate

CAS No. : 110429-35-1

Purity : 100 % [mass]

SECTION 4: First aid measures

4.1 Description of first aid measures
General information
When in doubt or if symptoms are observed, get medical advice.

Following inhalation
No special measures are necessary.

In case of skin contact
Wash immediately with: Water and soap Change contaminated, saturated clothing. Wash contaminated clothing prior to re-use.

After eye contact
Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.

After ingestion
Call a physician in any case! Do NOT induce vomiting. If major quantity of dust is swallowed or inhaled, immediately drink: Water

4.2 Most important symptoms and effects, both acute and delayed
The following symptoms may occur: No known symptoms to date.

4.3 Indication of any immediate medical attention and special treatment needed
None

SECTION 5: Firefighting measures

5.1 Extinguishing media
None

5.2 Special hazards arising from the substance or mixture
None

5.3 Advice for firefighters
None

5.4 Additional information
Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Protective equipment

Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2 Environmental precautions

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains. Make sure spills can be contained, e.g. in sump pallets or kerbed areas. In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

6.3 Methods and material for containment and cleaning up

For containment

Collect in closed and suitable containers for disposal. Treat the recovered material as prescribed in the section on waste disposal.

For cleaning up

Take up carefully when dry.

6.4 Reference to other sections

See protective measures under point 7 and 8.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

None

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions

Keep/Store only in original container.

Hints on joint storage

Storage class (TRGS 510) : 13

7.3 Specific end use(s)

None

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

None

8.2 Exposure controls

Personal protection equipment

Eye/face protection

Eye glasses with side protection

Skin protection

The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. DIN-/EN-Norms EN ISO 374 DIN EN 420 Suitable material NBR (Nitrile rubber) PVA (Polyvinyl alcohol) PVC (polyvinyl chloride)

Hand protection

Breakthrough time (maximum wearing time) : > 60 m.

Thickness of the glove material : > 0,5 mm

Respiratory protection

If technical exhaust or ventilation measures are not possible or insufficient, respiratory protection must be worn. Suitable respiratory protection apparatus Full-/half-/quarter-face masks (DIN EN 136/140) Filtering device (full mask or mouthpiece) with filter: ABEK-P3

General health and safety measures

Immediately remove any contaminated clothing, shoes or stockings. Wash contaminated clothing prior to re-use.

Environmental exposure controls

See section 7. No additional measures necessary.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : solid

Colour : white

Odour : No data available

Safety relevant basis data

Freezing point :	(1013 hPa)	No data available
Initial boiling point and boiling range :	(1013 hPa)	No data available
Flash point :		No data available
Ignition temperature :		No data available
Lower explosion limit :		No data available
Upper explosion limit :		No data available
Vapour pressure :	(50 °C)	No data available
Relative density :	(20 °C)	No data available
Water solubility :	(20 °C)	No data available
pH :		not determined
log P O/W :		No data available
Cinematic viscosity :	(40 °C)	No data available
Relative vapour density :	(20 °C)	No data available
Evaporation rate :		No data available
Flammable solids :	No data available.	
Oxidising solids :	No data available.	

9.2 Other information

None

SECTION 10: Stability and reactivity

10.1 Reactivity

not applicable

10.2 Chemical stability

Stable under normal conditions of use

10.3 Possibility of hazardous reactions

No information available.

10.4 Conditions to avoid

No information available.

10.5 Incompatible materials

Strong oxidizers

10.6 Hazardous decomposition products

No information available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute effects

Acute toxicity

Irritant and corrosive effects

Primary irritation to the skin

irritant.

Irritation to eyes

irritant.

Irritation to respiratory tract

No data available

Sensitisation

not sensitising.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity

This substance does not meet the criteria for classification as CMR category 1A or 1B according to CLP.

Germ cell mutagenicity

No indications of human germ cell mutagenicity exist.

Reproductive toxicity

This substance does not meet the criteria for classification as CMR category 1A or 1B according to CLP.

STOT-single exposure

not applicable

STOT-repeated exposure

Prolonged or repeated contact with skin or mucous membrane result in irritation symptoms such as redness, blistering, dermatitis, etc.

SECTION 12: Ecological information

12.1 Toxicity

harmless to aquatic organisms up to the tested concentration

12.2 Persistence and degradability

Biodegradable.

12.3 Bioaccumulative potential

No indication of bioaccumulation potential.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII.

12.6 Other adverse effects

None

12.7 Additional ecotoxicological information

None

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Delivery to an approved waste disposal company. Contaminated packages must be completely emptied and can be re-used following proper cleaning. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

14.1 UN number

No dangerous good in sense of these transport regulations.

14.2 UN proper shipping name

No dangerous good in sense of these transport regulations.

14.3 Transport hazard class(es)

No dangerous good in sense of these transport regulations.

14.4 Packing group

No dangerous good in sense of these transport regulations.

14.5 Environmental hazards

No dangerous good in sense of these transport regulations.

14.6 Special precautions for user

None

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

not applicable

SECTION 15: Regulatory information

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

EU legislation

Authorisations and/or restrictions on use

Restrictions on use

Use restriction according to REACH annex XVII, no. : 3

National regulations

Water hazard class (WGK)

Class : nwg (Non-hazardous to water)

15.2 Chemical safety assessment

Chemical safety assessments for substances in this preparation were not carried out.

SECTION 16: Other information

16.1 Indication of changes

None

16.2 Abbreviations and acronyms

a.i. = Active ingredient
ACGIH = American Conference of Governmental Industrial Hygienists (US)
ADR = European Agreement concerning the International Carriage of Dangerous Goods by Road
AFFF = Aqueous Film Forming Foam
AISE = International Association for Soaps, Detergents and Maintenance Products (joint project of AISE and CEFIC)
AOAC = AOAC International (formerly Association of Official Analytical Chemists)
aq. = Aqueous
ASTM = American Society of Testing and Materials (US)

atm = Atmosphere(s)
B.V. = Beperkt Vennootschap (Limited)
BCF = Bioconcentration Factor
bp = Boiling point at stated pressure
bw = Body weight
ca = (Circa) about
CAS No = Chemical Abstracts Service Number (see ACS - American Chemical Society)
CEFIC = European Chemical Industry Council (established 1972)
CIPAC = Collaborative International Pesticides Analytical Council
CLP = REGULATION (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.
Conc = Concentration
cP = CentiPoise
cSt = Centistokes
d = Day(s)
DIN = Deutsches Institut für Normung e.V.
DNEL = Derived No-Effect Level
DT50 = Time for 50% loss; half-life
EbC50 = Median effective concentration (biomass, e.g. of algae)
EC = European Community; European Commission
EC50 = Median effective concentration
EINECS = European Inventory of Existing Commercial Chemical Substances (EU, outdated, now replaced by EC Number)
ELINCS = European List of Notified (New) Chemicals (see Tab 7, Background - Guide)
ErC50 = Median effective concentration (growth rate, e.g. of algae)
EU = European Union
EWC = European Waste Catalogue
FAO = Food and Agriculture Organization (United Nations)
GIFAP = Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques (now CropLife International)
h = Hour(s)
hPa = HectoPascal (unit of pressure)
IARC = International Agency for Research on Cancer
IATA = International Air Transport Association
IC50 = Concentration that produces 50% inhibition
IMDG Code = International Maritime Dangerous Goods Code
IMO = International Maritime Organization
ISO = International Organization for Standardization
IUCLID = International Uniform Chemical Information Database
IUPAC = International Union of Pure and Applied Chemistry
kg = Kilogram
Kow = Distribution coefficient between n-octanol and water
kPa = KiloPascal (unit of pressure)
LC50 = Concentration required to kill 50% of test organisms
LD50 = Dose required to kill 50% of test organisms
LEL = Lower Explosive Limit/Lower Explosion Limit
LOAEL = Lowest observed adverse effect level
mg = Milligram
min = Minute(s)
ml = Milliliter
mmHg = Pressure equivalent to 1 mm of mercury (133.3 Pa)
mp = Melting point
MRL = Maximum Residue Limit
MSDS = Material Safety Data Sheet
n.o.s. = Not Otherwise Specified
NIOSH = National Institute for Occupational Safety and Health (US)
NOAEL = No Observed Adverse Effect Level
NOEC = No observed effect concentration
NOEL = No Observable Effect Level
NOx = Oxides of Nitrogen
OECD = Organization for Economic Cooperation and Development
OEL = Occupational Exposure Limits

Pa = Pascal (unit of pressure)
PBT = Persistent, Bioaccumulative or Toxic
pH = -log10 hydrogen ion concentration
pKa = -log10 acid dissociation constant
PNEC = Previsible Non Effect Concentration
POPs = Persistent Organic Pollutants
ppb = Parts per billion
PPE = Personal Protection Equipment
ppm = Parts per million
ppt = Parts per trillion
PVC = Polyvinyl Chloride
QSAR = Quantitative Structure-Activity Relationship
REACH = Registration, Evaluation and Authorization of CHemicals (EU, see NCP)
SI = International System of Units
STEL = Short-Term Exposure Limit
tech. = Technical grade
TSCA = Toxic Substances Control Act (US)
TWA = Time-Weighted Average
vPvB = Very Persistent and Very Bioacccumulative
WHO = World Health Organization = OMS
y = Year(s)

16.3 Key literature references and sources for data

None

16.4 Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

No information available.

16.4 Relevant H- and EUH-phrases (Number and full text)

None

16.5 Training advice

None

16.6 Additional information

None

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.