

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078942462

N/A

Effective Date 05.02.2021  
Revision 1.0

**SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING****1.1. Product identifier**

Trade name: Clevor® (ropinirole ophthalmic solution), 30 mg/mL  
Reach registration number: -

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

The uses of the chemical: Medicine  
Classification of the economic activities (NACE): 211  
Use categories (UC62): 41

**1.3. Details of the supplier of the safety data sheet:**

Manufacturer/importer: Orion Corporation  
Street address: Orionintie 1  
Post-office box: P.O. Box 65  
Postcode: 02101 Espoo, Finland  
Telephone number: +358 10 4261  
Telefax: +358 10 426 3815  
E-mail address: chemicalsafety@orion.fi  
VAT Reg. No: FI19992126

**1.4. Emergency telephone number**

Poison Center: +358 9 471 977

**SECTION 2: HAZARDS IDENTIFICATION****2.1. Classification of the substance or mixture**

Classification according to regulation (EC) No 1272/2008	Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.
H Statements	No Classification

**2.2. Label elements**

Hazard Pictograms

Effective Date 05.02.2021  
 Revision 1.0

**Signal word**
**H Statements**

No Classification

**P Statements**
**2.3. Other hazards**

-

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**
**3.2. Mixtures**

Name of the ingredient	Component Type	CAS-number:	EC-number	Reach registration number:	Concentration/ Limit	Classification according to regulation (EC) No 1272/2008
Ropinirole hydrochloride	Component	91374-20-8	-	-	<5%	Acute Tox. 4, Aquatic Acute 1 -H302 H400
Citric acid monohydrate	Component	5949-29-1	201-069-1	01-2119457026-42	<1%	Eye Irrit. 2 - H319
Sodium citrate	Component	6132-04-3	612-118-5	-	<1%	-
Sodium chloride	Component	7647-14-5	231-598-3	NA	<1%	-
Hydrochloric acid	Component	7647-01-0	231-595-7	01-2119484862-27	0 %<0,1%	Skin Corr. 1B, STOT SE 3, Met. Corr. 1 - H314 H335 H290

Effective Date 05.02.2021  
 Revision 1.0

Sodium hydroxide	Component	1310-73-2	215-185-5	01-2119457892-27	0 %<0,1%	Skin Corr. 1A, Met. Corr. 1, Eye Dam. 1 - H314 H290 H318
Water	Component	7732-18-5	231-791-2	-	94 %<100%	-

Other information -

**SECTION 4: FIRST AID MEASURES**

**4.1. Description of first aid measures**

**Special instructions**

Helpers should ensure their own protection.  
 Show this safety data sheet to the doctor in attendance.

**Inhalation**

If experiencing respiratory symptoms:  
 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.  
 Get Medical advice/attention if you feel unwell.

**Skin contact**

Remove/Take off immediately all contaminated clothing.  
 Wash with soap and water.

**Eye contact**

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

**Ingestion**

Rinse mouth.  
 Get Medical advice/attention if you feel unwell.

**4.2. Most important symptoms and effects, both acute and delayed**

See section 11.

Effective Date 05.02.2021  
Revision 1.0

#### 4.3. Indication of any immediate medical attention and special treatment needed

Data not available.

### SECTION 5: FIRE-FIGHTING MEASURES

#### 5.1. Extinguishing media

**Suitable extinguishing media** Choose suitable extinguishing media according to the environment.

#### 5.2. Special hazards arising from the substance or mixture

Data not available.

#### 5.3. Advice for fire-fighters

**Special protective equipment for fire-fighters** Isolating breathing apparatus eg. compressed breathing apparatus and protective clothing.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

#### 6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment as required.

#### 6.2. Environmental precautions

Do not put into water system, drain or soil.

#### 6.3. Methods and material for containment and cleaning up

Absorb spillage with e.g. earth, sand or inert absorbent material.  
Collect up into tightly sealable containers for disposal.

#### 6.4. Reference to other sections

See Section 8 and 13

Effective Date 05.02.2021  
 Revision 1.0

**SECTION 7: HANDLING AND STORAGE**
**7.1. Precautions for safe handling**

Handle in accordance with good industrial hygiene and safety procedures.

**7.2. Conditions for safe storage, including any incompatibilities**

Store at 68-77°F (20-25°C), excursions permitted in range 59°F-86°F (15°C-30°C).

Keep only in original container.

Protect from light.

See incompatible materials in section 10.5.

**7.3. Specific end use(s)**

No information identified.

**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**
**8.1. Control parameters**

Substance	International OEL values	DNELs	PNECs
Ropinirole hydrochloride	-	-	-
Citric acid monohydrate	-	-	Sediment - Fresh water: 34,6 mg/kg, Sediment - Marine water: 3,46 mg/kg, Soil: 33,1 mg/kg, Fresh water: 0,44 mg/l, Marine water: 0,044 mg/l
Sodium citrate	-	-	-
Sodium chloride	-	-	-
Hydrochloric acid	-	Worker; long term exposure - local effects, inhalation: 8 mg/m <sup>3</sup> , Worker; short term exposure - local effects, inhalation: 15 mg/m <sup>3</sup>	Fresh water: 0,036 mg/l, Intermittent release: 0,045 mg/l, Marine water: 0,036 mg/l, Sewage treatment plant: 0,036 mg/l
Sodium hydroxide	-	Worker; long term exposure - local effects, inhalation: 1	-

Effective Date 05.02.2021  
Revision 1.0

		mg/m3	
Water	-	-	-

## 8.2. Exposure controls

### Respiratory protection

See standard working procedures/instructions or department's instructions for more detailed protection measures.

### Hand protection

Wear protective gloves.

### Eye protection

Use protective goggles.

### Skin protection

Wear protective clothing.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### Appearance

Physical state Liquid  
Colour Yellowish / Yellow  
Odour  
Odour threshold -

### 9.1. Information on basic physical and chemical properties

### 9.2. Other information

-

## SECTION 10: STABILITY AND REACTIVITY

### 10.1. Reactivity

-

Effective Date 05.02.2021  
Revision 1.0

### 10.2. Chemical stability

-

### 10.3. Possibility of hazardous reactions

-

### 10.4. Conditions to avoid

-

### 10.5. Incompatible materials

-

### 10.6 Hazardous decomposition products

-

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on toxicological effects

<b>Acute toxicity</b>	Exposure to this drug may cause adverse reactions such as headache, nausea, vomiting, dizziness, orthostatic hypotension, and sleepiness.  Ropinirole hydrochloride: LD50: 396 mg/kg (rat, oral)
<b>Skin irritation and corrosion</b>	Data not available.
<b>Skin sensitization</b>	Data not available.
<b>Serious eye damage and irritation</b>	Data not available.
<b>Respiratory irritation</b>	Data not available.
<b>Respiratory sensitization</b>	Data not available.

Effective Date 05.02.2021  
Revision 1.0

**Carcinogenicity** Data not available.

**Germ cell mutagenicity** Data not available.

**Reproductive toxicity** Avoid contact with the product if pregnant, planning to become pregnant, or breast-feeding, as exposure has been shown to have adverse effects on embryo-fetal development based on rodent studies.

**STOT-single exposure** Data not available.

**STOT-repeated exposure** Data not available.

**Aspiration hazard** Data not available.

**Repeated dose toxicity** Data not available.

Effective Date 05.02.2021  
Revision 1.0

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

#### Aquatic toxicity

Ropinirole hydrochloride:  
LC50(96 h): 0,394 mg/l, Pimephales promelas

#### Toxic effects on other organisms

Data not available.

### 12.2. Persistence and degradability

Data not available.

### 12.3. Bioaccumulative potential

**Octanol-water partition coefficient**

Data not available.

**Bioconcentration factor**

Data not available.

### 12.4. Mobility in soil

Data not available.

### 12.5. Results of PBT and vPvB assessment

Data not available.

### 12.6. Other adverse effects

Data not available.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

Chemical incinerator equipped with an afterburner and scrubber is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

Effective Date 05.02.2021  
Revision 1.0

**SECTION 14: TRANSPORT INFORMATION****14.1. UN Number**

-

**14.2. UN Proper shipping name**

-

**14.3. Transport hazard class(es) (ADR/RID,IMDG,ICAO/IATA)**

This product is not regulated under the transport regulations.

**14.4. Packing group**

-

**14.5. Environmental hazard**

-

**14.6. Special precautions for user**

-

**14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code**

Not applicable

**SECTION 15: REGULATORY INFORMATION****15.1. Safety, health and environmental regulations/legislation specific for substance or mixture**

-

**15.2. Chemical Safety Assessment**

No

Effective Date 05.02.2021  
Revision 1.0

**SECTION 16: OTHER INFORMATION****List of H statements**

H302, H400	Harmful if swallowed. Very toxic to aquatic life.
H319	Causes serious eye irritation.
H314, H335, H290	Causes severe skin burns and eye damage. May cause respiratory irritation. May be corrosive to metals.
H314, H290, H318	Causes severe skin burns and eye damage. May be corrosive to metals. Causes serious eye damage.

**Sources of key data used to compile the Safety Data Sheet**