

**SAFETY DATA SHEET**

IN ACCORDANCE WITH REGULATION (CE) 1907/2006, (CE) 1272/2008 and (EU) 453/2010  
(Annex I)

**« 1. IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY »**

*Substance name:*

VERAPAMIL HYDROCHLORIDE

*Use of the substance/preparation:*

-pharmaceutical active ingredient (calcium Antagonist)

*Company/Undertaking identification:*

RECORDATI S.p.A.

04010 Campoverde di Aprilia (LT) -ITALY

Email contact: [cirilli.s@recordati.it](mailto:cirilli.s@recordati.it)

*Emergency telephone:*

-TEL. N° + 39-6-92900010 or call your nearest poison control centre

**« 2. HAZARDS IDENTIFICATION »**

*Classification of the substance or mixture*

*Classification according to Regulation (EC) No 1272/2008*

Acute toxicity, (Category 3)

*Classification according to European Directive 67/548/EEC as amended.*

Toxic by contact with skin and if swallowed

*Label elements according to Regulation (EC) No 1272/2008*



*Pictogram*

*Signal Word:*

*Danger*

*Hazard statement(s)*

H301: Toxic if swallowed

H311: Toxic in contact with skin

H335: May cause respiratory irritation

*Precautionary statement(s):*

- P260: Do not breathe dust/fume/gas/mist/vapours/spray  
P280: Wear protective gloves/protective clothing/eye protection/face protection  
P284: Wear respiratory protection  
P301 + P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician

*Label elements according to European Directive 67/548/EEC as amended*

*Hazard symbol(s)*                      *T; Toxic*

*Risk Phrases:*

- R24/25                                      Toxic in contact with skin and if swallowed  
R36/37/38:                                Irritating to eyes, respiratory system and skin

*S-phrases*

- S36/37:                                      Wear suitable protective clothing and gloves  
S45:    In case of accident or if you feel unwell seek medical advice immediately  
(show the label where possible)

*Other hazards*

None

**« 3. COMPOSITION/INFORMATION ON INGREDIENTS »**

*Chemical Name and Synonyms:*

VERAPAMIL HYDROCHLORIDE; 5-(N-(3,4-DIMETHOXYPHENETHYL)-  
METHYLAMINO)-2-(3,4-DIMETHOXYPHENYL)-2-ISOPROPYL VALERONITRILE  
HYDROCHLORIDE; ISOPTIN

*Molecular Formula:*

C<sub>27</sub>H<sub>38</sub>N<sub>2</sub>O<sub>4</sub>.HCl

*Molecular Weight:*

491.1

*N.CAS*                      *EC No*

152-11-4\*\*\*\*\* 205-800-5

*Classification*

Acute Tox. 3; H301, H311, H335

T,    R24/25 R35/36/37

For the full text of the H-statements mentioned in this Section, see Section 16

**« 4. FIRST-AID MEASURES »**

*General information:*

In case of doubt or when the symptoms persist you should consult a physician. Keep ready to hand the preparation/substance safety data sheet. Do not administer anything orally to a fainted person.

- *Contact with skin:*
  - wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician
- *Contact with eyes:*
  - rinse immediately with plenty of water
- *Inhalation:*
  - remove patient to fresh air. Consult a physician
- *Ingestion:*
  - seek medical advice

## « 5. FIRE FIGHTING MEASURES »

### *Suitable Extinguishing Media:*

- carbon dioxide
- dry chemical
- foam
- water

### *Special Protective Equipment for fire-fighters:*

Wear a self-contained breathing apparatus for fire fighting

## « 6. ACCIDENTAL RELEASE MEASURES »

### *General information:*

Review Sections 2, 8 and 13 before proceeding with clean up.

### *Personal Precautions:*

wear approved respiratory protection, wear chemically compatible gloves. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

### *Environmental Precautions:*

Prevent further leakage or spillage if safe to do so. Do not let product enter drains

### *Methods and materials for containment and cleaning up*

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed container for disposal.

## « 7. HANDLING AND STORAGE »

### *Precautions for safe handling*

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

*Conditions for safe storage*

Keep container tightly closed in a dry and well-ventilated place. Store in cool place.

Light sensitive

**« 8. EXPOSURE CONTROLS/PERSONAL PROTECTION »***-Respiratory protection:*

full face piece mask with filter for dust

*-Hand protection:*

rubber or PVC gloves

*-Eye protection:*

full face piece mask

*Skin and body protection:*

Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

*Additional Information:*

The personal safety equipment must be compliant to the requirements specified in the 89/686/CEE Directive and relevant changes (CE mark).

The equipment must be decided according to the workplace as part of a risk analysis compliant with the

89/686/CEE Directive and relevant changes.

It is necessary to maintain the concentrations in the workplace below the specified thresholds.

If the workplace thresholds are overcome and/or if great quantities are dispersed (losses, spreading, dust) the specified respirator must be used.

All the specified safety measures must be respected.

**« 9. PHYSICAL AND CHEMICAL PROPERTIES »***Molecular Formula:*

C<sub>27</sub>H<sub>38</sub>N<sub>2</sub>O<sub>4</sub>.HCl

*Molecular Weight:*

491.1

*Physical state and the colour:*

Almost white, crystalline powder

*Odour:*

odourless

*Melting point (°C):*

142°C (approx.)

*Ignition Temperature:*

305°C

*Flammability LFL:*

50 mg/l

*UFL:*

Not Available

*Water Solubility:*

5% (pH 4-6.5): soluble

*Fat Solubility:*

4% in ethyl alcohol: soluble;

40% in chloroform: freely soluble

*pH:*

4-6.5 (5% solution)

**« 10. STABILITY AND REACTIVITY »***Hazardous Decomposition Products:*

Hydrogen cyanide, hydrogen chloride, nitrogen oxides and carbon monoxide.

*Additional Information:*

Material is stable from a safety point of view

**« 11. TOXICOLOGICAL INFORMATION »***Route of Exposure:*

- skin contact
- eye contact
- inhalation
- ingestion

*Acute and chronic toxicity:*

- Acute toxicity: nausea, dizziness, fall in blood pressure and other circulatory troubles.
- It may irritate skin and eyes in case of contact
- It is used as an active drug (calcium-antagonist).

*Toxicity data:*

LD50: 108 mg/kg oral rats;

LD50: 107 mg/kg subcutaneous rats

LD50: 163 mg/kg oral mice;

**« 12. ECOLOGICAL INFORMATION »***Ecotoxicity:*

Material is not expected to cause long-term adverse effects in the aquatic environment (material is readily biodegradable).

**« 13. DISPOSAL CONSIDERATIONS »**

Disposal recommendations:

- dispose of waste in accordance with all applicable Federal, State and local laws

**« 14. TRANSPORT INFORMATION »**

*Specific Precautionary Transport Measures and Conditions:*

Proper shipping name: Toxic solid, organic, N.O.S. (Verapamil Hydrochloride).

ADR/RID:

Class and label: 6.1.  
Packing group III  
UN-Number: 2811

IMDG:

Class and label: 6.1.  
Packing group III  
UN-Number: 2811

IATA:

Class and label: 6.1.  
Packing group III  
UN-Number: 2811

**« 15. REGULATORY INFORMATION »**

This safety datasheet complies with the regulation (CE) 1907/2006, (CE) 1272/2008 and (EU) 453/2010 (Annex I)

*Additional Information:*

The information listed in this section specifically recalls the main prescriptions applicable to the products described in this safety data sheet.

The user should be aware of the existence of other dispositions completing these prescriptions. You should refer to all the applicable international, national or local measures or dispositions.

<b>« 16. OTHER INFORMATION »</b>
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*Text of H-code(s) and R-phrases mentioned in Section 3:*

Acute toxicity, Inhalation (Category 2)

Acute toxicity, Dermal (Category 3)

Acute toxicity, Oral (Category 3)

*Hazard statement(s)*

H301: Toxic if swallowed

H311: Toxic in contact with skin

H335: May cause respiratory irritation

*Precautionary statement(s):*

P260: Do not breathe dust/fume/gas/mist/vapours/spray

P280: Wear protective gloves/protective clothing/eye protection/face protection

P284: Wear respiratory protection

P301 + P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician

*T; Toxic*

*Risk Phrases:*

R24/25

Toxic in contact with skin and if swallowed

R36/37/38:

Irritating to eyes, respiratory system and skin

*S-phrases*

S36/37:

Wear suitable protective clothing and gloves

S45:

In case of accident or if you feel unwell seek medical advice immediately  
(show the label where possible)

*References:*

- NIOSH : Registry of Toxic Effects of Chemical Substances - ACGIH : Threshold Limit Values

-Flammability tests performed by Stazione Sperimentale per i Combustibili, Milano.

*Revisions:*

8: in accordance with the regulation (CE) 1272/2008

*Compiled by:*

Dr. R. Calabrese

*Date:*

09 November, 2010

*The information included in this safety data sheet correspond to our best knowledge of the product at the time of publication. The goal of this information is to allow the product use, stocking, transport and disposal according to the safest procedures. This information must not be considered as a warranty or a requirement of the product quality. They only refer to the specified material and they are not applicable when combined with other materials or processes not specifically indicated in this safety data sheet. The blank parts of this safety data sheet refer to unavailable information and/or elements not applicable in the case described*