



# VASUDHA PHARMA CHEM LIMITED

Unit-I : Plot No. 39 A & B, Phase-I, I.D.A., Jeedimetla, Hyderabad-500055, Telangana, INDIA.

Phone: +91-40-44754545

Fax : +91-40-44754555

E-mail: mwu1@vasudhapharma.com

Website: www.vasudhapharma.com

## SAFETY DATA SHEET

### CISAPRIDE MONOHYDRATE

SDS Number:

VPCL/SDS/028/00

Effective date:

24/06/2016

Page 1 of 7

## SECTION 1-IDENTIFICATION OF THE SUBSTANCE

### Product Identifier

Substance name

: Cisapride monohydrate

CAS No.

: 260779-88-2

Formula

:  $C_{23}H_{29}N_3O_4ClF \cdot H_2O$

Synonyms

: Cipril,  
Acenalin,  
cis-4-Amino-5-chloro-N-[1-[3-(4-fluorophenoxy)  
propyl]-3- methoxy-4-piperidinyl]-2methoxybenxamide  
monohydrate

### Intended use of the Product

Use of the substance / mixture

: Laboratory chemicals, Manufacture of substances

### Company Identification

Company name

: VASUDHA PHARMA CHEM LIMITED

Administrative Office

: 78/A, VENGALA RAO NAGAR,  
HYDERABAD-500 038.  
TELANGANA, INDIA.

Telephone No.

: +91-40-4476 3666, 2371 1717 / 1715

Fax No.

: +91-40-23811576 / 4476 3636

E-mail

: vasudha@vasudhapharma.com

## SECTION 2-HAZARDS IDENTIFICATION

### Classification of the substance or mixture

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

Serious eye damage (Category 1)

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Risk of serious damage to eyes.

### 2.2 Label elements

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

Pictogram



Signal word

Danger

Hazard statement(s)

H318

Causes serious eye damage.

Precautionary statement(s)

P280

Wear protective gloves/ eye protection/ face protection.

P305 + P351 + P338

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



# VASUDHA PHARMA CHEM LIMITED

Unit-I : Plot No. 39 A & B, Phase-I, I.D.A., Jeedimetla, Hyderabad-500055, Telangana, INDIA.

Phone: +91-40-44754545

Fax : +91-40-44754555

E-mail: mwu1@vasudhapharma.com

Website: www.vasudhapharma.com

## SAFETY DATA SHEET

### CISAPRIDE MONOHYDRATE

SDS Number:	VPCL/SDS/028/00	Effective date:	24/06/2016
-------------	-----------------	-----------------	------------

Page 2 of 7

Supplemental Hazard

Statements

None

According to European Directive 67/548/EEC as amended.

Hazard symbol(s)



R-phrase(s)

R41

Risk of serious damage to eyes.

S-phrase(s)

S26

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S39

Wear eye/face protection.

2.3 Other hazards none

## SECTION 3-COMPOSITION/INFORMATION ON INGREDIENTS

Name	Product identifier CAS#	%	GHS-EU classification
Cisapride monohydrate	260779-88-2	-	-

## SECTION 4-FIRST-AID MEASURES

### 4.1 Description of first aid measures

#### General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

#### If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

#### In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

#### In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

#### If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

### 4.2 Most important symptoms and effects, both acute and delayed

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

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

No data available

## SECTION 5-FIRE-FIGHTING MEASURES

### 5.1 Extinguishing media

Suitable extinguishing media



# VASUDHA PHARMA CHEM LIMITED

Unit-I : Plot No. 39 A & B, Phase-I, I.D.A., Jeedimetla, Hyderabad-500055, Telangana, INDIA.

Phone: +91-40-44754545

Fax : +91-40-44754555

E-mail: mwu1@vasudhapharma.com

Website: www.vasudhapharma.com

## SAFETY DATA SHEET

### CISAPRIDE MONOHYDRATE

SDS Number:	VPCL/SDS/028/00	Effective date:	24/06/2016
-------------	-----------------	-----------------	------------

Page 3 of 7

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

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

Carbon oxides, nitrogen oxides (NO<sub>x</sub>), Hydrogen chloride gas, Hydrogen fluoride

#### 5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

#### 5.4 Further information

No data available

### SECTION 6-ACCIDENTAL RELEASE MEASURES

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

Use personal protective equipment. Avoid dust formation. Avoid breathing vapor, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

#### 6.2 Environmental precautions

Do not let product enter drains.

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

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

#### 6.4 Reference to other sections

For disposal see section 13.

### SECTION 7-HANDLING AND STORAGE

#### 7.1 Precautions for safe handling

Avoid formation of dust and aerosols.

Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

#### 7.2 Conditions for safe storage, including any incompatibilities

Preserve in well closed, light -resistant containers and store at 25±2°C.

(Short term excursions are allowed between 15 °C and 30 °C)

#### 7.3 Specific end uses

No data available

### SECTION 8-EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

Components with workplace control parameters

#### 8.2 Exposure controls

##### Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

##### Personal protective equipment

##### Eye/face protection

Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

##### Skin protection



# VASUDHA PHARMA CHEM LIMITED

Unit-I : Plot No. 39 A & B, Phase-I, I.D.A., Jeedimetla, Hyderabad-500055, Telangana, INDIA.

Phone: +91-40-44754545

Fax : +91-40-44754555

E-mail: mwu1@vasudhapharma.com

Website: www.vasudhapharma.com

## SAFETY DATA SHEET

### CISAPRIDE MONOHYDRATE

SDS Number:	VPCL/SDS/028/00	Effective date:	24/06/2016
-------------	-----------------	-----------------	------------

Page 4 of 7

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

#### 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.

#### Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

## SECTION 9-PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

a) Appearance	: Form: solid
b) Odour	: No data available
c) Odour Threshold	: No data available
d) pH	: No data available
e) Melting point/freezing point	: No data available
f) Initial boiling point and boiling range	: No data available
g) Flash point	: No data available
h) Evaporation rate	: No data available
i) Flammability (solid, gas)	: No data available
j) Upper/lower flammability or explosive limits	: No data available
k) Vapour pressure	: No data available
l) Vapour density	: No data available
m) Relative density	: No data available
n) Water solubility	: No data available
o) Partition coefficient: octanol/water	: No data available
p) Auto-ignition temperature	: No data available
q) Decomposition temperature	: No data available
r) Viscosity	: No data available
s) Explosive properties	: No data available
t) Oxidizing properties	: No data available
9.2 Other safety information	: No data available

## SECTION 10-STABILITY AND REACTIVITY

### 10.1 Reactivity

No data available



# VASUDHA PHARMA CHEM LIMITED

Unit-I : Plot No. 39 A & B, Phase-I, I.D.A., Jeedimetla, Hyderabad-500055, Telangana, INDIA.

Phone: +91-40-44754545

Fax : +91-40-44754555

E-mail: mwu1@vasudhapharma.com

Website: www.vasudhapharma.com

## SAFETY DATA SHEET

### CISAPRIDE MONOHYDRATE

SDS Number:	VPCL/SDS/028/00	Effective date:	24/06/2016
-------------	-----------------	-----------------	------------

Page 5 of 7

#### 10.2 Chemical stability

No data available

#### 10.3 Possibility of hazardous reactions

No data available

#### 10.4 Conditions to avoid

No data available

#### 10.5 Incompatible materials

Strong oxidizing agents

#### 10.6 Hazardous decomposition products

Other decomposition products - no data available

## SECTION 11-TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

##### Acute toxicity

Oral Toxicity (RAT) LD 50 mg/kg: 4166 mg/kg;

Dermal Toxicity (RABBIT) LD 50 mg/kg: No data available;

Inhalation Toxicity (RAT) by Dusts & Mists LD 50 mg/kg: No data available;

LD 50 Oral (Mouse): 380 mg/kg;

Acute Oral Toxicity (Guinea Pig): No data available;

Intravenous LD 50 (RAT): No data available;

Intravenous LD 50 (Mouse): No data available

Remarks: Sense Organs and Special Senses (Nose, Eye, Ear, and Taste): Eye: Ptosis. Behavioural:

Change in motor activity (specific assay). Lungs, Thorax, or Respiration: Other changes.

##### Skin corrosion/irritation

May cause skin irritation

##### Serious eye damage/eye irritation

Causes serious eye damage

##### Respiratory or skin sensitization

No data available

##### Germ cell mutagenicity

No data available

##### Carcinogenicity

IARC: No components of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

##### Reproductive toxicity

No data available

##### Specific target organ toxicity - single exposure

No data available

##### Specific target organ toxicity - repeated exposure

No data available

##### Aspiration hazard

No data available

##### Potential health effects



# VASUDHA PHARMA CHEM LIMITED

Unit-I : Plot No. 39 A & B, Phase-I, I.D.A., Jeelimetla, Hyderabad-500055, Telangana, INDIA.

Phone: +91-40-44754545

E-mail: mwu1@vasudhapharma.com

Fax : +91-40-44754555

Website: www.vasudhapharma.com

SAFETY DATA SHEET			
CISAPRIDE MONOHYDRATE			
SDS Number:	VPCL/SDS/028/00	Effective date:	24/06/2016

Page 6 of 7

**Inhalation** May be harmful if inhaled. May cause respiratory tract irritation.

**Ingestion** May be harmful if swallowed.

**Skin** May be harmful if absorbed through skin. May cause skin irritation.

**Eyes** Causes eye burns.

## Signs and Symptoms of Exposure

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

## Additional Information

RTECS: CU9372000

## SECTION 12-ECOLOGICAL INFORMATION

### 12.1 Toxicity

No data available

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

No data available

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

No data available

### 12.6 Other adverse effects

No data available

## SECTION 13-DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

#### Product

Offer surplus and non-recyclable solutions to a licensed disposal company. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

#### Contaminated packaging

Dispose of as unused product.

## SECTION 14-TRANSPORT INFORMATION

### 14.1 UN number

ADR/RID: - IMDG: - IATA: -

### 14.2 UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

### 14.3 Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

### 14.4 Packaging group

ADR/RID: - IMDG: - IATA: -





# VASUDHA PHARMA CHEM LIMITED

Unit-I : Plot No. 39 A & B, Phase-I, I.D.A., Jeedimetla, Hyderabad-500055, Telangana, INDIA.

Phone: +91-40-44754545

E-mail: mwu1@vasudhapharma.com

Fax : +91-40-44754555

Website: www.vasudhapharma.com

SAFETY DATA SHEET			
CISAPRIDE MONOHYDRATE			
SDS Number:	VPCL/SDS/028/00	Effective date:	24/06/2016

Page 7 of 7

## 14.5 Environmental hazards

ADR/RID: no

IMDG Marine pollutant: no

IATA: no

## 14.6 Special precautions for user

No data available

## SECTION 15-REGULATORY INFORMATION

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

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

No data available

### 15.2 Chemical Safety Assessment

No data available

## SECTION 16-OTHER INFORMATION

The information provided in this Safety Data Sheet (SDS) has been compiled from our experience and the data presented in various technical publications. Above data is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall *Vasudha Pharma Chem Limited* be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if *Vasudha Pharma Chem Limited* has been advised of the possibility of such damages. We reserve the right to revise the SDS from time to time as new information becomes available. It is recommended that the user contact the company to make sure the SDS is in use is the latest one issued.

Compiled by:	Checked by:	Approved by:
Sign: G. Skao	Sign: J. Sasli	Sign: [Signature]
Date: 24/06/16	Date: 24/06/16	Date: 24/06/16