



RAWPHARMA BIZ PRIVATE LIMITED

1101-CITY CENTRE-2, SCIENCE CITY ROAD,
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SECTION 1: Identification of the substance/mixture and of the company/ undertaking

1.1 Product identifier

Crospovidone (Type B), Ph. Eur. (104161)

Crospovidone ; CAS No. : 9003-39-8 ; REACH No. : N/D

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

Relevant identified uses

For manufacturing, processing, laboratory or repacking use only.

Uses advised against

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet

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

Rawpharma Biz Private Limited

Street : 1101, City Center – 2, Science city road,

Postal code/City : Sola, Ahmedabad, Gujarat - 380060

Telephone : +91 – 79460 48549

Information contact : info@sbfpharma.com

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

2.2 Label elements

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

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

2.3 Other hazards

None

SECTION 3: Composition/information on ingredients

3.1 Substances

Substance name : Crospovidone

REACH No. : N/D

CAS No. : 9003-39-8

Purity : 100 % [mass]

SECTION 4: First aid measures

4.1 Description of first aid measures

Due to the composition and type of the substances present in the product, no particular warnings are necessary.

Following inhalation

Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

In case of skin contact

Remove contaminated clothing.

After eye contact

Remove contact lenses, if present and if it is easy to do. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance. Don't let the person to rub the affected eye.

Following ingestion

Keep calm. NEVER induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

No known acute or delayed effects from exposure to the product.

4.3 Indication of any immediate medical attention and special treatment needed

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Extinguisher powder or CO₂. In case of more serious fires, also alcohol-resistant foam and water spray.

Unsuitable extinguishing media

Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

5.2 Special hazards arising from the substance or mixture

Fire can cause thick, black smoke. As a result of thermal decomposition, dangerous products can form: carbon monoxide, carbon dioxide. Exposure to combustion or decomposition products can be harmful to your health.

5.3 Advice for firefighters

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account.

Special protective equipment for firefighters

According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For exposure control and individual protection measures, see section 8.

For non-emergency personnel

Follow established procedures.

For emergency responders

Follow established procedures.

6.2 Environmental precautions

Product not classified as hazardous for the environment, avoid spillage as much as possible.

6.3 Methods and material for containment and cleaning up

The contaminated area should be immediately cleaned with an appropriate de-contaminator. Pour the decontaminator on the remains in an opened container and let it act various days until no further reaction is produced.

For containment

Follow established procedures.

For cleaning up

Follow established procedures.

6.4 Reference to other sections

For exposure control and individual protection measures, see section 8. For later elimination of waste, follow the recommendations under section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

The product does not require special handling measures, the following general measures are recommended: For personal protection, see section 8. Never use pressure to empty the containers. They are not pressure-resistant containers. In the application area, smoking, eating, and drinking must be prohibited. Follow legislation on occupational health and safety. Keep the product in containers made of a material identical to the original.

Protective measures



Measures to prevent aerosol and dust generation

No special measures are necessary.

Environmental precautions

No special measures are necessary.

Specific requirements or handling rules

No special measures are necessary.

Advices on general occupational hygiene

No special measures are necessary.

7.2 Conditions for safe storage, including any incompatibilities

As general storage measures, sources of heat, radiation, electricity and contact with food should be avoided. Keep away from oxidising agents and from highly acidic or alkaline materials. Store according to local legislation. Observe indications on the label. The product is not affected by Directive 2012/18/EU (SEVESO III).

Technical measures and storage conditions

Storage temperature :

Keep in a cool, well-ventilated place.

Requirements for storage rooms and vessels

Only use containers specifically approved for the substance/product.

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

The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values.

8.2 Exposure controls

Only wear fitting, comfortable and clean protective clothing.

Personal protection equipment

Eye/face protection



Eye glasses EN 166

Skin protection

Hand protection



Tested protective gloves must be worn EN ISO 374. 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.

Body protection

No special measures are necessary.

Respiratory protection

No special measures are necessary.

Thermal hazards

No special measures are necessary.

Environmental exposure controls

No information available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : solid

Safety characteristics

Melting point/freezing point :	(1013 hPa)	110 - 180 °C
Initial boiling point and boiling range :	(1013 hPa)	No data available



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Decomposition temperature :	(1013 hPa)	No data available	
Flash point :		No data available	
Auto-ignition temperature :		No data available	
Lower explosion limit :		No data available	
Upper explosion limit :		No data available	
Vapour pressure :	(50 °C)	No data available	
Density :	(20 °C)	1.2 g/cm ³	
Solvent separation test :	(20 °C)	not applicable	
Water solubility :	(20 °C)	No data available	
Fat solubility :	(20 °C)	No data available.	
pH :	(20 °C / 10 g/l)	5 - 8	
pH :	(20 °C / 50 g/l)	3 - 7	
log P O/W :		0.37	
Flow time :	(20 °C)	No data available	DIN- cup 4 mm
Viscosity :	(20 °C)	No data available	
Relative vapour density :	(20 °C)	No data available	
Evaporation rate :		No data available	
Flammable solids :	No data available.		
Flammable gases :	No data available.		
Explosive properties :	No data available.		

9.2 Other information

None

SECTION 10: Stability and reactivity

10.1 Reactivity

The product does not present hazards by their reactivity.

10.2 Chemical stability

Stable under the recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions

The product does not present possibility of hazardous reactions.

10.4 Conditions to avoid

Avoid any improper handling.

10.5 Incompatible materials

Keep away from oxidising agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.

10.6 Hazardous decomposition products

No decomposition if used for the intended uses.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Acute oral toxicity

Parameter : LD50 (Crospovidone ; CAS No. : 9003-39-8)
Exposure route : Oral

Species : Rat
Effective dose : 100000 mg/kg

Corrosion

Skin corrosion/irritation

No information available.

Serious eye damage/eye irritation

No information available.

Respiratory or skin sensitisation

No information available.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity

No information available.

Germ cell mutagenicity

No information available.

Reproductive toxicity

No information available.

STOT-single exposure

No information available.

STOT-repeated exposure

No information available.

Aspiration hazard

No information available.

11.2 Information on other hazards

No information available.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity

Acute (short-term) fish toxicity

Parameter : LC50 (Crospovidone ; CAS No. : 9003-39-8)
Species : Leuciscus idus (golden orfe)
Evaluation parameter : Acute (short-term) fish toxicity
Effective dose : > 10000 mg/l
Exposure time : 96 h

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

Parameter : Log KOW (Crospovidone ; CAS No. : 9003-39-8)
Partition coefficient n-octanol/water (log value)
Partition coefficient n-octanol/water (log value)
Value : 0.37

12.4 Mobility in soil

No information available.



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12.5 Results of PBT and vPvB assessment

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

12.6 Endocrine disrupting properties

No information available.

12.7 Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recycle according to official regulations.

Product/Packaging disposal

Waste treatment options

Do not dump into sewers or waterways.

Appropriate disposal / Product

Waste and empty containers must be handled and eliminated according to current local/national legislation.

Appropriate disposal / Package

Non-contaminated packages must be recycled or disposed of. Packing which cannot be properly cleaned must be disposed of. Follow the provisions of Directive 2008/98/EC regarding waste management.

SECTION 14: Transport information

14.1 UN number

No information available.

14.2 UN proper shipping name

No information available.

14.3 Transport hazard class(es)

No information available.

14.4 Packing group

No information available.

14.5 Environmental hazards

No information available.

14.6 Special precautions for user

None

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

No information available.

SECTION 15: Regulatory information

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

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH) Classification according to Regulation (EC) No 1272/2008 [CLP] according to Regulation (EU) No. 2020/878

National regulations



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Water hazard class

Class : nwg (Non-hazardous to water)

15.2 Chemical Safety Assessment

No information available.

SECTION 16: Other information

16.1 Indication of changes

None

16.2 Abbreviations and acronyms

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
ASTM:	ASTM International, originally known as American Society for Testing and Materials (ASTM)
EINECS:	European Inventory of Existing Commercial Chemical Substances
EC50:	Effective Concentration 50 (Maximum Effective Concentration for 0% of Individuals)
LC50:	Lethal Concentration 50 (Lethal Concentration for 50% of Individuals)
IC50:	Inhibitor Concentration 50 (Inhibitory Concentration for 50% of Individuals)
NOEL:	No Observed Effect Level (Maximum dose without effect)
DNEL:	Derived No Effect Level (Derived no-effect dose)
DMEL:	Derived Minimum Effect Level (Derived dose of minimal effect)
CLP:	Classification, Labelling and Packaging
CSR:	Chemical Safety Report
LD50:	Lethal Dose 50 (Lethal Dose for 50% of Individuals)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
Codice IMDG:	International Maritime Dangerous Goods code
PBT:	Persistent, bioaccumulative and toxic
RID:	Regulations concerning the international rail transport of Dangerous Goods
STEL:	Short term exposure limit
TLV:	Threshold limit value
TWA:	Time Weighted Average
UE:	European Union
vPvB:	Very persistent very bioaccumulative
N.D.:	Unavailable
N.A.:	Not applicable
VwWvS.:	Text of Administrative Regulation on the Classification of Substances hazardous to waters into Water Hazard Classes

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.