



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

1.1. Product identifier

Product name. : Zantac Injection

Other means of identification : ZANTAC INJECTION 25 MG/ML * ZANTAC INJECTION Premixed 50 MG/ 50 ML * RANITIDINE HYDROCHLORIDE, FORMULATED PRODUCT

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

Use of the substance/preparation : Pharmaceutical Agent

1.3. Details of the supplier of the safety data sheet

Covis Pharma S.à.r.l.
Luxembourg, Zug Branch
Bahnhofstrasse 11
CH-6300 Zug, Switzerland

CH General Information:

Office : 0041 (0) 41 748 04 04 / Fax : 0041 (0) 41 748 04 09

Note : Zug Area code is 041. In Switzerland this area code must be used before the 7 digit tel. number

Medical Emergency : see U.S. information below

Information and Advice: US number, available 24 hours

Multi-language response

1.4. Emergency telephone number

Covis Pharmaceuticals, Inc

1513 Walnut Street

Suite 270

Cary, NC 27511

P : 919-535-3049 / Fax : 866-869-9215

e : info@covispharma.com

Transport Emergency: For Chemical Emergency, Spill, Leak, Fire, Exposure, or Accident Call CHEMTREC Day or Night

Within USA and Canada: 1-800-424-9300

Outside USA and Canada: +1 703-527-3887 (collect calls accepted)

Medical Emergency +1-866-488-4423

US number, available 24 hours

Multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GHS-US classification

Not Classified

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2.2. Label elements

GHS-US labelling

No labelling applicable

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS-US classification
N-[2-[[5- [[Dimethylamino)methyl]furfuryl]thio]ethyl]-N'-methyl-2-nitrovinylidenediamine hydrochloride	(CAS No.) 66357-59-3	3	Not classified

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : If not breathing, give artificial respiration.

First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

First-aid measures after eye contact : In case of dust contact with eyes, rinse immediately with plenty of water.

First-aid measures after ingestion : Go into open air and ventilate suspected area.

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

No additional information available

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

Medical treatment in cases of overexposure should be treated as an overdose of a histamine antagonist (H2-type). Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information center.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.

5.2. Special hazards arising from the substance or mixture

Fire hazard : None known.

5.3. Advice for firefighters

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : No special measures required.

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6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

None.

6.3. Methods and material for containment and cleaning up

For containment : Recover the product by vacuuming, shovelling or sweeping.

Methods for cleaning up : Recycle product or dispose properly.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.

Hand protection : Use neoprene or rubber gloves.

Eye protection : In case of dust production: protective goggles.

Skin and body protection : Wear suitable working clothes.

Respiratory protection : Wear NIOSH approved respirator when handling.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Colour : No data available

Odour : No data available

Odour threshold : No data available

pH : No data available

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12.2. Persistence and degradability

* Biodegradation

This material contains an active pharmaceutical ingredient that is not readily biodegradable but is inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and is not expected to persist in the environment.

Aerobic - Ready

Percent Degradation: < 1 %, 28 days, Modified Sturm test.

Aerobic - Inherent

Percent Degradation: 43 %, 28 days, Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

Aerobic - Inherent

Percent Degradation: 2 %, 28 days, Modified Zahn-Wellens, DOC removal., Activated sludge

Anaerobic

Percent Degradation: 12 %, 35 days

Aerobic - Soil

Percent Degradation: 3 to 10 %, 67 days

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

In accordance with DOT / ADR / RID / ADN / IMDG / ICAO / IATA

14.1. UN number

No dangerous good in sense of transport regulations.

14.2. UN proper shipping name

Not applicable

14.2 Additional information

Other information : No supplementary information available.

Overland transport

No additional information available

Transport by sea

No additional information available

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Air transport

No additional information available

SECTION 15: Regulatory information

15.1. US Federal regulations

No additional information available

15.2. US State regulations

No additional information available

SECTION 16: Other information

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.