

Metamizol Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.0	14.04.2025	10558933-00013	Date of first issue: 14.01.2022

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Trade name : Metamizol Injection Formulation

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

Use of the Sub-
stance/Mixture : Veterinary product

Recommended restrictions
on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
20 Spartan Road
1619 Spartan, South Africa

Telephone : +27119239300

E-mail address of person
responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Skin sensitisation, Category 1

H317: May cause an allergic skin reaction.

Reproductive toxicity, Category 2

H361: Suspected of damaging fertility or the unborn child.

Specific target organ toxicity - repeated
exposure, Category 1

H372: Causes damage to organs through prolonged or repeated exposure.

Long-term (chronic) aquatic hazard, Category 2

H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Hazard pictograms :



Signal word : Danger

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Hazard statements : H317 May cause an allergic skin reaction.
H361 Suspected of damaging fertility or the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P391 Collect spillage.

Hazardous components which must be listed on the label:

Metamizol
Benzyl alcohol

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Metamizol	68-89-3 200-694-7	Repr. 2; H361 STOT RE 1; H372 (Blood) Aquatic Chronic 2; H411	≥ 30 - < 50
Benzyl alcohol	100-51-6 202-859-9 603-057-00-5	Acute Tox. 4; H302 Eye Irrit. 2; H319 Skin Sens. 1B; H317	≥ 1 - < 10

For explanation of abbreviations see section 16.

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SECTION 4: First aid measures

4.1 Description of first aid measures

- | | | |
|----------------------------|---|---|
| General advice | : | In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice. |
| Protection of first-aiders | : | First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8). |
| If inhaled | : | If inhaled, remove to fresh air.
Get medical attention. |
| In case of skin contact | : | In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse. |
| In case of eye contact | : | If in eyes, rinse well with water.
Get medical attention if irritation develops and persists. |
| If swallowed | : | If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water. |

4.2 Most important symptoms and effects, both acute and delayed

- | | | |
|-------|---|--|
| Risks | : | Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

May cause an allergic skin reaction.
Suspected of damaging fertility or the unborn child.
Causes damage to organs through prolonged or repeated exposure. |
|-------|---|--|

4.3 Indication of any immediate medical attention and special treatment needed

- | | | |
|-----------|---|---|
| Treatment | : | Treat symptomatically and supportively. |
|-----------|---|---|
-

SECTION 5: Firefighting measures

5.1 Extinguishing media

- | | | |
|------------------------------|---|--|
| Suitable extinguishing media | : | Water spray
Alcohol-resistant foam
Carbon dioxide (CO ₂)
Dry chemical |
| Unsuitable extinguishing | : | None known. |
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media

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

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mine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- | | | |
|-------------------------|---|---|
| Technical measures | : | Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. |
| Local/Total ventilation | : | Use only with adequate ventilation. |
| Advice on safe handling | : | Do not get on skin or clothing.
Do not breathe mist or vapours.
Do not swallow.
Avoid contact with eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment. |
| Hygiene measures | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. |

7.2 Conditions for safe storage, including any incompatibilities

- | | | |
|---|---|--|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations. |
| Advice on common storage | : | Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases |

7.3 Specific end use(s)

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Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Metamizol	68-89-3	TWA	3 mg/m ³ (OEB 1)	Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
Benzyl alcohol	Workers	Inhalation	Long-term systemic effects	22 mg/m ³
	Workers	Inhalation	Acute systemic effects	110 mg/m ³
	Workers	Skin contact	Long-term systemic effects	8 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	40 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	5,4 mg/m ³
	Consumers	Inhalation	Acute systemic effects	27 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	20 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	20 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Benzyl alcohol	Fresh water	1 mg/l
	Marine water	0,1 mg/l
	Intermittent use/release	2,3 mg/l
	Sewage treatment plant	39 mg/l
	Fresh water sediment	5,27 mg/kg
	Marine sediment	0,527 mg/kg
	Soil	0,456 mg/kg

8.2 Exposure controls

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

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Laboratory operations do not require special containment.

Personal protective equipment

Eye/face protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection	:	
Material	:	Chemical-resistant gloves
Skin and body protection	:	Work uniform or laboratory coat.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type	:	Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Appearance	:	liquid
Colour	:	colourless
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available

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Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: Not applicable
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, kinematic	: No data available
Explosive properties	: Not explosive
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

9.2 Other information

Molecular weight	: No data available
Particle size	: Not applicable

SECTION 10: Stability and reactivity**10.1 Reactivity**

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
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10.4 Conditions to avoid

Conditions to avoid	: Heat, flames and sparks. Avoid dust formation.
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10.5 Incompatible materials

Materials to avoid	: Oxidizing agents
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10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information**11.1 Information on toxicological effects**

Information on likely routes of exposure	: Inhalation Skin contact Ingestion Eye contact
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Acute toxicity

|| Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Components:**Metamizol:**

Acute oral toxicity : LD50 Oral (Rat): 3.000 mg/kg
Target Organs: Central nervous system

LD50 Oral (Rabbit): 2.150 mg/kg
Target Organs: Central nervous system

LD50 Oral (Guinea pig): 1.000 mg/kg
Target Organs: Central nervous system

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1.200 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5,4 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: The substance or mixture has no acute inhalation toxicity

Skin corrosion/irritation

|| Not classified based on available information.

Components:**Benzyl alcohol:**

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Serious eye damage/eye irritation

|| Not classified based on available information.

Components:**Benzyl alcohol:**

Species : Rabbit
Method : OECD Test Guideline 405
Result : Irritation to eyes, reversing within 21 days

Respiratory or skin sensitisation**Skin sensitisation**

|| May cause an allergic skin reaction.

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Respiratory sensitisation

|| Not classified based on available information.

Components:**Benzyl alcohol:**

Test Type	: Human repeat insult patch test (HRIPT)
Exposure routes	: Skin contact
Species	: Humans
Result	: positive

Assessment	: Probability or evidence of low to moderate skin sensitisation rate in humans
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Germ cell mutagenicity

|| Not classified based on available information.

Components:**Metamizol:**

Genotoxicity in vitro	: Test Type: Ames test Result: negative Test Type: Mutagenicity (in vitro mammalian cytogenetic test) Test system: Chinese hamster lung cells Result: negative
Genotoxicity in vivo	: Test Type: Micronucleus test Species: Mouse Result: negative

Benzyl alcohol:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative

Carcinogenicity

|| Not classified based on available information.

Components:**Metamizol:**

Species	: Mouse, male
Application Route	: oral (feed)
Exposure time	: 2 Years
	: 375 mg/kg bw/day
Result	: negative

Species	: Mouse, female
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Application Route	: oral (feed)
Exposure time	: 2 Years
	: 442 mg/kg bw/day
Result	: negative

Species	: Rat, male
Application Route	: oral (drinking water)
Exposure time	: 2 Years
	: 150 mg/kg bw/day
Result	: negative

Species	: Rat, female
Application Route	: oral (drinking water)
Exposure time	: 2 Years
	: 193 mg/kg bw/day
Result	: negative

Benzyl alcohol:

Species	: Mouse
Application Route	: Ingestion
Exposure time	: 103 weeks
Method	: OECD Test Guideline 451
Result	: negative

Reproductive toxicity

|| Suspected of damaging fertility or the unborn child.

Components:**Metamizol:**

Effects on fertility	: Test Type: Fertility/early embryonic development Species: Rat Application Route: Oral Early Embryonic Development: NOAEL: 100 mg/kg body weight Result: Fetotoxicity, Maternal toxicity observed., May cause adverse reproductive effects. Test Type: Fertility/early embryonic development Species: Rat Application Route: Oral Early Embryonic Development: NOAEL: 400 mg/kg body weight Result: Fetotoxicity, Increased resorptions. Test Type: Fertility/early embryonic development Species: Rabbit Application Route: Oral Early Embryonic Development: NOAEL: 25 mg/kg body weight Result: Fetotoxicity, Increased resorptions.
Effects on foetal development	: Test Type: Two-generation study Species: Rat

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Application Route: Oral
Developmental Toxicity: NOAEL: 250 mg/kg body weight
Result: Maternal toxicity observed., Reduced maternal body weight gain, Reduced maternal food consumption, Reduced number of viable fetuses

Reproductive toxicity - Assessment : Suspected of damaging fertility. Suspected of damaging the unborn child.

Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
Species: Mouse
Application Route: Ingestion
Result: negative

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Components:**Metamizol:**

Exposure routes : Oral
Target Organs : Blood
Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Components:****Metamizol:**

Species : Rat
NOAEL : 50 mg/kg
Application Route : Subcutaneous
Exposure time : 28 d
Target Organs : Blood
Symptoms : blood effects

Species : Rat
NOAEL : 150 mg/kg
Application Route : Intravenous
Exposure time : 28 d
Target Organs : Blood
Symptoms : blood effects

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Species	: Rat
NOAEL	: 300 mg/kg
Application Route	: Oral
Exposure time	: 26 Weeks
Target Organs	: Blood
Symptoms	: blood effects

Species	: Dog
NOAEL	: 150 mg/kg
Application Route	: Subcutaneous
Exposure time	: 28 d
Target Organs	: Blood
Symptoms	: blood effects

Species	: Dog
NOAEL	: 50 mg/kg
Application Route	: Intravenous
Exposure time	: 28 d
Target Organs	: Blood, Gastrointestinal tract
Symptoms	: blood effects, Salivation, Vomiting

Species	: Dog
NOAEL	: 100 mg/kg
Application Route	: Oral
Exposure time	: 26 Weeks
Target Organs	: Blood, Liver, Kidney, spleen
Symptoms	: blood effects

Benzyl alcohol:

Species	: Rat
NOAEL	: 1,072 mg/l
Application Route	: inhalation (dust/mist/fume)
Exposure time	: 28 Days
Method	: OECD Test Guideline 412

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Metamizol:**

Ingestion	: Target Organs: Blood Symptoms: blood effects, Bloody urine, Diarrhoea, Nausea, Rash, hypotension
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SECTION 12: Ecological information**12.1 Toxicity****Components:****Metamizol:**

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Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 47 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Raphidocelis subcapitata (freshwater green alga)): > 50,8 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	EC10: 0,725 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

Benzyl alcohol:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 460 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 51 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

12.2 Persistence and degradability**Components:****Metamizol:**

Biodegradability	:	Result: Not readily biodegradable. Biodegradation: 18 - 23 %
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Benzyl alcohol:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 92 - 96 % Exposure time: 14 d
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12.3 Bioaccumulative potential

Components:**Benzyl alcohol:**

Partition coefficient: n-octanol/water : log Pow: 1,05

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Product:

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADN	: UN 3082
ADR	: UN 3082
RID	: UN 3082
IMDG	: UN 3082
IATA	: UN 3082

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14.2 UN proper shipping name

ADN	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Metamizol)
ADR	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Metamizol)
RID	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Metamizol)
IMDG	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Metamizol)
IATA	:	Environmentally hazardous substance, liquid, n.o.s. (Metamizol)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	:	9
ADR	:	9
RID	:	9
IMDG	:	9
IATA	:	9

14.4 Packing group

ADN	
Packing group	: III
Classification Code	: M6
Hazard Identification Number	: 90
Labels	: 9
ADR	
Packing group	: III
Classification Code	: M6
Hazard Identification Number	: 90
Labels	: 9
Tunnel restriction code	: (-)
RID	
Packing group	: III
Classification Code	: M6
Hazard Identification Number	: 90
Labels	: 9
IMDG	
Packing group	: III
Labels	: 9
EmS Code	: F-A, S-F
IATA (Cargo)	
Packing instruction (cargo)	: 964

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aircraft)
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards**ADN**

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****The components of this product are reported in the following inventories:**

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Metamizol Injection Formulation

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5.0	14.04.2025	10558933-00013	Date of first issue: 14.01.2022

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

H302 : Harmful if swallowed.
H317 : May cause an allergic skin reaction.
H319 : Causes serious eye irritation.
H361 : Suspected of damaging fertility or the unborn child.
H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.
H411 : Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Repr. : Reproductive toxicity
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Classification of the mixture:

Skin Sens. 1	H317
Repr. 2	H361
STOT RE 1	H372
Aquatic Chronic 2	H411

Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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