# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878

# Metamizol Injection Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024 |
|---|---|---|---|
| 5.0 | 14.04.2025 | 10562759-00014 | 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 Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

### 1.3 Details of the supplier of the safety data sheet

Company : MSD
Drynam Road
K67 P263 Dublin, Ireland

Telephone : +1-908-740-4000

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

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.

Ecological information: 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.

Toxicological information: 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.

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.<br>EC-No.<br>Index-No.<br>Registration number | Classification | Concentration (% w/w) |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Metamizol | 68-89-3<br>200-694-7 | Repr. 2; H361<br>STOT RE 1; H372 (Blood)<br>Aquatic Chronic 2; H411 | >= 30 - < 50 |
| Benzyl alcohol | 100-51-6<br>202-859-9<br>603-057-00-5 | Acute Tox. 4; H302<br>Eye Irrit. 2; H319<br>Skin Sens. 1B; H317<br>———————<br>Acute toxicity estimate<br><br>Acute oral toxicity: 1,200 mg/kg | >= 1 - < 10 |

For explanation of abbreviations see section 16.

## 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 (CO2)
Dry chemical

Unsuitable extinguishing media : None known.

**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 determine 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)

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/m3 (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/m3 |
| | Workers | Inhalation | Acute systemic effects | 110 mg/m3 |
| | 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/m3 |
| | Consumers | Inhalation | Acute systemic effects | 27 mg/m3 |
| | Consumers | Skin contact | Long-term systemic effects | 4 mg/kg bw/day |
| | Consumers | Skin contact | Acute systemic ef- | 20 mg/kg |

| | | | | |
|---|---|---|---|---|
| | | | fects | 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.
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 should conform to I.S. EN 14387

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

Physical state : liquid

Colour : colourless

Odour : No data available

Odour Threshold : No data available

| | | |
|---|---|---|
| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling range | : | 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 |
| Flash point | : | No data available |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| pH | : | No data available |
| Viscosity | | |
| Viscosity, kinematic | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Vapour pressure | : | No data available |
| Relative density | : | No data available |
| Density | : | No data available |
| Relative vapour density | : | No data available |
| Particle characteristics | | |
| Particle size | : | Not applicable |

**9.2 Other information**

| | | |
|---|---|---|
| Explosives | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |

| | | |
|---|---|---|
| Evaporation rate | : | No data available |
| Molecular weight | : | No data available |

## 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.<br>Can react with strong oxidizing agents. |

### 10.4 Conditions to avoid

| | | |
|---|---|---|
| Conditions to avoid | : | Heat, flames and sparks.<br>Avoid dust formation. |

### 10.5 Incompatible materials

| | | |
|---|---|---|
| Materials to avoid | : | Oxidizing agents |

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## SECTION 11: Toxicological information

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

| | | |
|---|---|---|
| Information on likely routes of exposure | : | Inhalation<br>Skin contact<br>Ingestion<br>Eye contact |

**Acute toxicity**

Not classified based on available information.

**Product:**

| | | |
|---|---|---|
| Acute oral toxicity | : | Acute toxicity estimate: > 2,000 mg/kg<br>Method: Calculation method |

**Components:**

**Metamizol:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 Oral (Rat): 3,000 mg/kg<br>Target Organs: Central nervous system<br><br>LD50 Oral (Rabbit): 2,150 mg/kg<br>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<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Method: OECD Test Guideline 403<br>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.

**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 |

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**Metamizol:**

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

**Benzyl alcohol:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Intraperitoneal injection<br>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 |
| 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<br>Species: Rat<br>Application Route: Oral<br>Early Embryonic Development: NOAEL: 100 mg/kg body weight<br>Result: Fetotoxicity, Maternal toxicity observed., May cause adverse reproductive effects.<br><br>Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Oral<br>Early Embryonic Development: NOAEL: 400 mg/kg body weight<br>Result: Fetotoxicity, Increased resorptions.<br><br>Test Type: Fertility/early embryonic development<br>Species: Rabbit<br>Application Route: Oral<br>Early Embryonic Development: NOAEL: 25 mg/kg body weight<br>Result: Fetotoxicity, Increased resorptions. |
| Effects on foetal development | : | Test Type: Two-generation study<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 250 mg/kg body weight<br>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<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative<br>Remarks: Based on data from similar materials |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Mouse<br>Application Route: Ingestion<br>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 |

| | | |
|---|---|---|
| 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.

### 11.2 Information on other hazards

**Endocrine disrupting properties**

Not classified based on available information.

**Product:**

| | | |
|---|---|---|
| Assessment | : | 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. |

**Experience with human exposure**

**Components:**

**Metamizol:**

| | | |
|---|---|---|
| Ingestion | : | Target Organs: Blood<br>Symptoms: blood effects, Bloody urine, Diarrhoea, Nausea, Rash, hypotension |

## SECTION 12: Ecological information

### 12.1 Toxicity

**Components:**

**Metamizol:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203 |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 47 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | : | EC50 (Raphidocelis subcapitata (freshwater green alga)): > 50.8 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | EC10: 0.725 mg/l<br>Exposure time: 21 d<br>Species: Daphnia magna (Water flea)<br>Method: OECD Test Guideline 211 |

**Benzyl alcohol:**

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

### 12.2 Persistence and degradability

**Components:**

**Metamizol:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 18 - 23 % |

**Benzyl alcohol:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Readily biodegradable.<br>Biodegradation: 92 - 96 %<br>Exposure time: 14 d |

### 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 Endocrine disrupting properties

**Product:**

| | | |
|---|---|---|
| Assessment | : | 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. |

### 12.7 Other adverse effects

No data available

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

| | | |
|---|---|---|
| Product | : | Dispose of in accordance with local regulations.<br>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.<br>Waste codes should be assigned by the user, preferably in |

| | | |
|---|---|---|
| | | discussion with the waste disposal authorities.<br>Do not dispose of waste into sewer. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product. |

## SECTION 14: Transport information

### 14.1 UN number or ID number

| | | |
|---|---|---|
| **ADN** | : | UN 3082 |
| **ADR** | : | UN 3082 |
| **RID** | : | UN 3082 |
| **IMDG** | : | UN 3082 |
| **IATA** | : | UN 3082 |

### 14.2 UN proper shipping name

| | | |
|---|---|---|
| **ADN** | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Metamizol) |
| **ADR** | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Metamizol) |
| **RID** | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Metamizol) |
| **IMDG** | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Metamizol) |
| **IATA** | : | Environmentally hazardous substance, liquid, n.o.s.<br>(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 aircraft) | : | 964 |
| 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 Maritime transport in bulk according to IMO instruments**

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**

| | | |
|---|---|---|
| REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) | : | Conditions of restriction for the following entries should be considered: Number on list 3<br><br>Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.<br><br>Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not. |
| REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). | : | Not applicable |
| Regulation (EU) No 2024/590 on substances that deplete the ozone layer | : | Not applicable |
| Regulation (EU) 2019/1021 on persistent organic pollutants (recast) | : | Not applicable |
| Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals | : | Not applicable |
| REACH - List of substances subject to authorisation (Annex XIV) | : | Not applicable |

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

| | | Quantity 1 | Quantity 2 |
|---|---|---|---|
| E2 | ENVIRONMENTAL HAZARDS | 200 t | 500 t |

**Other regulations:**

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

**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

| | | |
|---|---|---|
| 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; AIIC - 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 - Interna-

tional 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

**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:** | | **Classification procedure:** |
|---|---|---|
| Skin Sens. 1 | H317 | Calculation method |
| Repr. 2 | H361 | Calculation method |
| STOT RE 1 | H372 | Calculation method |
| Aquatic Chronic 2 | H411 | Calculation method |

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

IE / EN