

SAFETY DATA SHEET

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



Ivermectin (with Propylene Glycol) Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
| 6.1 | 28.09.2024 | 4710828-00019 | Date of first issue: 30.07.2019 |

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

1.1 Product identifier

Trade name : Ivermectin (with Propylene Glycol) 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
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

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)

| | |
|--|--|
| Flammable liquids, Category 2 | H225: Highly flammable liquid and vapour. |
| Eye irritation, Category 2 | H319: Causes serious eye irritation. |
| Specific target organ toxicity - single exposure, Category 2 | H371: May cause damage to organs. |
| Specific target organ toxicity - repeated exposure, Category 2 | H373: May cause damage to organs through prolonged or repeated exposure. |
| Short-term (acute) aquatic hazard, Category 1 | H400: Very toxic to aquatic life. |
| Long-term (chronic) aquatic hazard, Category 1 | H410: Very toxic to aquatic life with long lasting effects. |

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

SAFETY DATA SHEET

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



Ivermectin (with Propylene Glycol) Formula- tion

Version 6.1 Revision Date: 28.09.2024 SDS Number: 4710828-00019 Date of last issue: 06.04.2024
Date of first issue: 30.07.2019

- Hazard pictograms : 
- Signal word : Danger
- Hazard statements : H225 Highly flammable liquid and vapour.
H319 Causes serious eye irritation.
H371 May cause damage to organs.
H373 May cause damage to organs through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.
- Precautionary statements : **Prevention:**
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 Keep container tightly closed.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.
P391 Collect spillage.

Hazardous components which must be listed on the label:
Ivermectin

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.

Vapours may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

SAFETY DATA SHEET

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



Ivermectin (with Propylene Glycol) Formula- tion

Version 6.1 Revision Date: 28.09.2024 SDS Number: 4710828-00019 Date of last issue: 06.04.2024
Date of first issue: 30.07.2019

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|-----------------|---|--|--------------------------|
| 1,3-Dioxan-5-ol | 4740-78-7 225-248-9 | Eye Irrit. 2; H319 | >= 30 - < 50 |
| Butanone | 78-93-3 201-159-0 606-002-00-3 | Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336 EUH066 | >= 10 - < 20 |
| Ivermectin | 70288-86-7 274-536-0 | Acute Tox. 2; H300 Acute Tox. 3; H311 STOT SE 1; H370 (Central nervous system) STOT RE 1; H372 (Central nervous system) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10.000 M-Factor (Chronic aquatic toxicity): 10.000 | >= 1 - < 2,5 |

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 if symptoms occur.
- In case of skin contact : Remove contaminated clothing and shoes.

SAFETY DATA SHEET

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



Ivermectin (with Propylene Glycol) Formula- tion

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
| 6.1 | 28.09.2024 | 4710828-00019 | Date of first issue: 30.07.2019 |

In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.

If swallowed : If swallowed, DO NOT induce vomiting.
If vomiting occurs have person lean forward.
Call a physician or poison control centre immediately.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Risks : Causes serious eye irritation.
May cause damage to organs.
May cause 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 : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Do not use a solid water stream as it may scatter and spread fire.
Flash back possible over considerable distance.
Vapours may form explosive mixtures with air.
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 meth- : Use extinguishing measures that are appropriate to local cir-

SAFETY DATA SHEET

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



Ivermectin (with Propylene Glycol) Formula- tion

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
| 6.1 | 28.09.2024 | 4710828-00019 | Date of first issue: 30.07.2019 |

ods cumstances 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 : Remove all sources of ignition.
Ventilate the area.
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 : Non-sparking tools should be used.
Soak up with inert absorbent material.
Suppress (knock down) gases/vapours/mists with a water spray jet.
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 : See Engineering measures under EXPOSURE

SAFETY DATA SHEET

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



Ivermectin (with Propylene Glycol) Formula- tion

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
| 6.1 | 28.09.2024 | 4710828-00019 | Date of first issue: 30.07.2019 |

- Local/Total ventilation : CONTROLS/PERSONAL PROTECTION section.
: If sufficient ventilation is unavailable, use with local exhaust ventilation.
Use explosion-proof electrical, ventilating and lighting equipment.
- Advice on safe handling : Do not breathe mist or vapours.
Do not swallow.
Do not get in eyes.
Avoid prolonged or repeated contact with skin.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Non-sparking tools should be used.
Keep container tightly closed.
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
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. 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. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Keep away from heat and sources of ignition.
- Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Flammable solids
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Substances and mixtures, which in contact with water, emit flammable gases
Explosives
Gases
Very acutely toxic substances and mixtures

SAFETY DATA SHEET

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



Ivermectin (with Propylene Glycol) Formula- tion

Version 6.1 Revision Date: 28.09.2024 SDS Number: 4710828-00019 Date of last issue: 06.04.2024
Date of first issue: 30.07.2019

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 |
|------------------|---------------------------------|-------------------------------|----------------------------------|---------------------|
| Propylene glycol | 57-55-6 | TWA | 25 ppm 79 mg/m ³ | FOR-2011-12-06-1358 |
| Butanone | 78-93-3 | TWA | 75 ppm 220 mg/m ³ | FOR-2011-12-06-1358 |
| | | STEL | 300 ppm 900 mg/m ³ | 2000/39/EC |
| | Further information: Indicative | | | |
| | | TWA | 200 ppm 600 mg/m ³ | 2000/39/EC |
| | Further information: Indicative | | | |
| Ivermectin | 70288-86-7 | TWA | 30 µg/m ³ (OEB 3) | Internal |
| | Further information: Skin | | | |
| | | Wipe limit | 300 µg/100 cm ² | Internal |

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

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|------------------|-----------|-----------------|----------------------------|-----------------------|
| Butanone | Workers | Inhalation | Long-term systemic effects | 600 mg/m ³ |
| | | Skin contact | Long-term systemic effects | 1161 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 106 mg/m ³ |
| | | Skin contact | Long-term systemic effects | 412 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 31 mg/kg bw/day |
| | | | | |
| Propylene glycol | Workers | Inhalation | Long-term local effects | 10 mg/m ³ |
| | | Inhalation | Long-term systemic effects | 168 mg/m ³ |
| | Consumers | Inhalation | Long-term local effects | 10 mg/m ³ |
| | | Inhalation | Long-term systemic effects | 50 mg/m ³ |

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

| Substance name | Environmental Compartment | Value |
|----------------|---------------------------|-------|
|----------------|---------------------------|-------|

SAFETY DATA SHEET

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



Ivermectin (with Propylene Glycol) Formula- tion

Version 6.1 Revision Date: 28.09.2024 SDS Number: 4710828-00019 Date of last issue: 06.04.2024
Date of first issue: 30.07.2019

| | | |
|------------------|----------------------------|--------------------------------|
| Butanone | Fresh water | 55,8 mg/l |
| | Freshwater - intermittent | 55,8 mg/l |
| | Marine water | 55,8 mg/l |
| | Sewage treatment plant | 709 mg/l |
| | Fresh water sediment | 284,74 mg/kg dry weight (d.w.) |
| | Marine sediment | 284,7 mg/kg dry weight (d.w.) |
| | Soil | 22,5 mg/kg dry weight (d.w.) |
| | Oral (Secondary Poisoning) | 1000 mg/kg food |
| Propylene glycol | Fresh water | 260 mg/l |
| | Freshwater - intermittent | 183 mg/l |
| | Marine water | 26 mg/l |
| | Sewage treatment plant | 20000 mg/l |
| | Fresh water sediment | 572 mg/kg dry weight (d.w.) |
| | Marine sediment | 57,2 mg/kg dry weight (d.w.) |
| | Soil | 50 mg/kg dry weight (d.w.) |

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.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

Use explosion-proof electrical, ventilating and lighting equipment.

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

Remarks : Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.

Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

SAFETY DATA SHEET

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



Ivermectin (with Propylene Glycol) Formula- tion

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
| 6.1 | 28.09.2024 | 4710828-00019 | Date of first issue: 30.07.2019 |

| | | |
|------------------------|---|--|
| Respiratory protection | : | Use appropriate degowning techniques to remove potentially contaminated clothing. If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS 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 | : | Colorless to pale yellow |
| Odour | : | characteristic |
| Odour Threshold | : | No data available |
| Melting point/freezing point | : | < -66 °C |
| Initial boiling point and boiling range | : | 81,5 °C |
| Flammability (solid, gas) | : | Not applicable |
| Flammability (liquids) | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Flash point | : | 16 °C |
| 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 | : | slightly soluble |

SAFETY DATA SHEET

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



Ivermectin (with Propylene Glycol) Formula- tion

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
| 6.1 | 28.09.2024 | 4710828-00019 | Date of first issue: 30.07.2019 |

| | | |
|---|---|-------------------|
| Partition coefficient: n-octanol/water | : | Not applicable |
| Vapour pressure | : | No data available |
| Relative density | : | 1,04 - 1,08 |
| 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 | : | Highly flammable liquid and vapour. Vapours may form explosive mixture with air. Can react with strong oxidizing agents. |
|---------------------|---|--|

10.4 Conditions to avoid

| | | |
|---------------------|---|--------------------------|
| Conditions to avoid | : | Heat, flames and sparks. |
|---------------------|---|--------------------------|

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

SAFETY DATA SHEET

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



Ivermectin (with Propylene Glycol) Formula- tion

| | | | |
|----------------|------------------------------|------------------------------|---|
| Version 6.1 | Revision Date: 28.09.2024 | SDS Number: 4710828-00019 | Date of last issue: 06.04.2024 Date of first issue: 30.07.2019 |
|----------------|------------------------------|------------------------------|---|

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

Acute toxicity

Not classified based on available information.

Product:

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

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

Components:

1,3-Dioxan-5-ol:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg
Remarks: Based on data from similar materials

Butanone:

Acute oral toxicity : LD50 (Rat): > 2.000 - 5.000 mg/kg
Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 25,5 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: OECD Test Guideline 436
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 5.000 mg/kg

Ivermectin:

Acute oral toxicity : LD50 (Rat): 50 mg/kg
LD50 (Mouse): 25 mg/kg
LD50 (Monkey): > 24 mg/kg
Target Organs: Central nervous system
Symptoms: Vomiting, Dilatation of the pupil
Remarks: No mortality observed at this dose.

Acute inhalation toxicity : LC50 (Rat): 5,11 mg/l
Exposure time: 1 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): 406 mg/kg

SAFETY DATA SHEET

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



Ivermectin (with Propylene Glycol) Formula- tion

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
| 6.1 | 28.09.2024 | 4710828-00019 | Date of first issue: 30.07.2019 |

LD50 (Rat): > 660 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

1,3-Dioxan-5-ol:

| | | |
|---------|---|--------------------------------------|
| Species | : | Rabbit |
| Method | : | OECD Test Guideline 404 |
| Result | : | No skin irritation |
| Remarks | : | Based on data from similar materials |

Butanone:

| | | |
|------------|---|---|
| Assessment | : | Repeated exposure may cause skin dryness or cracking. |
|------------|---|---|

| | | |
|---------|---|--------------------------------------|
| Species | : | Rabbit |
| Method | : | OECD Test Guideline 404 |
| Result | : | No skin irritation |
| Remarks | : | Based on data from similar materials |

Ivermectin:

| | | |
|---------|---|--------------------|
| Species | : | Rabbit |
| Result | : | No skin irritation |

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

1,3-Dioxan-5-ol:

| | | |
|---------|---|--|
| Species | : | Rabbit |
| Method | : | OECD Test Guideline 405 |
| Result | : | Irritation to eyes, reversing within 21 days |
| Remarks | : | Based on data from similar materials |

Butanone:

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

Ivermectin:

| | | |
|---------|---|---------------------|
| Species | : | Rabbit |
| Result | : | Mild eye irritation |

SAFETY DATA SHEET

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



Ivermectin (with Propylene Glycol) Formula- tion

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
| 6.1 | 28.09.2024 | 4710828-00019 | Date of first issue: 30.07.2019 |

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

1,3-Dioxan-5-ol:

| | |
|-----------------|--|
| Test Type | : Maximisation Test |
| Exposure routes | : Skin contact |
| Species | : Guinea pig |
| Method | : OECD Test Guideline 406 |
| Result | : negative |
| Remarks | : Based on data from similar materials |

Butanone:

| | |
|-----------------|---------------------------|
| Test Type | : Buehler Test |
| Exposure routes | : Skin contact |
| Species | : Guinea pig |
| Method | : OECD Test Guideline 406 |
| Result | : negative |

Ivermectin:

| | |
|-----------------|--------------------------------------|
| Exposure routes | : Dermal |
| Species | : Humans |
| Result | : Does not cause skin sensitisation. |

Germ cell mutagenicity

Not classified based on available information.

Components:

1,3-Dioxan-5-ol:

| | |
|-----------------------|---|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES) Result: negative |
| | : Test Type: In vitro mammalian cell gene mutation test Result: negative |
| Genotoxicity in vivo | : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Result: negative Remarks: Based on data from similar materials |

Butanone:

| | |
|-----------------------|--|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES) |
|-----------------------|--|

SAFETY DATA SHEET

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



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| | | | |
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| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
| 6.1 | 28.09.2024 | 4710828-00019 | Date of first issue: 30.07.2019 |

Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Test Type: DNA damage and repair, unscheduled DNA syn-
thesis in mammalian cells (in vitro)
Result: negative

Test Type: Saccharomyces cerevisiae, gene mutation assay
(in vitro)
Result: negative

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

Ivermectin:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: DNA damage and repair, unscheduled DNA syn-
thesis in mammalian cells (in vitro)
Test system: human diploid fibroblasts
Result: negative

Test Type: Mouse Lymphoma
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Ivermectin:

Species : Rat
Application Route : Oral
NOAEL : 1,5 mg/kg body weight
Result : negative
Remarks : Based on data from similar materials

Species : Mouse
Application Route : Oral
NOAEL : 2,0 mg/kg body weight
Result : negative
Remarks : Based on data from similar materials

SAFETY DATA SHEET

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



Ivermectin (with Propylene Glycol) Formula- tion

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
| 6.1 | 28.09.2024 | 4710828-00019 | Date of first issue: 30.07.2019 |

Reproductive toxicity

Not classified based on available information.

Components:

Butanone:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal develop- : Test Type: Embryo-foetal development
ment Species: Rat
Application Route: Inhalation
Method: OECD Test Guideline 414
Result: negative

Ivermectin:

Effects on fertility : Test Type: Fertility
Species: Rat
Application Route: Oral
Fertility: NOAEL: 0,6 mg/kg body weight
Result: Animal testing did not show any effects on fertility.

Effects on foetal develop- : Test Type: Development
ment Species: Mouse
Application Route: Oral
Developmental Toxicity: NOAEL: 0,2 mg/kg body weight
Result: Teratogenic effects, Embryotoxic effects and adverse
effects on the offspring were detected only at high maternally
toxic doses

Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 0,4 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the off-
spring were detected.
Remarks: The mechanism or mode of action may not be rele-
vant in humans.

Test Type: Development
Species: Rabbit
Application Route: Oral
Result: Teratogenic effects, Embryotoxic effects and adverse
effects on the offspring were detected only at high maternally
toxic doses

SAFETY DATA SHEET

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



Ivermectin (with Propylene Glycol) Formula- tion

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
| 6.1 | 28.09.2024 | 4710828-00019 | Date of first issue: 30.07.2019 |

STOT - single exposure

May cause damage to organs.

Components:

Butanone:

Assessment : May cause drowsiness or dizziness.

Ivermectin:

Target Organs : Central nervous system
Assessment : Causes damage to organs.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Ivermectin:

Target Organs : Central nervous system
Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Butanone:

Species : Rat
NOAEL : 14,84 mg/l
Application Route : inhalation (vapour)
Exposure time : 90 Days
Method : OECD Test Guideline 413

Ivermectin:

Species : Dog
NOAEL : 0,5 mg/kg
LOAEL : 1 mg/kg
Application Route : Oral
Exposure time : 14 Weeks
Target Organs : Central nervous system
Symptoms : Dilatation of the pupil, Tremors, Lack of coordination, anorexia

Species : Monkey
NOAEL : 1,2 mg/kg
Application Route : Oral
Exposure time : 2 Weeks
Remarks : No significant adverse effects were reported

Species : Rat
NOAEL : 0,4 mg/kg

SAFETY DATA SHEET

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



Ivermectin (with Propylene Glycol) Formula- tion

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
| 6.1 | 28.09.2024 | 4710828-00019 | Date of first issue: 30.07.2019 |

LOAEL : 0,8 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : spleen, Bone marrow, Kidney

Aspiration toxicity

Not classified based on available information.

Components:

Butanone:

The substance or mixture causes concern owing to the assumption that it causes a human aspiration toxicity hazard.

11.2 Information on other hazards

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.

Experience with human exposure

Components:

Ivermectin:

Skin contact : Remarks: Can be absorbed through skin.
Eye contact : Remarks: May irritate eyes.
Ingestion : Symptoms: Drowsiness, Dilatation of the pupil, Tremors, Vomiting, anorexia, Lack of coordination

SECTION 12: Ecological information

12.1 Toxicity

Components:

1,3-Dioxan-5-ol:

Toxicity to fish : LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other : EL50 (Daphnia magna (Water flea)): > 100 mg/l
aquatic invertebrates : Exposure time: 48 h
Remarks: Based on data from similar materials

SAFETY DATA SHEET

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



Ivermectin (with Propylene Glycol) Formula- tion

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
| 6.1 | 28.09.2024 | 4710828-00019 | Date of first issue: 30.07.2019 |

Toxicity to algae/aquatic plants : EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 : > 1.000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

Butanone:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 2.993 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 308 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 2.029 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 1.240 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201

Ivermectin:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0,003 mg/l
Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): 0,0048 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0,000025 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 9,1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 9,1

SAFETY DATA SHEET

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



Ivermectin (with Propylene Glycol) Formula- tion

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
| 6.1 | 28.09.2024 | 4710828-00019 | Date of first issue: 30.07.2019 |

mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox- : 10.000
icity)

M-Factor (Chronic aquatic : 10.000
toxicity)

12.2 Persistence and degradability

Components:

1,3-Dioxan-5-ol:

Biodegradability : Result: Inherently biodegradable.
Remarks: Based on data from similar materials

Butanone:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 98 %
Exposure time: 28 d
Method: OECD Test Guideline 301D

Ivermectin:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 50 %
Exposure time: 240 d

12.3 Bioaccumulative potential

Components:

1,3-Dioxan-5-ol:

Partition coefficient: n- : log Pow: -0,65
octanol/water

Butanone:

Partition coefficient: n- : log Pow: 0,3
octanol/water

Ivermectin:

Bioaccumulation : Bioconcentration factor (BCF): 74

Partition coefficient: n- : log Pow: 3,22
octanol/water

12.4 Mobility in soil

No data available

SAFETY DATA SHEET

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



Ivermectin (with Propylene Glycol) Formula- tion

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
| 6.1 | 28.09.2024 | 4710828-00019 | Date of first issue: 30.07.2019 |

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. 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. Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

ADN : UN 1193
ADR : UN 1193
RID : UN 1193
IMDG : UN 1193
IATA : UN 1193

SAFETY DATA SHEET

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



Ivermectin (with Propylene Glycol) Formula- tion

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
| 6.1 | 28.09.2024 | 4710828-00019 | Date of first issue: 30.07.2019 |

14.2 UN proper shipping name

ADN : ETHYL METHYL KETONE, SOLUTION
ADR : ETHYL METHYL KETONE, SOLUTION
RID : ETHYL METHYL KETONE, SOLUTION
IMDG : ETHYL METHYL KETONE, SOLUTION
(Ivermectin)
IATA : Ethyl methyl ketone, solution

14.3 Transport hazard class(es)

| | Class | Subsidiary risks |
|-------------|-------|------------------|
| ADN | : 3 | |
| ADR | : 3 | |
| RID | : 3 | |
| IMDG | : 3 | |
| IATA | : 3 | |

14.4 Packing group

ADN
Packing group : II
Classification Code : F1
Hazard Identification Number : 33
Labels : 3

ADR
Packing group : II
Classification Code : F1
Hazard Identification Number : 33
Labels : 3
Tunnel restriction code : (D/E)

RID
Packing group : II
Classification Code : F1
Hazard Identification Number : 33
Labels : 3

IMDG
Packing group : II
Labels : 3
EmS Code : F-E, S-D

IATA (Cargo)
Packing instruction (cargo aircraft) : 364
Packing instruction (LQ) : Y341
Packing group : II
Labels : Flammable Liquids

SAFETY DATA SHEET

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



Ivermectin (with Propylene Glycol) Formula- tion

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
| 6.1 | 28.09.2024 | 4710828-00019 | Date of first issue: 30.07.2019 |

IATA (Passenger)

Packing instruction (passenger aircraft) : 353
Packing instruction (LQ) : Y341
Packing group : II
Labels : Flammable Liquids

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : 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

Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

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.

SAFETY DATA SHEET

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



Ivermectin (with Propylene Glycol) Formula- tion

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
| 6.1 | 28.09.2024 | 4710828-00019 | Date of first issue: 30.07.2019 |

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) 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
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 |
|-----|-----------------------|------------|------------|
| P5c | FLAMMABLE LIQUIDS | 5.000 t | 50.000 t |
| E1 | ENVIRONMENTAL HAZARDS | 100 t | 200 t |

Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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

H225 : Highly flammable liquid and vapour.
H300 : Fatal if swallowed.
H311 : Toxic in contact with skin.
H319 : Causes serious eye irritation.
H336 : May cause drowsiness or dizziness.
H370 : Causes damage to organs if swallowed.
H372 : Causes damage to organs through prolonged or repeated

SAFETY DATA SHEET

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



Ivermectin (with Propylene Glycol) Formula- tion

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
| 6.1 | 28.09.2024 | 4710828-00019 | Date of first issue: 30.07.2019 |

H400 : exposure if swallowed.
H410 : Very toxic to aquatic life.
H411 : Very toxic to aquatic life with long lasting effects.
EUH066 : Repeated exposure may cause skin dryness or cracking.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Flam. Liq. : Flammable liquids
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure
2000/39/EC : Europe. Commission Directive 2000/39/EC establishing a first
list of indicative occupational exposure limit values
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits
2000/39/EC / TWA : Limit Value - eight hours
2000/39/EC / STEL : Short term exposure limit
FOR-2011-12-06-1358 / TWA : Long term exposure limit

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

SAFETY DATA SHEET

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



Ivermectin (with Propylene Glycol) Formula- tion

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
| 6.1 | 28.09.2024 | 4710828-00019 | Date of first issue: 30.07.2019 |

- United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; 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:

| | |
|-------------------|------|
| Flam. Liq. 2 | H225 |
| Eye Irrit. 2 | H319 |
| STOT SE 2 | H371 |
| STOT RE 2 | H373 |
| Aquatic Acute 1 | H400 |
| Aquatic Chronic 1 | H410 |

Classification procedure:

| |
|-------------------------------------|
| Based on product data or assessment |
| Calculation method |

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.

NO / EN