

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ertugliflozin (< 5%) / Sitagliptin Formulation

Version
6.1

Revision Date:
11.08.2025

SDS Number:
9373451-00010

Date of last issue: 14.04.2025
Date of first issue: 27.08.2021

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

1.1 Product identifier

Trade name : Ertugliflozin (< 5%) / Sitagliptin Formulation

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

Use of the Substance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
120 Moorgate
EC2M 6UR London, United Kingdom

Telephone : +44 (0) 2081548000

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) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Skin irritation, Category 2 H315: Causes skin irritation.

Serious eye damage, Category 1 H318: Causes serious eye damage.

Long-term (chronic) aquatic hazard, Category 3 H412: Harmful to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



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Hazard pictograms :



Signal word :

Danger

Hazard statements :

H315 Causes skin irritation.
H318 Causes serious eye damage.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/ eye protection/ face protection.

Response:

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Hazardous components which must be listed on the label:

Ertugliflozin

EUH208 Contains Propyl 3,4,5-trihydroxybenzoate. May produce an allergic reaction.

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.

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) |
|-----------------------|---|--------------------------------------|--------------------------|
| Sitagliptin Phosphate | 654671-77-9 | Eye Irrit. 2; H319 | >= 30 - < 50 |
| Ertugliflozin | 1210344-83-4 | Acute Tox. 4; H302 Skin Corr. 1B; | >= 3 - < 5 |

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ertugliflozin (< 5%) / Sitagliptin Formulation

Version
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| | | | |
|--|---------------------------------------|--|---------------|
| | | H314 Eye Dam. 1; H318 STOT RE 2; H373 (Kidney, Stomach, Prostate) | |
| Propyl 3,4,5-trihydroxybenzoate | 121-79-9 204-498-2 607-198-00-3 | Acute Tox. 4; H302 Eye Dam. 1; H318 Skin Sens. 1; H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1 | >= 0.25 - < 1 |
| Substances with a workplace exposure limit : | | | |
| Cellulose | 9004-34-6 232-674-9 | | >= 20 - < 30 |

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 : In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

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 immediately.

If swallowed : If swallowed, DO NOT induce vomiting.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ertugliflozin (< 5%) / Sitagliptin Formulation

Version
6.1

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11.08.2025

SDS Number:
9373451-00010

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Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks : May produce an allergic reaction.
Causes skin irritation.
Causes serious eye damage.

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 : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Metal oxides
Oxides of phosphorus

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.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ertugliflozin (< 5%) / Sitagliptin Formulation

Version
6.1

Revision Date:
11.08.2025

SDS Number:
9373451-00010

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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.
Retain and dispose of contaminated wash water.
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
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.
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 dust.
Do not swallow.
Do not get in 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
Keep container tightly closed.
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.
Take care to prevent spills, waste and minimize release to the

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ertugliflozin (< 5%) / Sitagliptin Formulation

Version 6.1 Revision Date: 11.08.2025 SDS Number: 9373451-00010 Date of last issue: 14.04.2025
Date of first issue: 27.08.2021

Hygiene measures : environment.
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. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents

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

dust of any kind 10 mg/m³
Value type (Form of exposure): TWA (Inhalable)
Basis: GB EH40

4 mg/m³
Value type (Form of exposure): TWA (Respirable fraction)
Basis: GB EH40

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|-----------------------|--------------|-------------------------------|-------------------------------|----------|
| Sitagliptin Phosphate | 654671-77-9 | TWA | 0.6 mg/m ³ (OEB 2) | Internal |
| Cellulose | 9004-34-6 | TWA (inhalable dust) | 10 mg/m ³ | GB EH40 |
| | | TWA (Respirable dust) | 4 mg/m ³ | GB EH40 |
| | | STEL (inhalable dust) | 20 mg/m ³ | GB EH40 |
| Ertugliflozin | 1210344-83-4 | TWA | 10 µg/m ³ (OEB 3) | Internal |
| | | Wipe limit | 100 µg/100 cm ² | Internal |

Derived No Effect Level (DNEL)

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ertugliflozin (< 5%) / Sitagliptin Formulation

Version
6.1

Revision Date:
11.08.2025

SDS Number:
9373451-00010

Date of last issue: 14.04.2025
Date of first issue: 27.08.2021

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|---------------------------------|-----------|-----------------|----------------------------|------------------------|
| Propyl 3,4,5-trihydroxybenzoate | Workers | Inhalation | Long-term systemic effects | 6.66 mg/m ³ |
| | Workers | Skin contact | Long-term systemic effects | 1.89 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 1.17 mg/m ³ |
| | Consumers | Skin contact | Long-term systemic effects | 0.675 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 0.675 mg/kg bw/day |

Predicted No Effect Concentration (PNEC)

| Substance name | Environmental Compartment | Value |
|---------------------------------|-----------------------------|----------------------------------|
| Propyl 3,4,5-trihydroxybenzoate | Fresh water | 0.37 µg/l |
| | Freshwater - intermittent | 3.7 µg/l |
| | Marine water | 0.037 µg/l |
| | Marine water - intermittent | 0.37 µg/l |
| | Sewage treatment plant | 6.36 mg/l |
| | Fresh water sediment | 0.0045 mg/kg dry weight (d.w.) |
| | Marine sediment | 0.00045 mg/kg dry weight (d.w.) |
| | Soil | 0.000688 mg/kg dry weight (d.w.) |

8.2 Exposure controls

Engineering measures

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.

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.

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 REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Ertugliflozin (< 5%) / Sitagliptin Formulation

Version Revision Date: SDS Number: Date of last issue: 14.04.2025
6.1 11.08.2025 9373451-00010 Date of first issue: 27.08.2021

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|------------------------|--|
| Respiratory protection | <p>Use appropriate degowning techniques to remove potentially contaminated clothing.</p> <p>If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to BS EN 143</p> |
| Filter type | <p>Particulates type (P)</p> |

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

| | | |
|--|---|---|
| Appearance | : | powder |
| Colour | : | No data available |
| 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 | : | Not applicable |
| Evaporation rate | : | Not applicable |
| Flammability (solid, gas) | : | May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids) | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapour pressure | : | Not applicable |
| Relative vapour density | : | Not applicable |
| Relative density | : | No data available |
| Density | : | No data available |
| 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 |

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ertugliflozin (< 5%) / Sitagliptin Formulation

Version 6.1 Revision Date: 11.08.2025 SDS Number: 9373451-00010 Date of last issue: 14.04.2025
Date of first issue: 27.08.2021

Viscosity

Viscosity, kinematic : Not applicable

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 : 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.
Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.
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 toxicological effects

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

Acute toxicity

Not classified based on available information.

Product:

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ertugliflozin (< 5%) / Sitagliptin Formulation

| | | | |
|----------------|------------------------------|------------------------------|---|
| Version 6.1 | Revision Date: 11.08.2025 | SDS Number: 9373451-00010 | Date of last issue: 14.04.2025 Date of first issue: 27.08.2021 |
|----------------|------------------------------|------------------------------|---|

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Components:

Sitagliptin Phosphate:

Acute oral toxicity : LD50 (Rat): > 3,000 mg/kg
LD50 (Mouse): 3,000 mg/kg

Ertugliflozin:

Acute oral toxicity : LD50 (Rat): 500 mg/kg
Acute inhalation toxicity : Remarks: No data available
Acute dermal toxicity : Remarks: No data available

Propyl 3,4,5-trihydroxybenzoate:

Acute oral toxicity : LD50 (Mouse): 1,700 mg/kg
Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Skin corrosion/irritation

Causes skin irritation.

Components:

Sitagliptin Phosphate:

Species : Rabbit
Method : Draize Test
Result : No skin irritation

Ertugliflozin:

Result : Corrosive

Propyl 3,4,5-trihydroxybenzoate:

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Ertugliflozin (< 5%) / Sitagliptin Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 14.04.2025 |
| 6.1 | 11.08.2025 | 9373451-00010 | Date of first issue: 27.08.2021 |

Species : reconstructed human epidermis (RhE)
Method : OECD Test Guideline 439

Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

Sitagliptin Phosphate:

Species : Rabbit
Method : Draize Test
Result : Irritating to eyes.

Ertugliflozin:

Result : Severe irritation

Propyl 3,4,5-trihydroxybenzoate:

Species : Rabbit
Method : OECD Test Guideline 405
Result : Irreversible effects on the eye

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Sitagliptin Phosphate:

Test Type : Local lymph node assay (LLNA)
Species : Mouse
Method : OECD Test Guideline 429
Result : Not a skin sensitizer.

Ertugliflozin:

Test Type : Local lymph node assay (LLNA)
Result : Not a skin sensitizer.

Propyl 3,4,5-trihydroxybenzoate:

Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Result : positive

Assessment : Probability or evidence of skin sensitisation in humans

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ertugliflozin (< 5%) / Sitagliptin Formulation

Version
6.1

Revision Date:
11.08.2025

SDS Number:
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Date of last issue: 14.04.2025
Date of first issue: 27.08.2021

Germ cell mutagenicity

Not classified based on available information.

Components:

Sitagliptin Phosphate:

Genotoxicity in vitro : Test Type: Ames test
Result: negative

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster ovary cells
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Test system: rat hepatocytes
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

Ertugliflozin:

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

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Rat
Result: negative

Propyl 3,4,5-trihydroxybenzoate:

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

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

Test Type: Chromosome aberration test in vitro
Result: positive

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

Test Type: In vitro sister chromatid exchange assay in mam-

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ertugliflozin (< 5%) / Sitagliptin Formulation

| | | | |
|----------------|------------------------------|------------------------------|---|
| Version 6.1 | Revision Date: 11.08.2025 | SDS Number: 9373451-00010 | Date of last issue: 14.04.2025 Date of first issue: 27.08.2021 |
|----------------|------------------------------|------------------------------|---|

malian cells
Result: positive

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

Cellulose:

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
Application Route: Ingestion
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Sitagliptin Phosphate:

Species : Mouse
Application Route : Oral
Exposure time : 2 Years
Result : negative

Species : Rat
Application Route : oral (drinking water)
Exposure time : 2 Years
Result : positive
Target Organs : Liver
Remarks : Significant toxicity observed in testing

Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

Ertugliflozin:

Species : Mouse
Application Route : Oral
Exposure time : 2 Years
Result : negative

Species : Rat
Application Route : Oral

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ertugliflozin (< 5%) / Sitagliptin Formulation

| | | | |
|----------------|------------------------------|------------------------------|---|
| Version 6.1 | Revision Date: 11.08.2025 | SDS Number: 9373451-00010 | Date of last issue: 14.04.2025 Date of first issue: 27.08.2021 |
|----------------|------------------------------|------------------------------|---|

| | | |
|------------------------------|---|--|
| Exposure time | : | 2 Years |
| Result | : | negative |
| Carcinogenicity - Assessment | : | Weight of evidence does not support classification as a carcinogen |

Propyl 3,4,5-trihydroxybenzoate:

| | | |
|-------------------|---|-----------|
| Species | : | Rat |
| Application Route | : | Ingestion |
| Exposure time | : | 103 weeks |
| Result | : | negative |

Cellulose:

| | | |
|-------------------|---|-----------|
| Species | : | Rat |
| Application Route | : | Ingestion |
| Exposure time | : | 72 weeks |
| Result | : | negative |

Reproductive toxicity

Not classified based on available information.

Components:

Sitagliptin Phosphate:

| | | |
|-------------------------------|---|--|
| Effects on fertility | : | Test Type: Fertility/early embryonic development Species: Rat Application Route: Oral Fertility: NOAEL Parent: 1,000 mg/kg body weight Result: Animal testing did not show any effects on fertility. |
| Effects on foetal development | : | Test Type: Embryo-foetal development Species: Rat Application Route: Oral Teratogenicity: LOAEL: 250 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected., No teratogenic effects |
| | | Test Type: Embryo-foetal development Species: Rabbit Teratogenicity: NOAEL: 125 mg/kg body weight Result: No teratogenic effects |

Ertugliflozin:

| | | |
|----------------------|---|--|
| Effects on fertility | : | Test Type: Fertility/early embryonic development Species: Rat Application Route: Oral Fertility: NOAEL: 250 mg/kg body weight Remarks: Maternal toxicity observed. No significant adverse effects were reported |
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SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ertugliflozin (< 5%) / Sitagliptin Formulation

Version
6.1

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11.08.2025

SDS Number:
9373451-00010

Date of last issue: 14.04.2025
Date of first issue: 27.08.2021

Test Type: Fertility/early embryonic development
Species: Rabbit
Application Route: Oral
Fertility: NOAEL: 200 mg/kg body weight
Remarks: No significant adverse effects were reported

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 50 mg/kg body weight
Remarks: Adverse developmental effects were observed

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 250 mg/kg body weight
Remarks: No significant adverse effects were reported

Propyl 3,4,5-trihydroxybenzoate:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

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

Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:

Ertugliflozin:

Exposure routes : Oral
Target Organs : Kidney, Stomach, Prostate

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ertugliflozin (< 5%) / Sitagliptin Formulation

| | | | |
|----------------|------------------------------|------------------------------|---|
| Version 6.1 | Revision Date: 11.08.2025 | SDS Number: 9373451-00010 | Date of last issue: 14.04.2025 Date of first issue: 27.08.2021 |
|----------------|------------------------------|------------------------------|---|

Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Sitagliptin Phosphate:

| | |
|-------------------|--|
| Species | : Mouse |
| NOAEL | : 500 mg/kg |
| LOAEL | : 1,000 mg/kg |
| Application Route | : Oral |
| Exposure time | : > 2 yr |
| Target Organs | : Kidney |
| Species | : Rat |
| NOAEL | : 500 mg/kg |
| LOAEL | : 1,000 mg/kg |
| Application Route | : Oral |
| Exposure time | : 14 Weeks |
| Target Organs | : Liver, Kidney, Heart, Teeth |
| Species | : Dog |
| NOAEL | : 10 mg/kg |
| LOAEL | : 50 mg/kg |
| Application Route | : Oral |
| Exposure time | : 53 Weeks |
| Target Organs | : Central nervous system |
| Symptoms | : Loss of balance |
| Remarks | : The mechanism or mode of action may not be relevant in humans. |
| Species | : Dog |
| NOAEL | : 2 mg/kg |
| LOAEL | : 10 mg/kg |
| Application Route | : Oral |
| Exposure time | : 27 Weeks |
| Target Organs | : Skeletal muscle, Central nervous system |
| Symptoms | : Loss of balance |
| Remarks | : The mechanism or mode of action may not be relevant in humans. |
| Species | : Monkey |
| NOAEL | : 100 mg/kg |
| Application Route | : Oral |
| Exposure time | : 14 Weeks |
| Remarks | : No significant adverse effects were reported |

Ertugliflozin:

| | |
|-------------------|-------------|
| Species | : Rat |
| LOAEL | : 500 mg/kg |
| Application Route | : Oral |

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Ertugliflozin (< 5%) / Sitagliptin Formulation

Version Revision Date: SDS Number: Date of last issue: 14.04.2025
6.1 11.08.2025 9373451-00010 Date of first issue: 27.08.2021

Exposure time : 30 d

| | | |
|-------------------|---|-----------|
| Species | : | Rat |
| LOAEL | : | 250 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 30 d |
| Target Organs | : | Kidney |

Species : Rat
LOAEL : 25 mg/kg
Application Route : Oral
Exposure time : 180 d
Target Organs : Kidney, Bone, Stomach

Species : Rat
LOAEL : 25 mg/kg
Exposure time : 90 d
Target Organs : Kidney, Gastrointestinal tract, Prostate

Species : Dog
NOAEL : 150 mg/kg
Application Route : Oral
Exposure time : 270 d
Remarks : No significant adverse effects were reported

Species : Mouse
NOAEL : 100 mg/kg
Application Route : Oral
Exposure time : 90 d
Remarks : No significant adverse effects were reported

Species : Mouse
NOAEL : 100 mg/kg
Application Route : Oral
Exposure time : 28 d
Target Organs : Bone
Remarks : No significant adverse effects were reported

Propyl 3,4,5-trihydroxybenzoate:

Species : Rat
NOAEL : 135 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks

Cellulose:

Species : Rat
NOAEL : $\geq 9,000$ mg/kg
Application Route : Ingestion
Exposure time : 90 Days

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ertugliflozin (< 5%) / Sitagliptin Formulation

Version
6.1

Revision Date:
11.08.2025

SDS Number:
9373451-00010

Date of last issue: 14.04.2025
Date of first issue: 27.08.2021

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Sitagliptin Phosphate:

Inhalation : Symptoms: upper respiratory tract infection, pharyngitis, Headache

Ingestion : Symptoms: upper respiratory tract infection, nasopharyngitis, Headache, Nausea, Abdominal pain, Diarrhoea

Ertugliflozin:

Ingestion : Symptoms: The most common side effects are:, Headache, constipation, Diarrhoea, Nausea, urinary tract infection, muscle pain, upper respiratory tract infection

SECTION 12: Ecological information

12.1 Toxicity

Components:

Sitagliptin Phosphate:

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)): 60 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 39 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 2.2 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50 : > 150 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC : 150 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition

Toxicity to fish (Chronic tox- : NOEC: 9.2 mg/l

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ertugliflozin (< 5%) / Sitagliptin Formulation

| | | | |
|----------------|------------------------------|------------------------------|---|
| Version 6.1 | Revision Date: 11.08.2025 | SDS Number: 9373451-00010 | Date of last issue: 14.04.2025 Date of first issue: 27.08.2021 |
|----------------|------------------------------|------------------------------|---|

icity)
Exposure time: 33 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 9.8 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

Ertugliflozin:

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 77 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 50 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50 : > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC : 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity) : NOEC: 1 mg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 2.14 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility

Propyl 3,4,5-trihydroxybenzoate:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 19.6 mg/l
Exposure time: 48 h
Test substance: Neutralised product
Method: OECD Test Guideline 202
Remarks: The test was conducted according to guideline

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.22 mg/l
Exposure time: 72 h
Test substance: Neutralised product

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ertugliflozin (< 5%) / Sitagliptin Formulation

Version
6.1

Revision Date:
11.08.2025

SDS Number:
9373451-00010

Date of last issue: 14.04.2025
Date of first issue: 27.08.2021

Method: OECD Test Guideline 201
Remarks: The test was conducted according to guideline

EC10 (Pseudokirchneriella subcapitata (green algae)): 0.096 mg/l
Exposure time: 72 h
Test substance: Neutralised product
Method: OECD Test Guideline 201
Remarks: The test was conducted according to guideline

M-Factor (Acute aquatic toxicity) : 1

Toxicity to microorganisms : EC50 (activated sludge): 636 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

M-Factor (Chronic aquatic toxicity) : 1

Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

12.2 Persistence and degradability

Components:

Sitagliptin Phosphate:

Biodegradability : Result: not rapidly degradable
Biodegradation: 39.7 %
Exposure time: 28 d
Method: OECD Test Guideline 314

Stability in water : pH: 7
Hydrolysis: 50 %(401 d)
Method: OECD Test Guideline 111

Ertugliflozin:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 40.8 %
Exposure time: 28 d

Propyl 3,4,5-trihydroxybenzoate:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 49.4 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

Cellulose:

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ertugliflozin (< 5%) / Sitagliptin Formulation

| | | | |
|----------------|------------------------------|------------------------------|---|
| Version 6.1 | Revision Date: 11.08.2025 | SDS Number: 9373451-00010 | Date of last issue: 14.04.2025 Date of first issue: 27.08.2021 |
|----------------|------------------------------|------------------------------|---|

Biodegradability : Result: Readily biodegradable.

12.3 Bioaccumulative potential

Components:

Sitagliptin Phosphate:

Partition coefficient: n-octanol/water : log Pow: -0.03

Ertugliflozin:

Partition coefficient: n-octanol/water : log Pow: 2.47

Propyl 3,4,5-trihydroxybenzoate:

Partition coefficient: n-octanol/water : log Pow: 1.8
Remarks: Calculation

12.4 Mobility in soil

Components:

Sitagliptin Phosphate:

Distribution among environmental compartments : log Koc: 4.37

Ertugliflozin:

Distribution among environmental compartments : log Koc: 2.88

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 : This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f).

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.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ertugliflozin (< 5%) / Sitagliptin Formulation

Version
6.1

Revision Date:
11.08.2025

SDS Number:
9373451-00010

Date of last issue: 14.04.2025
Date of first issue: 27.08.2021

Contaminated packaging : Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
Do not dispose of waste into sewer.
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 : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.4 Packing group

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA (Cargo) : Not regulated as a dangerous good
IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ertugliflozin (< 5%) / Sitagliptin Formulation

| | | | |
|----------------|------------------------------|------------------------------|---|
| Version 6.1 | Revision Date: 11.08.2025 | SDS Number: 9373451-00010 | Date of last issue: 14.04.2025 Date of first issue: 27.08.2021 |
|----------------|------------------------------|------------------------------|---|

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

Relevant EU provisions transposed through retained EU law

| | |
|--|---|
| UK REACH List of restrictions (Annex 17) | : Not applicable |
| UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation | : Not applicable |
| The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain) | : Not applicable |
| Regulation (EU) No 2024/590 on substances that deplete the ozone layer | : Not applicable |
| UK REACH List of substances subject to authorisation (Annex XIV) | : Not applicable |
| GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation | : Not applicable |
| The Control of Explosives Precursors and Poisons Regulations (Poisons Act, as amended) | |
| This product is regulated by the Poisons Act 1972 (as amended). All suspicious transactions, and significant disappearances and thefts must be reported. | Calcium hydrogenorthophosphate (Schedule 1A Part 4) |

Control of Major Accident Hazards Regulations 2015 (COMAH)
Not applicable

Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ertugliflozin (< 5%) / Sitagliptin Formulation

Version
6.1

Revision Date:
11.08.2025

SDS Number:
9373451-00010

Date of last issue: 14.04.2025
Date of first issue: 27.08.2021

are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

| | |
|------|---|
| H302 | : Harmful if swallowed. |
| H314 | : Causes severe skin burns and eye damage. |
| H317 | : May cause an allergic skin reaction. |
| H318 | : Causes serious eye damage. |
| H319 | : Causes serious eye irritation. |
| H373 | : May cause damage to organs through prolonged or repeated exposure if swallowed. |
| H400 | : Very toxic to aquatic life. |
| H410 | : Very toxic to aquatic life with long lasting effects. |

Full text of other abbreviations

| | |
|-----------------|--|
| Acute Tox. | : Acute toxicity |
| Aquatic Acute | : Short-term (acute) aquatic hazard |
| Aquatic Chronic | : Long-term (chronic) aquatic hazard |
| Eye Dam. | : Serious eye damage |
| Eye Irrit. | : Eye irritation |
| Skin Corr. | : Skin corrosion |
| Skin Sens. | : Skin sensitisation |
| STOT RE | : Specific target organ toxicity - repeated exposure |
| GB EH40 | : UK. EH40 WEL - Workplace Exposure Limits |
| GB EH40 / TWA | : Long-term exposure limit (8-hour TWA reference period) |
| GB EH40 / STEL | : Short-term exposure limit (15-minute reference period) |

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; KECL - 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 Re-

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ertugliflozin (< 5%) / Sitagliptin Formulation

Version
6.1

Revision Date:
11.08.2025

SDS Number:
9373451-00010

Date of last issue: 14.04.2025
Date of first issue: 27.08.2021

Striction 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

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 Irrit. 2 | H315 |
| Eye Dam. 1 | H318 |
| Aquatic Chronic 3 | H412 |

Classification procedure:

| |
|--------------------|
| Calculation method |
| Calculation method |
| 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.

GB / EN