

**Raltegravir Pediatric Granules Formulation**

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue:             |
| 9.1     | 13.11.2025     | 20458-00026 | 09.05.2025                      |
|         |                |             | Date of first issue: 09.10.2014 |

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**Section 1: Identification**

Product name : Raltegravir Pediatric Granules Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908  
Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800 CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

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**Section 2: Hazard identification****GHS Classification**

Serious eye damage/eye irritation : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - single exposure : Category 3

**GHS label elements**

Hazard pictograms :



Signal word : Danger

Hazard statements : H318 Causes serious eye damage.  
H335 May cause respiratory irritation.  
H361d Suspected of damaging the unborn child.

Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.

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P261 Avoid breathing dust.  
P271 Use only outdoors or in a well-ventilated area.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.  
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.  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards which do not result in classification**

Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

**Section 3: Composition/information on ingredients**

Substance / Mixture : Mixture

**Components**

| Chemical name      | CAS-No.     | Concentration (% w/w) |
|--------------------|-------------|-----------------------|
| Raltegravir        | 871038-72-1 | >= 20 -< 30           |
| Cellulose          | 9004-34-6   | >= 20 -< 30           |
| Magnesium stearate | 557-04-0    | >= 1 -< 10            |
| Ammonium hydroxide | 1336-21-6   | >= 0.1 -< 0.25        |

**Section 4: 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.

If inhaled : If inhaled, remove to fresh air.  
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water

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|   |   |  |
|---|---|--|
|   |   | for at least 15 minutes.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention immediately.   |
| If swallowed  | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.  |
| Most important symptoms and effects, both acute and delayed | : | Causes serious eye damage.<br>May cause respiratory irritation.<br>Suspected of damaging the unborn child.<br>Contact with dust can cause mechanical irritation or drying of the skin. |
| 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).            |
| Notes to physician  | : | Treat symptomatically and supportively.  |

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### Section 5: Fire-fighting measures

|   |   |   |
|---|---|---|
| Suitable extinguishing media                  | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical  |
| Unsuitable extinguishing media                | : | None known.   |
| 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.<br>Exposure to combustion products may be a hazard to health.                   |
| Hazardous combustion products                 | : | Carbon oxides<br>Nitrogen oxides (NO <sub>x</sub> )<br>Fluorine compounds<br>Metal oxides   |
| Specific extinguishing methods                | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |

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### Section 6: Accidental release measures

|   |   |  |
|---|---|--|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions   | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.   |

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Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Surround spill with absorbents and place a damp covering over the area to minimise entry of the material into the air. Add excess liquid to allow the material to enter into solution. Soak up with inert absorbent material. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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.

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**Section 7: Handling and storage**

|                         |   |
|-------------------------|---|
| Technical measures      | : Static electricity may accumulate and ignite suspended dust causing an explosion.<br>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.  |
| Local/Total ventilation | : If sufficient ventilation is unavailable, use with local exhaust ventilation.   |
| Advice on safe handling | : Avoid breathing dust.<br>Do not swallow.<br>Do not get in eyes.<br>Avoid prolonged or repeated contact with skin.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>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.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.  |

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- 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.
- Conditions for safe storage : 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.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

### Section 8: Exposure controls/personal protection

#### Components with workplace control parameters

| Components         | CAS-No.     | Value type<br>(Form of exposure)    | Control parameters / Permissible concentration | Basis    |
|--------------------|-------------|-------------------------------------|--|----------|
| Raltegravir        | 871038-72-1 | TWA                                 | 1000 (µg/m <sup>3</sup> )<br>(OEB 1)           | Internal |
| Cellulose          | 9004-34-6   | WES-TWA                             | 10 mg/m <sup>3</sup>                           | NZ OEL   |
|                    |             | TWA                                 | 10 mg/m <sup>3</sup>                           | ACGIH    |
| Magnesium stearate | 557-04-0    | WES-TWA                             | 10 mg/m <sup>3</sup>                           | NZ OEL   |
|                    |             | TWA (Inhalable particulate matter)  | 10 mg/m <sup>3</sup>                           | ACGIH    |
|                    |             | TWA (Respirable particulate matter) | 3 mg/m <sup>3</sup>                            | ACGIH    |
| Ammonium hydroxide | 1336-21-6   | TWA                                 | 25 ppm<br>(Ammonia)                            | ACGIH    |
|                    |             | STEL                                | 35 ppm<br>(Ammonia)                            | ACGIH    |

- Engineering measures** : Use feasible engineering controls to minimize exposure to compound.  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

#### Personal protective equipment

- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Particulates type
- Hand protection : Chemical-resistant gloves
- Material
- Eye protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions,

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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.

Skin and body protection : Work uniform or laboratory coat.

**Section 9: Physical and chemical properties**

|  |   |
|--|---|
| Appearance                                       | : powder  |
| Colour   | : off-white   |
| Odour  | : odourless   |
| Odour Threshold                                  | : No data available   |
| pH   | : No data available   |
| Melting point/freezing point                     | : No data available   |
| Initial boiling point and boiling range          | : No data available   |
| Flash point                                      | : No data available   |
| Evaporation rate                                 | : No data available   |
| Flammability (solid, gas)                        | : May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids)                           | : No data available   |
| Upper explosion limit / Upper flammability limit | : No data available   |
| Lower explosion limit / Lower flammability limit | : No data available   |
| Vapour pressure                                  | : No data available   |
| Relative vapour density                          | : No data available   |
| Relative density                                 | : No data available   |
| Solubility(ies)<br>Water solubility              | : No data available   |
| Partition coefficient: n-octanol/water           | : No data available   |
| Auto-ignition temperature                        | : No data available   |
| Decomposition temperature                        | : No data available   |
| Viscosity<br>Viscosity, kinematic                | : No data available   |

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|                          |   |  |
|--------------------------|---|--|
| Explosive properties     | : | Not explosive  |
| Oxidizing properties     | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight         | : | No data available  |
| Particle characteristics | : |  |
| Particle size            | : | No data available  |

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**Section 10: Stability and reactivity**

|                                    |   |  |
|------------------------------------|---|--|
| Reactivity                         | : | Not classified as a reactivity hazard.   |
| Chemical stability                 | : | Stable under normal conditions.  |
| Possibility of hazardous reactions | : | May form explosive dust-air mixture during processing, handling or other means.<br>Can react with strong oxidizing agents. |
| Conditions to avoid                | : | Heat, flames and sparks.<br>Avoid dust formation.  |
| Incompatible materials             | : | Oxidizing agents   |
| Hazardous decomposition products   | : | No hazardous decomposition products are known.   |

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**Section 11: Toxicological information**

|                 |   |  |
|-----------------|---|--|
| Exposure routes | : | Inhalation<br>Skin contact<br>Ingestion<br>Eye contact |
|-----------------|---|--|

**Acute toxicity**

Not classified based on available information.

**Components:****Raltegravir:**

|                     |   |  |
|---------------------|---|--|
| Acute oral toxicity | : | LD50 (Mouse, male and female): > 2,000 mg/kg |
|---------------------|---|--|

**Cellulose:**

|                     |   |                           |
|---------------------|---|---------------------------|
| Acute oral toxicity | : | LD50 (Rat): > 5,000 mg/kg |
|---------------------|---|---------------------------|

|                           |   |  |
|---------------------------|---|--|
| Acute inhalation toxicity | : | LC50 (Rat): > 5.8 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist |
|---------------------------|---|--|

|                       |   |                              |
|-----------------------|---|------------------------------|
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg |
|-----------------------|---|------------------------------|

**Magnesium stearate:**

|                     |   |  |
|---------------------|---|--|
| Acute oral toxicity | : | LD50 (Rat): > 2,000 mg/kg<br>Method: OECD Test Guideline 423 |
|---------------------|---|--|

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Assessment: The substance or mixture has no acute oral toxicity

Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Remarks: Based on data from similar materials

**Ammonium hydroxide:**

Acute oral toxicity : LD50 (Rat): 350 mg/kg

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Raltegravir:**

Species : Rabbit  
Result : No skin irritation

**Magnesium stearate:**

Species : Rabbit  
Result : No skin irritation  
Remarks : Based on data from similar materials

**Ammonium hydroxide:**

Species : Rabbit  
Result : Corrosive after 3 minutes to 1 hour of exposure  
Remarks : Based on national or regional regulation.

**Serious eye damage/eye irritation**

Causes serious eye damage.

**Components:****Raltegravir:**

Species : Bovine cornea  
Result : Severe irritation

**Magnesium stearate:**

Species : Rabbit  
Result : No eye irritation  
Remarks : Based on data from similar materials

**Ammonium hydroxide:**

Result : Irreversible effects on the eye  
Remarks : Based on skin corrosivity.



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**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****Raltegravir:**

|           |   |                               |
|-----------|---|-------------------------------|
| Test Type | : | Local lymph node assay (LLNA) |
| Species   | : | Mouse                         |
| Result    | : | negative                      |

**Magnesium stearate:**

|                 |   |                                      |
|-----------------|---|--------------------------------------|
| 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 |

**Chronic toxicity****Germ cell mutagenicity**

Not classified based on available information.

**Components:****Raltegravir:**

|                       |   |  |
|-----------------------|---|--|
| Genotoxicity in vitro | : | Test Type: reverse mutation assay<br>Result: negative                                    |
|                       |   | Test Type: Alkaline elution assay<br>Test system: rat hepatocytes<br>Result: negative    |
|                       |   | Test Type: Chromosomal aberration<br>Method: OECD Test Guideline 473<br>Result: negative |
| Genotoxicity in vivo  | : | Test Type: In vivo micronucleus test<br>Species: Mouse<br>Result: negative               |
|                       |   | Test Type: Chromosomal aberration<br>Method: OECD Test Guideline 475<br>Result: negative |

**Cellulose:**

|                       |   |  |
|-----------------------|---|--|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative |
|-----------------------|---|--|

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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

**Magnesium stearate:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

**Ammonium hydroxide:**

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

**Carcinogenicity**

Not classified based on available information.

**Components:****Raltegravir:**

Species : Mouse, male and female  
Exposure time : 104 weeks  
Result : negative

**Cellulose:**

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

**Reproductive toxicity**

Suspected of damaging the unborn child.

**Components:****Raltegravir:**

Effects on fertility : Test Type: Fertility/early embryonic development

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Species: Rat, male and female  
Application Route: Oral  
General Toxicity - Parent: NOAEL: 600 mg/kg body weight  
Result: negative

Effects on foetal development : Species: Rat  
Application Route: Oral  
General Toxicity Maternal: NOAEL:  $\geq$  600 mg/kg body weight  
Teratogenicity: LOAEL F1: 300 mg/kg body weight  
Symptoms: Skeletal malformations  
Result: positive

Species: Rabbit  
General Toxicity Maternal: NOAEL:  $\geq$  1,000 mg/kg body weight  
Teratogenicity: NOAEL:  $\geq$  1,000 mg/kg body weight  
Result: negative

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

**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

**Magnesium stearate:**

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

**STOT - single exposure**

May cause respiratory irritation.

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**Components:****Raltegravir:**

|                 |                                     |
|-----------------|-------------------------------------|
| Exposure routes | : Inhalation                        |
| Target Organs   | : Respiratory Tract                 |
| Assessment      | : May cause respiratory irritation. |

**STOT - repeated exposure**

Not classified based on available information.

**Repeated dose toxicity****Components:****Raltegravir:**

|                   |            |
|-------------------|------------|
| Species           | : Dog      |
| NOAEL             | : 90 mg/kg |
| Application Route | : Oral     |
| Exposure time     | : 371 d    |
| Symptoms          | : Vomiting |

|                   |             |
|-------------------|-------------|
| Species           | : Rat       |
| NOAEL             | : 30 mg/kg  |
| LOAEL             | : 120 mg/kg |
| Application Route | : Oral      |
| Exposure time     | : 189 d     |
| Target Organs     | : Stomach   |

|                   |             |
|-------------------|-------------|
| Species           | : Mouse     |
| NOAEL             | : 50 mg/kg  |
| LOAEL             | : 500 mg/kg |
| Application Route | : Oral      |
| Exposure time     | : 14 Weeks  |
| Target Organs     | : Stomach   |

|                   |             |
|-------------------|-------------|
| Species           | : Rat       |
| NOAEL             | : 50 mg/kg  |
| LOAEL             | : 200 mg/kg |
| Application Route | : Oral      |
| Exposure time     | : 8 Weeks   |
| Target Organs     | : Stomach   |

**Cellulose:**

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

**Magnesium stearate:**

|                   |                 |
|-------------------|-----------------|
| Species           | : Rat           |
| NOAEL             | : $> 100$ mg/kg |
| Application Route | : Ingestion     |
| Exposure time     | : 90 Days       |

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Remarks : Based on data from similar materials

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

### Components:

#### Raltegravir:

Ingestion : Symptoms: Nausea, Diarrhoea, Headache, Fever, Rash, Skin irritation

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## Section 12: Ecological information

### Ecotoxicity

### Components:

#### Raltegravir:

|  |   |  |
|--|---|--|
| Toxicity to fish   | : | LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203        |
|  |   | LC50 (Cyprinodon variegatus (sheepshead minnow)): > 100 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203   |
| Toxicity to daphnia and other aquatic invertebrates                    | : | EC50 (Daphnia magna (Water flea)): > 100 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202                  |
| Toxicity to algae/aquatic plants                                       | : | EC50 (Pseudokirchneriella subcapitata (green algae)): 66 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 201  |
|  |   | NOEC (Pseudokirchneriella subcapitata (green algae)): 3.8 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 201 |
| Toxicity to fish (Chronic toxicity)                                    | : | NOEC (Pimephales promelas (fathead minnow)): 9.3 mg/l<br>Exposure time: 33 d<br>Method: OECD Test Guideline 210          |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 9.5 mg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211                    |
| Toxicity to microorganisms   | : | EC50: > 1,000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209         |

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

**Cellulose:**

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

**Magnesium stearate:**

Toxicity to fish : LC50 (*Leuciscus idus* (Golden orfe)): > 100 mg/l  
Exposure time: 48 h  
Method: DIN 38412  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EL50 (*Daphnia magna* (Water flea)): > 1 mg/l  
Exposure time: 47 h  
Test substance: Water Accommodated Fraction  
Method: Directive 67/548/EEC, Annex V, C.2.  
Remarks: Based on data from similar materials  
No toxicity at the limit of solubility

Toxicity to algae/aquatic plants : EL50 (*Pseudokirchneriella subcapitata* (green algae)): > 1 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials  
No toxicity at the limit of solubility

NOELR (*Pseudokirchneriella subcapitata* (green algae)): > 1 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 (*Pseudomonas putida*): > 100 mg/l  
Exposure time: 16 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

**Ammonium hydroxide:**

Toxicity to fish : LC50 (*Oncorhynchus mykiss* (rainbow trout)): 0.89 mg/l  
Exposure time: 96 h  
Test substance: Neutralised product

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): 101 mg/l  
Exposure time: 48 h

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M-Factor (Acute aquatic toxicity) : 1

Toxicity to fish (Chronic toxicity) : NOEC (Oncorhynchus mykiss (rainbow trout)): 0.0135 mg/l  
Exposure time: 73 d  
Test substance: Neutralised product

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.961 mg/l  
Exposure time: 21 d  
Remarks: Based on data from similar materials

**Persistence and degradability****Components:****Raltegravir:**

Biodegradability : Result: rapidly degradable  
Biodegradation: 50 %  
Exposure time: 9 d  
Method: OECD Test Guideline 302B

Stability in water : Hydrolysis: < 10 %(5 d)  
Method: OECD Test Guideline 111

**Cellulose:**

Biodegradability : Result: Readily biodegradable.

**Magnesium stearate:**

Biodegradability : Result: Not biodegradable  
Remarks: Based on data from similar materials

**Bioaccumulative potential****Components:****Raltegravir:**

Partition coefficient: n-octanol/water : log Pow: -0.328

**Magnesium stearate:**

Partition coefficient: n-octanol/water : log Pow: > 4

**Mobility in soil**

No data available

**Other adverse effects**

No data available

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**Section 13: Disposal considerations****Disposal methods**

Waste from residues : Do not dispose of waste into sewer.

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

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**Section 14: Transport information****International Regulations****UNRTDG**

Not regulated as a dangerous good

|                           |                  |
|---------------------------|------------------|
| UN number                 | : Not applicable |
| Proper shipping name      | : Not applicable |
| Class                     | : Not applicable |
| Subsidiary risk           | : Not applicable |
| Packing group             | : Not applicable |
| Labels                    | : Not applicable |
| Environmentally hazardous | : no             |

**IATA-DGR**

Not regulated as a dangerous good

|  |                  |
|--|------------------|
| UN/ID No.                                | : Not applicable |
| Proper shipping name                     | : Not applicable |
| Class                                    | : Not applicable |
| Subsidiary risk                          | : Not applicable |
| Packing group                            | : Not applicable |
| Labels                                   | : Not applicable |
| Packing instruction (cargo aircraft)     | : Not applicable |
| Packing instruction (passenger aircraft) | : Not applicable |

**IMDG-Code**

Not regulated as a dangerous good

|                      |                  |
|----------------------|------------------|
| UN number            | : Not applicable |
| Proper shipping name | : Not applicable |
| Class                | : Not applicable |
| Subsidiary risk      | : Not applicable |
| Packing group        | : Not applicable |
| Labels               | : Not applicable |
| EmS Code             | : Not applicable |
| Marine pollutant     | : Not applicable |

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**National Regulations****NZS 5433**

Not regulated as a dangerous good

|                      |                  |
|----------------------|------------------|
| UN number            | : Not applicable |
| Proper shipping name | : Not applicable |
| Class                | : Not applicable |
| Subsidiary risk      | : Not applicable |
| Packing group        | : Not applicable |
| Labels               | : Not applicable |



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Hazchem Code : Not applicable

**Special precautions for user**

Not applicable

**Section 15: Regulatory information****Safety, health and environmental regulations/legislation specific for the substance or mixture****HSNO Approval Number**

not allocated

**Tolerable Exposure Limits (TEL)**

Not applicable

**Environmental Exposure Limits (EEL)**

Not applicable

**The components of this product are reported in the following inventories:**

AICS : not determined

CA. DSL : not determined

IECSC : not determined

**Section 16: Other information**

Revision Date : 13.11.2025

**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/>

Date format : dd.mm.yyyy

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / TWA : 8-hour, time-weighted average

ACGIH / STEL : Short-term exposure limit

NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; GHS - Globally Harmonised Sys-

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tem; 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 Organisation; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; 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; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organisation 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECL - 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; WHMIS - Workplace Hazardous Materials Information System

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

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