SAFETY DATA SHEET

Raltegravir Formulation

SECTION 1. IDENTIFICATION

Product name : Raltegravir Formulation

Manufacturer or supplier's details
Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
            Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Combustible dust
Serious eye damage : Category 1
Reproductive toxicity : Category 2
Specific target organ toxicity - single exposure : Category 3

GHS label elements
Hazard pictograms
Signal Word : Danger

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
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.
P261 Avoid breathing dust.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves, protective clothing, eye protection
and face protection.

Response:
P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a 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.
P308 + P313 IF exposed or concerned: Get medical attention.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents and container to an approved waste disposal plant.

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Component

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raltegravir</td>
<td>871038-72-1</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

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 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. Get medical attention.
Most important symptoms and effects, both acute and delayed: Contact with dust can cause mechanical irritation or drying of the skin. Causes serious eye damage. May cause respiratory irritation. Suspected of damaging the unborn child.

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.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
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. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)
Fluorine compounds
Metal oxides

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.

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

Environmental precautions: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. 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 minimize 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.

SECTION 7. HANDLING AND STORAGE

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: If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling: Avoid breathing dust.
Do not swallow.
Do not get in eyes.
Avoid prolonged or repeated contact with skin.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Already sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.
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 environment.

Conditions for safe storage: Keep in properly labeled 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

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Type of尘埃</th>
<th>Workplace Control Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>inert or nuisance dust</td>
<td>50 Million particles per cubic foot</td>
</tr>
</tbody>
</table>

Value type (Form of exposure): TWA (total dust)
Basis: OSHA Z-3
SAFETY DATA SHEET

Raltegravir Formulation

Version 6.0  Revision Date: 04/04/2023  SDS Number: 741583-00018  Date of last issue: 10/01/2022  Date of first issue: 06/06/2016

15 mg/m³  Value type (Form of exposure): TWA (total dust)  Basis: OSHA Z-3

5 mg/m³  Value type (Form of exposure): TWA (respirable fraction)  Basis: OSHA Z-3

15 Million particles per cubic foot  Value type (Form of exposure): TWA (respirable fraction)  Basis: OSHA Z-3

Dust, nuisance dust and particulates  Value type (Form of exposure): PEL (Total dust)  Basis: CAL PEL

Components  CAS-No.  Value type (Form of exposure)  Control parameters / Permissible concentration  Basis

Raltegravir  871038-72-1  TWA  1000 µg/m³ (OEB 1)  Internal

Cellulose  9004-34-6  TWA  10 mg/m³  ACGIH

Magnesium stearate  557-04-0  TWA (Inhalable particulate matter)  10 mg/m³  ACGIH

Engineering measures:
Minimize workplace exposure concentrations.
Apply measures to prevent dust explosions.
Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). If sufficient ventilation is unavailable, use with local exhaust ventilation.

Personal protective equipment
Respiratory protection: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where
concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection

Wear the following personal protective equipment:

Chemical resistant goggles must be worn.
If splashes are likely to occur, wear:
Face-shield

Skin and body protection

Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder
Color : No data available
Odor : No data available
Odor 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 : 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

Vapor pressure : No data available

Relative vapor density : No data available

Density : No data available

Solubility(ies)
   Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity
   Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

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.
   Can react with strong oxidizing agents.

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

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.
SECTION 11. TOXICOLOGICAL INFORMATION

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: 4,026 mg/kg
Method: Calculation method

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
  Exposure time: 4 h
  Test atmosphere: dust/mist
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Magnesium stearate:
Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
  Method: OECD Test Guideline 423
  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

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

Serious eye damage/eye irritation
Causes serious eye damage.

Components:

Raltegravir:

<table>
<thead>
<tr>
<th>Species</th>
<th>Bovine cornea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Severe irritation</td>
</tr>
</tbody>
</table>

Magnesium stearate:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Raltegravir:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Local lymph node assay (LLNA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

Magnesium stearate:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximization Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 406</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Germ cell mutagenicity
Not classified based on available information.

Components:

Raltegravir:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: reverse mutation assay</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Test Type: Alkaline elution assay</td>
</tr>
<tr>
<td></td>
<td>Test system: rat hepatocytes</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Test Type: Chromosomal aberration</td>
</tr>
</tbody>
</table>
## Genotoxicity in vivo

**Method:** OECD Test Guideline 473  
**Result:** negative

**Test Type:** In vivo micronucleus test  
**Species:** Mouse  
**Result:** negative

**Test Type:** Chromosomal aberration  
**Method:** OECD Test Guideline 475  
**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

### 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

### Carcinogenicity

Not classified based on available information.

## Components:

### Raltegravir:

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse, male and female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>104 weeks</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

### Cellulose:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>72 weeks</td>
</tr>
</tbody>
</table>
Result: negative

IARC: No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA: No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP: No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity:

Suspected of damaging the unborn child.

Components:

Raltegravir:

- Effects on fertility:
  - Test Type: Fertility/early embryonic development
  - Species: Rat, male and female
  - Application Route: Oral
  - General Toxicity Parent: NOAEL: 600 mg/kg body weight
  - Result: negative

- Effects on fetal development:
  - Species: Rat
  - Application Route: Oral
  - General Toxicity Maternal: NOAEL: >= 600 mg/kg body weight
  - Teratogenicity: LOAEL F1: 300 mg/kg body weight
  - Symptoms: Skeletal malformations.
  - Result: positive

  - Species: Rabbit
  - General Toxicity Maternal: NOAEL: >= 1,000 mg/kg body weight
  - Teratogenicity: NOAEL: >= 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 fetal 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 fetal development
Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

STOT-single exposure
May cause respiratory irritation.

Components:

Raltegravir:
Routes of exposure: 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

<table>
<thead>
<tr>
<th>Cells</th>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>Rat</td>
<td>&gt;= 9,000 mg/kg</td>
<td>Ingestion</td>
<td>90 Days</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Rat</td>
<td>&gt; 100 mg/kg</td>
<td>Ingestion</td>
<td>90 Days</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

**Components:**

**Raltegravir:**

| Ingestion | Symptoms: Nausea, Diarrhea, Headache, Fever, Rash, Skin irritation |

### Ecotoxicity

**Components:**

**Raltegravir:**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Pimephales promelas (fathead minnow)): &gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 203</td>
</tr>
<tr>
<td></td>
<td>LC50 (Cyprinodon variegatus (sheepshead minnow)): &gt; 100 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 202</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): 66 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

<p>|                           | NOEC (Pseudokirchneriella subcapitata (green algae)): 3.8 mg/l |
|                           | Exposure time: 96 h                                       |</p>
<table>
<thead>
<tr>
<th>Method: OECD Test Guideline 201</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC (Pimephales promelas (fathead minnow)): 9.3 mg/l</td>
</tr>
<tr>
<td>Exposure time: 33 d</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Method: OECD Test Guideline 210</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC (Daphnia magna (Water flea)): 9.5 mg/l</td>
</tr>
<tr>
<td>Exposure time: 21 d</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EC50: &gt; 1,000 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 3 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Method: OECD Test Guideline 209</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC: 1,000 mg/l</td>
</tr>
<tr>
<td>Exposure time: 3 h</td>
</tr>
</tbody>
</table>

### Cellulose:

<table>
<thead>
<tr>
<th>Test Type: Respiration inhibition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method: OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

### Magnesium stearate:

<table>
<thead>
<tr>
<th>Method: DIN 38412</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 (Oryzias latipes (Japanese medaka)): &gt; 100 mg/l</td>
</tr>
<tr>
<td>Exposure time: 48 h</td>
</tr>
</tbody>
</table>

| Remarks: Based on data from similar materials |

<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>EL50 (Daphnia magna (Water flea)): &gt; 1 mg/l</td>
</tr>
<tr>
<td>Exposure time: 47 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test substance: Water Accommodated Fraction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

| No toxicity at the limit of solubility. |

### Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Method: OECD Test Guideline 201</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOELR (Pseudokirchneriella subcapitata (green algae)): &gt; 1 mg/l</td>
</tr>
<tr>
<td>Exposure time: 72 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test substance: Water Accommodated Fraction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

| No toxicity at the limit of solubility. |

### Toxicity to microorganisms

<table>
<thead>
<tr>
<th>EC10 (Pseudomonas putida): &gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
</tbody>
</table>

| Remarks: Based on data from similar materials |

| No toxicity at the limit of solubility. |
Exposure time: 16 h  
Test substance: Water Accommodated Fraction  
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

**SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods**
- Waste from residues: Dispose of in accordance with local regulations.  
  Do not dispose of waste into sewer.
- Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.  
  If not otherwise specified: Dispose of as unused product.
SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

49 CFR
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards
- Combustible dust
- Reproductive toxicity
- Serious eye damage or eye irritation
- Specific target organ toxicity (single or repeated exposure)

SARA 313
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
- Raltegravir 871038-72-1
- Cellulose 9004-34-6
- Croscarmellose sodium 74811-65-7
- Hydroxypropyl methylcellulose 9004-65-3

California Permissible Exposure Limits for Chemical Contaminants
- Cellulose 9004-34-6
- Magnesium stearate 557-04-0
The ingredients of this product are reported in the following inventories:

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

### SECTION 16. OTHER INFORMATION

**Further information**

**NFPA 704:**

- **Flammability:** 1
- **Health:** 3
- **Instability:** 0

**HMIS® IV:**

- **HEALTH:** *
- **FLAMMABILITY:** 3
- **PHYSICAL HAZARD:** 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

**Full text of other abbreviations**

- **ACGIH**: USA. ACGIH Threshold Limit Values (TLV)
- **CAL PEL**: California permissible exposure limits for chemical contaminants (Title 8, Article 107)
- **NIOSH REL**: USA. NIOSH Recommended Exposure Limits
- **OSHA Z-1**: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- **OSHA Z-3**: USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
- **ACGIH / TWA**: 8-hour, time-weighted average
- **CAL PEL / PEL**: Permissible exposure limit
- **NIOSH REL / TWA**: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
- **OSHA Z-1 / TWA**: 8-hour time weighted average
- **OSHA Z-3 / TWA**: 8-hour time weighted average

**AIIC** - Australian Inventory of Industrial Chemicals; **ASTM** - American Society for the Testing of Materials; **bw** - Body weight; **CERCLA** - Comprehensive Environmental Response, Compensation, and Liability Act; **CMR** - Carcinogen, Mutagen or Reproductive Toxicant; **DIN** - Standard of the German Institute for Standardisation; **DOT** - Department of Transportation; **DSL** - Domestic Substances List (Canada); **ECx** - Concentration associated with x% response; **EHS** - Extremely Haz-
ardous Substance; 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 Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; u.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; 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


Revision Date: 04/04/2023

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

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

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