



| Version<br>6.2 | Revision Date:<br>06.04.2024               |      | S Number:<br>213-00025           | Date of last issue: 26.09.2023<br>Date of first issue: 16.09.2014 |
|----------------|--|------|----------------------------------|---|
|                |  |      |                                  |   |
|                | 1: IDENTIFICATION<br>uct name              | :    | Raltegravir Adult                | Formulation   |
| Manu           | ufacturer or supplier's o                  | deta | ils                              |   |
| Com            | pany                                       | :    | MSD                              |   |
| Addr           | ess  | :    |                                  | el 1/26 Talavera Rd<br>NSW, Australia 2113                        |
| Telep          | phone                                      | :    | 1 800 033 461                    |   |
| Emei           | rgency telephone numbe                     | r :  | Poisons Informat                 | tion Centre: Phone 13 11 26                                       |
| E-ma           | ail address                                | :    | EHSDATASTEW                      | /ARD@msd.com  |
| Reco           | ommended use of the c                      | hem  | ical and restriction             | ons on use  |
|                | ommended use<br>rictions on use            | :    | Pharmaceutical<br>Not applicable |   |
| SECTION        | 2. HAZARDS IDENTIFI                        | САТ  | ION                              |   |
|                | Classification<br>bus eye damage/eye irri- | :    | Category 1                       |   |
| Repr           | oductive toxicity                          | :    | Category 2                       |   |

| Specific target organ toxicity - single exposure | : | Category 3 |
|--|---|------------|
| Single exposure                                  |   |            |

### **GHS** label elements

| Hazard pictograms        | : |   |
|--------------------------|---|---|
| Signal word              | : | Danger  |
| Hazard statements        | : | H318 Causes serious eye damage.<br>H335 May cause respiratory irritation.<br>H361d Suspected of damaging the unborn child.                              |
| Precautionary statements | : | <b>Prevention:</b><br>P201 Obtain special instructions before use.<br>P202 Do not handle until all safety precautions have been read<br>and understood. |



| Version | Revision Date: | SDS Number: | Date of last issue: 26.09.2023  |
|---------|----------------|-------------|---------------------------------|
| 6.2     | 06.04.2024     | 13213-00025 | Date of first issue: 16.09.2014 |

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 | >= 30 -< 60           |
| Cellulose          | 9004-34-6   | >= 10 -< 30           |
| Magnesium stearate | 557-04-0    | < 10                  |

#### **SECTION 4. FIRST AID MEASURES**

| General advice          | : In the case of accident or if you feel unwell, seek medical ad-<br>vice 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                      |
| In case of eye contact  | Thoroughly clean shoes before reuse.   |



| Version<br>6.2 | Revision Date:<br>06.04.2024                         | -  | OS Number:<br>213-00025  | Date of last issue: 26.09.2023<br>Date of first issue: 16.09.2014   |  |
|----------------|--|----|--|---|--|
|                |  |    |  |   |  |
|                |  |    |  | inutes.<br>nove contact lens, if worn.<br>ntion immediately.  |  |
| If sw          | allowed  | :  | Get medical atte   | ) NOT induce vomiting.<br>ntion.<br>roughly with water.   |  |
|                | important symptoms<br>effects, both acute and<br>/ed | :  | Causes serious<br>May cause respi<br>Suspected of da                                   | eye damage.   |  |
| Prote          | ection of first-aiders                               | :  | First Aid respond<br>and use the reco  | ders should pay attention to self-protection,<br>ommended personal protective equipment<br>ial for exposure exists (see section 8).                                   |  |
| Note           | s to physician                                       | :  | Treat symptomatically and supportively.  |   |  |
| SECTION        | I 5. FIREFIGHTING MEA                                | SU | RES  |   |  |
| Suita          | ble extinguishing media                              | :  | Water spray<br>Alcohol-resistan<br>Carbon dioxide (<br>Dry chemical                    |   |  |
| Unsu<br>medi   | uitable extinguishing<br>a                           | :  | None known.  |   |  |
| Spec<br>fighti | sific hazards during fire-<br>ng                     | :  | concentrations, a potential dust ex  | g dust; fine dust dispersed in air in sufficient<br>and in the presence of an ignition source is a<br>plosion hazard.<br>houstion products may be a hazard to health. |  |
| Haza<br>ucts   | ardous combustion prod-                              | :  | Carbon oxides<br>Metal oxides<br>Oxides of phosp<br>Nitrogen oxides<br>Fluorine compou | (NOx)   |  |
| Spec<br>ods    | ific extinguishing meth-                             | :  | cumstances and Use water spray   | ng measures that are appropriate to local cir-<br>the surrounding environment.<br>to cool unopened containers.<br>aged containers from fire area if it is safe to d   |  |
| 0              |  |    |  |   |  |

#### SECTION 6. ACCIDENTAL RELEASE MEASURES

Special protective equipment :

for firefighters

| Personal precautions, protec- : | Use personal protective equipment.   |
|---------------------------------|--|
| tive equipment and emer-        | Follow safe handling advice (see section 7) and personal pro-  |
| gency procedures                | tective equipment recommendations (see section 8).   |
| Environmental precautions :     | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water. |

Use personal protective equipment.

In the event of fire, wear self-contained breathing apparatus.



| Version<br>6.2   | Revision Date:<br>06.04.2024 |   | 9S Number:<br>213-00025  | Date of last issue: 26.09.2023<br>Date of first issue: 16.09.2014  |
|--|------------------------------|---|--|--|
|  |                              |   | Local authorities s cannot be contain  | should be advised if significant spillages<br>ied.   |
| Methods and materials for<br>containment and cleaning up |                              | : | over the area to n<br>Add excess liquid<br>Soak up with iner<br>Avoid dispersal of<br>with compressed<br>Dust deposits sho<br>es, as these may<br>leased into the att<br>Clean up remainin<br>bent.<br>Local or national<br>posal of this mate<br>employed in the of<br>mine which regula<br>Sections 13 and | h absorbents and place a damp covering<br>ninimise entry of the material into the air.<br>to allow the material to enter into solution.<br>t absorbent material.<br>f dust in the air (i.e., clearing dust surfaces<br>air).<br>buld not be allowed to accumulate on surfac-<br>form an explosive mixture if they are re-<br>mosphere in sufficient concentration.<br>ng materials from spill with suitable absor-<br>regulations may apply to releases and dis-<br>trial, as well as those materials and items<br>cleanup of releases. You will need to deter-<br>ations are applicable.<br>15 of this SDS provide information regarding<br>ational requirements. |

### SECTION 7. HANDLING AND STORAGE

| Technical measures      | <ul> <li>Static electricity may accumulate and ignite suspended d<br/>causing an explosion.</li> <li>Provide adequate precautions, such as electrical groundi<br/>and bonding, or inert atmospheres.</li> </ul>   |       |
|-------------------------|---|-------|
| Local/Total ventilation | <ul> <li>If sufficient ventilation is unavailable, use with local exhau ventilation.</li> </ul>   | JSt   |
| Advice on safe handling | <ul> <li>Avoid breathing dust.</li> <li>Do not swallow.</li> <li>Do not get in eyes.</li> <li>Avoid prolonged or repeated contact with skin.</li> <li>Handle in accordance with good industrial hygiene and sa practice, based on the results of the workplace exposure sessment</li> <li>Keep container tightly closed.</li> </ul> |       |
|                         | Already sensitised individuals, and those susceptible<br>to asthma, allergies, chronic or recurrent respiratory disea<br>should consult their physician regarding working with resp<br>tory irritants or sensitisers.<br>Minimize dust generation and accumulation.   |       |
|                         | 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 t<br>environment.   | o the |
| Hygiene measures        | <ul> <li>If exposure to chemical is likely during typical use, provid<br/>flushing systems and safety showers close to the working<br/>place.</li> <li>When using do not eat, drink or smoke.</li> </ul>  |       |



| Versio<br>6.2 | n Revision Date:<br>06.04.2024 | SDS Number:<br>13213-00025         | Date of last issue: 26.09.2023<br>Date of first issue: 16.09.2014   |
|---------------|--------------------------------|------------------------------------|---|
|               | onditions for safe storage     | Wash contamin                      | ated clothing before re-use.<br>y labelled containers.  |
| М             | aterials to avoid              | Keep in a cool,<br>Store in accord | well-ventilated place.<br>ance with the particular national regulations.<br>th the following product types: |

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

| Components         | CAS-No.     | Value type<br>(Form of<br>exposure)                | Control parame-<br>ters / Permissible<br>concentration | Basis    |
|--------------------|-------------|--|--|----------|
| Raltegravir        | 871038-72-1 | TWA  | 1000 µg/m3 (OEB<br>1)                                  | Internal |
| Cellulose          | 9004-34-6   | TWA  | 10 mg/m3   | AU OEL   |
|                    |             | TWA  | 10 mg/m3   | ACGIH    |
| Magnesium stearate | 557-04-0    | TWA  | 10 mg/m3   | AU OEL   |
|                    |             | TWA (Inhal-<br>able particu-<br>late matter)       | 10 mg/m3   | ACGIH    |
|                    |             | TWA (Res-<br>pirable par-<br>ticulate mat-<br>ter) | 3 mg/m3  | ACGIH    |

### Components with workplace control parameters

| Engineering measures           | :   | Minimize workplace exposure concentrations.<br>Apply measures to prevent dust explosions.<br>Ensure that dust-handling systems (such as exhaust ducts,<br>dust collectors, vessels, and processing equipment) are de-<br>signed in a manner to prevent the escape of dust into the<br>work area (i.e., there is no leakage from the equipment).<br>If sufficient ventilation is unavailable, use with local exhaust<br>ventilation. |
|--------------------------------|-----|---|
| Personal protective equipme    | ent |   |
| Respiratory protection         | :   | If adequate local exhaust ventilation is not available or expo-<br>sure assessment demonstrates exposures outside the rec-<br>ommended guidelines, use respiratory protection.  |
| Filter type<br>Hand protection | :   | Particulates type   |
| Material                       | :   | Chemical-resistant gloves   |
| Remarks                        | :   | Choose gloves to protect hands against chemicals depending<br>on the concentration and quantity of the hazardous sub-<br>stance and specific to place of work. Breakthrough time is not<br>determined for the product. Change gloves often! For special   |

Evaporation rate



# Raltegravir Adult Formulation

| Version<br>6.2 | Revision Date:<br>06.04.2024           | SDS Numb<br>13213-000  |   |
|----------------|--|--|---|
| -              | e protection<br>in and body protection | chemic<br>glove n<br>end of<br>: Wear ti<br>Chemic<br>If splas<br>Face-s<br>: Select<br>resistan<br>potenti<br>Skin co | appropriate protective clothing based on chemical ance data and an assessment of the local exposure |
| SECTIC         | ON 9. PHYSICAL AND C                   | HEMICAL PR   | ROPERTIES   |
| Ар             | pearance                               | : powde  | er  |
| Co             | lour                                   | : No da  | ata available   |
| Od             | our                                    | : No da  | ata available   |
| Od             | our Threshold                          | : No da  | ata available   |

| рН                                      | : | No data available |
|---|---|-------------------|
| Melting point/freezing point            | : | No data available |
| Initial boiling point and boiling range | : | No data available |
| Flash point                             | : | No data available |

: Not applicable

| Flammability (solid, gas) | : | May form explosive dust-air mixture during processing, han-<br>dling or other means. |
|---------------------------|---|--|
| Flammability (liquids)    | : | No data available  |
| Self-ignition             | : | No data available  |

| Upper explosion limit / Upper<br>flammability limit | : | No data available |
|---|---|-------------------|
| Lower explosion limit / Lower<br>flammability limit | : | No data available |
| Vapour pressure                                     | : | No data available |
| Relative vapour density                             | : | No data available |
| Density   | : | No data available |



| Versic<br>6.2 | on                   | Revision Date:<br>06.04.2024 | - | S Number:<br>213-00025 | Date of last issue: 26.09.2023<br>Date of first issue: 16.09.2014 |
|---------------|----------------------|------------------------------|---|------------------------|---|
|               |                      |                              |   |                        |   |
|               |                      |                              |   |                        |   |
| S             | Solubili<br>Wate     | ty(ies)<br>er solubility     | : | No data available      | 9   |
|               | Partition            | n coefficient: n-            | : | No data available      | )   |
| -             |                      | nition temperature           | : | No data available      | )   |
| D             | Decom                | position temperature         | : | No data available      | 2   |
| V             | /iscosit<br>Visc     | y<br>osity, dynamic          | : | No data available      | )   |
|               | Visc                 | osity, kinematic             | : | No data available      | 9   |
| F             | low tin              | ne                           | : | No data available      | 9   |
| E             | Explosi              | ve properties                | : | Not explosive          |   |
|               |                      |                              |   | <b>—</b> , , ,         |   |
| C             | Dxidizir             | ng properties                | : | The substance of       | r mixture is not classified as oxidizing.                         |
| Ν             | /lolecul             | ar weight                    | : | No data available      | 9   |
|               | Particle<br>Particle | characteristics<br>size      | : | No data available      | 9   |

### SECTION 10. STABILITY AND REACTIVITY

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

### SECTION 11. TOXICOLOGICAL INFORMATION

| Exposure routes | : Inhalation |
|-----------------|--------------|
|                 | Skin contact |
|                 | Ingestion    |
|                 | Eye contact  |

#### Acute toxicity

Not classified based on available information.



| rsion  | Revision Date:<br>06.04.2024     |              | 9S Number:<br>213-00025                            | Date of last issue: 26.09.2023<br>Date of first issue: 16.09.2014  |
|--|----------------------------------|--------------|--|--|
|  |                                  |              |  |  |
|  |                                  |              |  |  |
| <u>Com</u>                                     | oonents:                         |              |  |  |
| Ralte  | gravir:                          |              |  |  |
| Acute  | oral toxicity                    | :            | LD50 (Mouse, I                                     | male and female): > 2,000 mg/kg  |
| Cellu  | lose:                            |              |  |  |
| Acute  | oral toxicity                    | :            | LD50 (Rat): > 5                                    | i,000 mg/kg  |
| Acute  | inhalation toxicity              | :            | LC50 (Rat): > 5<br>Exposure time:<br>Test atmosphe | 4 h  |
| Acute  | e dermal toxicity                | :            | LD50 (Rabbit):                                     | > 2,000 mg/kg  |
| Magn   | esium stearate:                  |              |  |  |
| -  | oral toxicity                    | :            | Assessment: T<br>icity                             | 2,000 mg/kg<br>Test Guideline 423<br>he substance or mixture has no acute oral to<br>ed on data from similar materials |
| Acute  | e dermal toxicity                | :            | LD50 (Rabbit):<br>Remarks: Base                    | > 2,000 mg/kg<br>ed on data from similar materials   |
| Skin   | corrosion/irritation             |              |  |  |
| Not c  | lassified based on ava           | ilable       | information.                                       |  |
| Com  | ponents:                         |              |  |  |
| Ralte  | gravir:                          |              |  |  |
| Speci<br>Resu                                  | es                               | :            | Rabbit<br>No skin irritatio                        | n  |
| Magn   | esium stearate:                  |              |  |  |
| Speci  | es                               | :            | Rabbit   |  |
| Resu<br>Rema                                   |                                  | :            | No skin irritation<br>Based on data                | n<br>from similar materials  |
|  |                                  |              | ~ ~  |  |
| Corio  | us eye damage/eye i              | mati         | on   |  |
|  | es serious eye damag             | e.           |  |  |
| Caus   | es serious eye damag<br>ponents: | e.           |  |  |
| Cause<br><u>Com</u>                            | oonents:                         | e.           |  |  |
| Cause<br><u>Com</u>                            | oonents:<br>gravir:<br>es        | e.<br>:      | Bovine cornea<br>Severe irritatior                 | ۱  |
| Cause<br><u>Com</u><br>Ralte<br>Speci<br>Resul | oonents:<br>gravir:<br>es        | e.<br>:<br>: |  | ۱  |





| Version<br>6.2                              | Revision Date:<br>06.04.2024                    | -        | )S Number:<br>213-00025  | Date of last issue: 26.09.2023<br>Date of first issue: 16.09.2014 |  |
|---|---|----------|--|---|--|
| Resu<br>Rema                                | •   | :        | · · · · · · · · · · · · · · · · · · ·  | on<br>a from similar materials                                    |  |
| Resp  | iratory or skin sensi                           | itisatio | n  |   |  |
| •   | sensitisation<br>lassified based on ava         | ailable  | information.   |   |  |
| -   | iratory sensitisation<br>lassified based on ava |          | information.   |   |  |
| <u>Com</u>                                  | ponents:  |          |  |   |  |
| Ralte<br>Test <sup>-</sup><br>Speci<br>Resu | ies   | :        | Local lymph n<br>Mouse<br>negative   | ode assay (LLNA)  |  |
| Test  | sure routes<br>ies<br>od<br>It                  |          | Maximisation<br>Skin contact<br>Guinea pig<br>OECD Test G<br>negative<br>Based on data |   |  |
| Chro  | nic 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 |



| rsion                | Revision Date:<br>06.04.2024 | SDS Number:<br>13213-00025        | Date of last issue: 26.09.2023<br>Date of first issue: 16.09.2014                  |
|----------------------|------------------------------|-----------------------------------|--|
|                      |                              |                                   |  |
|                      |                              |                                   |  |
| <b>Cellu</b><br>Geno | lose:<br>toxicity in vitro   | : Test Type: Ba<br>Result: negati | cterial reverse mutation assay (AMES)<br>ve  |
|                      |                              | Test Type: In<br>Result: negati   | vitro mammalian cell gene mutation test<br>ve                                      |
| Geno                 | toxicity in vivo             | cytogenetic as<br>Species: Mou    | se Dute: Ingestion   |
| Magn                 | esium stearate:              |                                   |  |
| Geno                 | toxicity in vitro            | Result: negati                    | vitro mammalian cell gene mutation test<br>ve<br>ed on data from similar materials |
|                      |                              |                                   | romosome aberration test in vitro<br>D Test Guideline 473<br>ve                    |
|                      |                              |                                   | ed on data from similar materials  |
|                      |                              | Result: negati                    | cterial reverse mutation assay (AMES)<br>ve<br>ed on data from similar materials   |
| Carci                | nogenicity                   |                                   |  |
|                      | lassified based on av        | ailable information.              |  |
| <u>Comp</u>          | oonents:                     |                                   |  |
| Ralte                | gravir:                      |                                   |  |
| Speci                |                              | : Mouse, male                     | and female   |
| Expos<br>Resul       | sure time<br>It              | : 104 weeks<br>: negative         |  |
|                      |                              | Ū                                 |  |
| Cellu                |                              |                                   |  |
| Speci                | es<br>cation Route           | : Rat<br>: Ingestion              |  |
|                      | sure time                    | : 72 weeks                        |  |
| Resul                |                              | : negative                        |  |
| Repro                | oductive toxicity            |                                   |  |
| -                    | -                            | e unborn child.                   |  |
|                      | solou or uarnaging in        |                                   |  |
| -                    | oonents:                     |                                   |  |
| Comp                 |                              |                                   |  |

## SAFETY DATA SHEET



# Raltegravir Adult Formulation

| Versi<br>6.2 | ion                                     | Revision Date:<br>06.04.2024 | - | OS Number:<br>213-00025  | Date of last issue: 26.09.2023<br>Date of first issue: 16.09.2014  |  |  |
|--------------|---|------------------------------|---|--|--|--|--|
|              |   |                              |   |  |  |  |  |
|              | Effects on fertility                    |                              | : | : Test Type: Fertility/early embryonic development<br>Species: Rat, male and female<br>Application Route: Oral<br>General Toxicity - Parent: NOAEL: 600 mg/kg body weigh<br>Result: negative |  |  |  |
|              | Effects on foetal develop-<br>ment      |                              | : | Teratogenicity: L  | e: Oral<br>Maternal: NOAEL: >= 600 mg/kg body weight<br>DAEL F1: 300 mg/kg body weight<br>etal malformations   |  |  |
|              |   |                              |   | weight   | Maternal: NOAEL: >= 1,000 mg/kg body<br>OAEL: >= 1,000 mg/kg body weight   |  |  |
|              | Reproductive toxicity - As-<br>sessment |                              | : | Some evidence c<br>animal experimer  | f adverse effects on development, based on<br>nts.   |  |  |
|              | Cellulose:                              |                              |   |  |  |  |  |
|              | Effects                                 | on fertility                 | : | Test Type: One-g<br>Species: Rat<br>Application Route<br>Result: negative  | eneration reproduction toxicity study  |  |  |
|              | Effects<br>ment                         | on foetal develop-           | : | Test Type: Fertilit<br>Species: Rat<br>Application Route<br>Result: negative   | y/early embryonic development<br>e: Ingestion  |  |  |
|              | Magne                                   | sium stearate:               |   |  |  |  |  |
|              | Effects                                 | on fertility                 | : | reproduction/deve<br>Species: Rat<br>Application Route<br>Method: OECD T<br>Result: negative   | ined repeated dose toxicity study with the<br>elopmental toxicity screening test<br>e: Ingestion<br>fest Guideline 422<br>on data from similar materials |  |  |
|              | Effects<br>ment                         | on foetal develop-           | : | Species: Rat<br>Application Route<br>Result: negative  | vo-foetal development<br>e: Ingestion<br>on data from similar materials  |  |  |

### STOT - single exposure

May cause respiratory irritation.



| ersion<br>.2            | Revision Date:<br>06.04.2024                | SDS Number:<br>13213-00025  | Date of last issue: 26.09.2023<br>Date of first issue: 16.09.2014 |
|-------------------------|---|---|---|
|                         |   |   |   |
| Comr                    | oonents:                                    |   |   |
|                         | gravir:                                     |   |   |
| Expos<br>Targe          | sure routes<br>t Organs<br>ssment           | : Inhalation<br>: Respiratory Tr<br>: May cause res                       | act<br>spiratory irritation.                                      |
|                         | - repeated exposur<br>assified based on ava |   |   |
| Repe                    | ated dose toxicity                          |   |   |
| Comp                    | oonents:                                    |   |   |
| Ralte                   | gravir:                                     |   |   |
| Speci<br>NOAE<br>Applic | es<br>EL<br>cation Route<br>sure time       | : Dog<br>: 90 mg/kg<br>: Oral<br>: 371 d<br>: Vomiting                    |   |
| Expos                   | EL  | : Rat<br>: 30 mg/kg<br>: 120 mg/kg<br>: Oral<br>: 189 d<br>: Stomach      |   |
| Expos                   | EL  | : Mouse<br>: 50 mg/kg<br>: 500 mg/kg<br>: Oral<br>: 14 Weeks<br>: Stomach |   |
| Expos                   | EL  | : Rat<br>: 50 mg/kg<br>: 200 mg/kg<br>: Oral<br>: 8 Weeks<br>: Stomach    |   |
| Cellul                  | lose:                                       |   |   |
| Speci<br>NOAE<br>Applic | es  | : Rat<br>: >= 9,000 mg/k<br>: Ingestion<br>: 90 Days                      | g   |
| Magn                    | esium stearate:                             |   |   |
| Speci<br>NOAE           | es  | : Rat<br>: > 100 mg/kg  |   |





| ersion<br>.2    | Revision Date:<br>06.04.2024                                    |      | OS Number:<br>213-00025               | Date of last issue: 26.09.2023<br>Date of first issue: 16.09.2014                  |
|-----------------|---|------|---------------------------------------|--|
|                 | cation Route<br>sure time<br>arks                               | :    | Ingestion<br>90 Days<br>Based on data | a from similar materials   |
| -               | ration toxicity<br>lassified based on availa                    | able | information.                          |  |
| Expe            | rience with human exp   | osi  | Ire                                   |  |
| <u>Com</u>      | ponents:  |      |                                       |  |
| Ralte<br>Inges  | <b>gravir:</b><br>ition   | :    | Symptoms: Na irritation               | ausea, Diarrhoea, Headache, Fever, Rash, Ski                                       |
| ECTION          | 12. ECOLOGICAL INFO   | ORN  | ATION                                 |  |
| Ecot            | oxicity   |      |                                       |  |
| <u>Com</u>      | ponents:  |      |                                       |  |
| Ralte           | gravir:   |      |                                       |  |
| Toxic           | ity to fish   | :    | Exposure time                         | aales promelas (fathead minnow)): > 100 mg/l<br>e: 96 h<br>D Test Guideline 203    |
|                 |   |      | mg/l<br>Exposure time                 | odon variegatus (sheepshead minnow)): > 100<br>e: 96 h<br>D Test Guideline 203     |
| <b>–</b> .      |   |      |                                       |  |
|                 | ity to daphnia and other tic invertebrates                      | :    | Exposure time                         | a magna (Water flea)): > 100 mg/l<br>e: 48 h<br>D Test Guideline 202               |
| Toxic<br>plants | ity to algae/aquatic<br>s                                       | :    | Exposure time                         | okirchneriella subcapitata (green algae)): 66 m<br>e: 96 h<br>D Test Guideline 201 |
|                 |   |      | mg/l<br>Exposure time                 | lokirchneriella subcapitata (green algae)): 3.8<br>e: 96 h<br>D Test Guideline 201 |
| Toxic<br>icity) | ity to fish (Chronic tox-                                       | :    | Exposure time                         | hales promelas (fathead minnow)): 9.3 mg/l<br>e: 33 d<br>D Test Guideline 210      |
|                 | ity to daphnia and other<br>tic invertebrates (Chron-<br>icity) |      | Exposure time                         | nia magna (Water flea)): 9.5 mg/l<br>e: 21 d<br>D Test Guideline 211               |
|                 |   |      |                                       |  |

## SAFETY DATA SHEET



| Version<br>6.2  | Revision Date:<br>06.04.2024                  |   | 0S Number:<br>213-00025  | Date of last issue: 26.09.2023<br>Date of first issue: 16.09.2014                                |
|-----------------|---|---|--|--|
| Toxic           | ity to microorganisms                         | : | Exposure time: 3<br>Test Type: Respi<br>Method: OECD T<br>NOEC: 1,000 mg<br>Exposure time: 3<br>Test Type: Respi | h<br>ration inhibition<br>est Guideline 209<br>/I<br>h   |
|                 | llose:  |   |  |  |
| Toxic           | ity to fish                                   | : | Exposure time: 4   | ipes (Japanese medaka)): > 100 mg/l<br>8 h<br>on data from similar materials                     |
| Magr            | nesium stearate:                              |   |  |  |
| Toxic           | ity to fish                                   | : | Exposure time: 4<br>Method: DIN 384  |  |
|                 | ity to daphnia and other<br>tic invertebrates | : | Exposure time: 4<br>Test substance: V<br>Method: Directive   | Vater Accommodated Fraction<br>e 67/548/EEC, Annex V, C.2.<br>on data from similar materials     |
| Toxic<br>plants | ity to algae/aquatic<br>s                     | : | mg/l<br>Exposure time: 72<br>Test substance: V<br>Method: OECD T   | Nater Accommodated Fraction<br>est Guideline 201<br>on data from similar materials               |
|                 |   |   | mg/l<br>Exposure time: 72<br>Test substance: \<br>Method: OECD T   | Nater Accommodated Fraction  |
| Toxic           | ity to microorganisms                         | : | Exposure time: 10<br>Test substance: \   | onas putida): > 100 mg/l<br>6 h<br>Vater Accommodated Fraction<br>on data from similar materials |



| ersion<br>.2 | Revision Date:<br>06.04.2024                         |        | S Number:<br>213-00025          | Date of last issue: 26.09.2023<br>Date of first issue: 16.09.2014 |
|--------------|--|--------|---------------------------------|---|
|              |  |        |                                 |   |
| Persi        | stence and degrada                                   | bility |                                 |   |
| Com          | ponents:   |        |                                 |   |
| Ralte        | gravir:  |        |                                 |   |
| Biode        | egradability   | :      | Biodegradation<br>Exposure time | n: 50 %   |
| Stabi        | lity in water  | :      |                                 | 0 %(5 d)<br>D Test Guideline 111                                  |
| Cellu        | llose:   |        |                                 |   |
| Biode        | egradability   | :      | Result: Readily                 | y biodegradable.  |
| Magr         | nesium stearate:                                     |        |                                 |   |
| Biode        | egradability   | :      | Result: Not bio<br>Remarks: Bas | odegradable<br>ed on data from similar materials                  |
| Bioa         | ccumulative potentia                                 | ıl     |                                 |   |
| Com          | ponents:   |        |                                 |   |
| Ralte        | gravir:  |        |                                 |   |
|              | ion coefficient: n-<br>ol/water                      | :      | log Pow: -0.32                  | 8   |
| Partit       | nesium stearate:<br>ion coefficient: n-<br>iol/water | :      | log Pow: > 4                    |   |
|              | <b>lity in soil</b><br>ata available                 |        |                                 |   |
|              | r adverse effects<br>ata available                   |        |                                 |   |

### SECTION 13. DISPOSAL CONSIDERATIONS

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

### SECTION 14. TRANSPORT INFORMATION

#### International Regulations



| UNRTDGUN numberNot applicableProper shipping nameNot applicableClassNot applicableSubsidiary riskNot applicablePacking groupNot applicableLabelsNot applicableEnvironmentally hazardousnoIATA-DGRUN/ID No.Not applicableProper shipping nameNot applicableClassNot applicableSubsidiary riskNot applicablePacking groupNot applicableClassNot applicableSubsidiary riskNot applicableSubsidiary riskNot applicablePacking instruction (cargoNot applicablePacking instruction (passen-<br>erraft)Not applicableIMDG-CodeUN numberNot applicableProper shipping nameNot applicableBacking instruction (passen-<br>erraft)Not applicablePacking instruction (passen-<br>erraft)Not applicableErroftImplicableDisplassNot applicableProper shipping nameNot applicableBasNot applicableProper shipping nameNot applicableEns CodeNot applicableProper shipping nameNot applicableProper shipping nameNot applicabl | Version<br>6.2  | Revision Date:<br>06.04.2024  | SDS Number:<br>13213-00025   | Date of last issue: 26.09.2023<br>Date of first issue: 16.09.2014 |
|---|---|---|--|---|
| UN/ID No.:Not applicableProper shipping name:Not applicableClass:Not applicableSubsidiary risk:Not applicablePacking group:Not applicableLabels:Not applicablePacking instruction (cargo:Not applicableaircraft):Not applicablePacking instruction (passen-<br>ger aircraft):Not applicableIMDG-Code:Not applicableUN number:Not applicableProper shipping name:Not applicableClass:Not applicableSubsidiary risk:Not applicablePacking group:Not applicableEndels::Not applicable:Proper shipping name::Not applicableClass:::Subsidiary risk::  | UN n<br>Prope<br>Class<br>Subs<br>Packi<br>Label                              | umber<br>er shipping name<br>idiary risk<br>ng group<br>s   | <ul> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> </ul>                         |   |
| UN number:Not applicableProper shipping name:Not applicableClass:Not applicableSubsidiary risk:Not applicablePacking group:Not applicableLabels:Not applicableEmS Code:Not applicable   | UN/IE<br>Prope<br>Class<br>Subs<br>Packi<br>Label<br>Packi<br>aircra<br>Packi | D No.<br>er shipping name<br>idiary risk<br>ng group<br>s<br>ng instruction (cargo<br>ift)<br>ng instruction (passen- | <ul> <li>Not applicable</li> </ul> |   |
|   | UN n<br>Prope<br>Class<br>Subsi<br>Packi<br>Label<br>EmS                      | umber<br>er shipping name<br>idiary risk<br>ng group<br>s<br>Code   | <ul> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> </ul>                         |   |
|   |   |   |  |   |

Not applicable for product as supplied.

#### National Regulations

| ADG<br>UN number<br>Proper shipping name<br>Class<br>Subsidiary risk<br>Packing group<br>Labels |   | Not applicable<br>Not applicable<br>Not applicable<br>Not applicable<br>Not applicable |
|---|---|--|
| 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

Therapeutic Goods (Poisons : No poison schedule number allocated (Please use the original



| Version<br>6.2 | Revision Date:<br>06.04.2024 | SDS Number:<br>13213-00025 | Date of last issue: 26.09.2023<br>Date of first issue: 16.09.2014  |
|----------------|------------------------------|----------------------------|--|
| Stand          | dard) Instrument             |                            | check for specific uses, specific conditions or<br>s that might apply for this chemical)   |
| Prohi          | bition/Licensing Requ        | irements                   | : There is no applicable prohibition,<br>authorisation and restricted use<br>requirements, including for carcino-<br>gens referred to in Schedule 10 of<br>the model WHS Act and Regula-<br>tions. |
| SECTION        | 16: ANY OTHER RE             | LEVANT INFORMATI           | ON   |
| Furth          | ner information              |                            |  |

| Revision Date<br>Sources of key data used to<br>compile the Safety Data<br>Sheet | :  | 06.04.2024<br>Internal technical data, data from raw material SDSs, OECD<br>eChem Portal search results and European Chemicals Agen-<br>cy, http://echa.europa.eu/ |
|--|----|--|
| Date format :  |    | dd.mm.yyyy   |
| Full text of other abbreviation  | ns |  |
| ACGIH  | :  | USA. ACGIH Threshold Limit Values (TLV)  |
| AU OEL   | :  | Australia. Workplace Exposure Standards for Airborne Con-<br>taminants.  |
| ACGIH / TWA  | :  | 8-hour, time-weighted average  |
| AU OEL / TWA   | :  | 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 Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; 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 - 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, Evalua-

### SAFETY DATA SHEET



## Raltegravir Adult Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 26.09.2023  |
|---------|----------------|-------------|---------------------------------|
| 6.2     | 06.04.2024     | 13213-00025 | Date of first issue: 16.09.2014 |

tion, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; 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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