

## **Raltegravir Formulation**

| Version | Revision Date: | SDS Number:  | Date of last issue: 04.04.2023  |
|---------|----------------|--------------|---------------------------------|
| 4.1     | 30.09.2023     | 741579-00017 | Date of first issue: 06.06.2016 |

#### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name

: Raltegravir Formulation

| Manufacturer or supplier's details                      |   |                                 |  |  |  |  |
|---|---|---------------------------------|--|--|--|--|
| Company name of supplier                                | : | MSD                             |  |  |  |  |
| 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@msd.com          |  |  |  |  |
| Recommended use of the chemical and restrictions on use |   |                                 |  |  |  |  |

| Recommended use     | : | Pharmaceutical |
|---------------------|---|----------------|
| Restrictions on use | : | Not applicable |

#### **SECTION 2. HAZARDS IDENTIFICATION**

| GHS Classification                               |   |  |
|--|---|--|
| Acute toxicity (Oral)                            | : | Category 5   |
| 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                                | • | H303 May be harmful if swallowed.<br>H318 Causes serious eye damage.<br>H335 May cause respiratory irritation.<br>H361d Suspected of damaging the unborn child.  |
| Precautionary Statements                         | : | Prevention:  |
|  |   | <ul> <li>P201 Obtain special instructions before use.</li> <li>P202 Do not handle until all safety precautions have been read and understood.</li> <li>P261 Avoid breathing dust.</li> <li>P271 Use only outdoors or in a well-ventilated area.</li> <li>P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.</li> </ul> |
|  |   | Response:  |



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|                |  | and keep at res<br>POISON CEN<br>P305 + P351 +<br>water for sever<br>and easy to do<br>CENTER or do | st in a position con<br>FER or doctor/ phy<br>P338 + P310 IF I<br>al minutes. Remov<br>. Continue rinsing.<br>octor/ physician. | D: Remove victim to fresh air<br>nfortable for breathing. Call a<br>rsician if you feel unwell.<br>N EYES: Rinse cautiously with<br>ve contact lenses, if present<br>Immediately call a POISON<br>r doctor/ physician if you feel |
|                |  | <b>Storage:</b><br>P405 Store loc   | ked up.   |   |
|                |  | <b>Disposal:</b><br>P501 Dispose<br>posal plant.  | of contents/ contai   | ner to an approved waste dis-   |
| Othe           | r hazards  |   |   |   |
|                | act with dust can cause<br>form explosive dust-air |   |   |   |
| SECTION        | 3. COMPOSITION/IN                                  | FORMATION ON ING  | REDIENTS  |   |
| Subs           | tance / Mixture                                    | : Mixture   |   |   |
| Com            | ponents  |   |   |   |
|                | a fa a bara a se a                                 |   |   | $\mathbf{O}$  |

| Chemical name      | CAS-No.     | Concentration (% w/w) |
|--------------------|-------------|-----------------------|
| Raltegravir        | 871038-72-1 | >= 50 -< 70           |
| Cellulose          | 9004-34-6   | >= 10 -< 20           |
| Magnesium stearate | 557-04-0    | >= 1 -< 5             |

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

| General advice          | : | In the case of accident or if you feel unwell, seek medical<br>advice immediately.<br>When symptoms persist or in all cases of doubt seek medical<br>advice.                        |
|-------------------------|---|---|
| If inhaled              | : | If inhaled, remove to fresh air.<br>Get medical attention.  |
| In case of skin contact | : | In case of contact, immediately flush skin with soap and plenty<br>of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.    |
| In case of eye contact  | : | Thoroughly clean shoes before reuse.<br>In case of contact, immediately flush eyes with plenty of water<br>for at least 15 minutes.<br>If easy to do, remove contact lens, if worn. |
| If swallowed            | : | Get medical attention immediately.<br>If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.   |
| Most important symptoms | : | May be harmful if swallowed.  |



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| and effects, both acute and delayed |                   |  | •   |   |  |
|                                     | Protect           | ion of first-aiders  | :   | First Aid responde<br>and use the recor                                 | ers should pay attention to self-protection,<br>nmended personal protective equipment<br>I for exposure exists (see section 8).                                  |
|                                     | Notes t           | o physician  | :   |   | cally and supportively.  |
| SEC                                 | CTION 5           | . FIRE-FIGHTING ME   | ASU | IRES  |  |
|                                     | Suitable          | e extinguishing media                                      | :   | Water spray<br>Alcohol-resistant<br>Carbon dioxide (C<br>Dry chemical   |  |
|                                     | Unsuita<br>media  | ble extinguishing  | :   | None known.   |  |
|                                     |                   | c hazards during fire                                      | :   | concentrations, and potential dust exp                                  | dust; fine dust dispersed in air in sufficient<br>nd in the presence of an ignition source is a<br>losion hazard.<br>pustion products may be a hazard to health. |
|                                     | Hazard<br>ucts    | ous combustion prod-                                       | :   | Carbon oxides<br>Nitrogen oxides (I<br>Fluorine compour<br>Metal oxides |  |
|                                     | Specific<br>ods   | c extinguishing meth-                                      | :   | cumstances and t<br>Use water spray t                                   | measures that are appropriate to local cir-<br>he surrounding environment.<br>o cool unopened containers.<br>ged containers from fire area if it is safe to do   |
|                                     | Special for fire- | protective equipment fighters                              | :   | In the event of fire  | e, wear self-contained breathing apparatus.<br>rective equipment.  |
| SEC                                 | CTION 6           | . ACCIDENTAL RELE  | ASI | EMEASURES   |  |
|                                     | tive equ          | al precautions, protec-<br>uipment and emer-<br>procedures | :   | Follow safe handl   | ective equipment.<br>ing advice (see section 7) and personal<br>ent recommendations (see section 8).   |
|                                     | Enviror           | nmental precautions  | :   | Retain and dispos   | akage or spillage if safe to do so.<br>se of contaminated wash water.<br>should be advised if significant spillages  |
|                                     | Method            | ls and materials for                                       | :   | Surround spill with   | n absorbents and place a damp covering   |



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|         |                           | surfaces, as the<br>released into the<br>Clean up remand<br>absorbent.<br>Local or nation<br>disposal of this<br>employed in the<br>determine white<br>Sections 13 and | should not be allowed to accumulate on<br>nese may form an explosive mixture if they are<br>the atmosphere in sufficient concentration.<br>aining materials from spill with suitable<br>hal regulations may apply to releases and<br>s material, as well as those materials and items<br>he cleanup of releases. You will need to<br>ch regulations are applicable.<br>Ind 15 of this SDS provide information regarding<br>r national requirements. |

#### 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<br>practice, based on the results of the workplace exposure<br>assessment<br>Keep container tightly closed.<br>Already sensitized individuals, and those susceptible<br>to asthma, allergies, chronic or recurrent respiratory disease,<br>should consult their physician regarding working with<br>respiratory irritants or sensitizers.<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 |
| Hygiene measures            | : | environment.<br>If exposure to chemical is likely during typical use, provide eye<br>flushing systems and safety showers close to the working<br>place.<br>When using do not eat, drink or smoke.   |
| Conditions for safe storage | : | Wash contaminated clothing before re-use.<br>Keep in properly labeled containers.<br>Store locked up.<br>Keep tightly closed.<br>Keep in a cool, well-ventilated place.<br>Store in accordance with the particular national regulations.  |
| Materials to avoid          | : | Do not store with the following product types:<br>Strong oxidizing agents   |



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#### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

| 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   | VLE-PPT                                      | 10 mg/m³   | NOM-010-<br>STPS-2014 |
|                    |             | TWA  | 10 mg/m <sup>3</sup>                                   | ACGIH                 |
| Magnesium stearate | 557-04-0    | VLE-PPT                                      | 10 mg/m <sup>3</sup>                                   | NOM-010-<br>STPS-2014 |
|                    |             | TWA<br>(Inhalable<br>particulate<br>matter)  | 10 mg/m³   | ACGIH                 |
|                    |             | TWA<br>(Respirable<br>particulate<br>matter) | 3 mg/m³  | ACGIH                 |

| 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<br>designed 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    |   |    |
| Respiratory protection         | If adequate local exhaust ventilation is not available or<br>exposure assessment demonstrates exposures outside th<br>recommended guidelines, use respiratory protection.   | ne |
| Filter type<br>Hand protection | Particulates type   |    |
| Material                       | Chemical-resistant gloves   |    |
| Remarks                        | Choose gloves to protect hands against chemicals depen<br>on the concentration specific to place of work. Breakthrou<br>time is not determined for the product. Change gloves ofte<br>For special applications, we recommend clarifying the<br>resistance to chemicals of the aforementioned protective<br>gloves with the glove manufacturer. Wash hands before<br>breaks and at the end of workday.                             | gh |
| Eye protection                 | Wear the following personal protective equipment:<br>Chemical resistant goggles must be worn.<br>If splashes are likely to occur, wear:<br>Face-shield  |    |
| Skin and body protection       | Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure  |    |



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|                |  |     |  | t be avoided by using impervious protective aprons, boots, etc).  |
| SECTIC         | ON 9. PHYSICAL AND CHI                         | EMI |  | S   |
| Ар             | pearance                                       | :   | powder                                   |   |
| Co             | lor  | :   | No data available                        | 9   |
| Od             | or   | :   | No data available                        | 9   |
| Od             | or Threshold                                   | :   | No data available                        | 9   |
| рH             |  | :   | No data available                        | 9   |
| Ме             | Iting point/freezing point                     | :   | No data available                        | 9   |
| Init<br>rar    | ial boiling point and boiling<br>ge            | :   | No data available                        | e   |
| Fla            | sh point                                       | :   | Not applicable                           |   |
| Eva            | aporation rate                                 | :   | No data available                        | 9   |
| Fla            | mmability (solid, gas)                         | :   | May form explosing the handling or other | ive dust-air mixture during processing,<br>means.                 |
| Fla            | mmability (liquids)                            | :   | No data available                        | 9   |
|                | per explosion limit / Upper<br>nmability limit | :   | No data available                        | 9   |
|                | wer explosion limit / Lower<br>mmability limit | :   | No data available                        | e   |
| Va             | por pressure                                   | :   | No data available                        | 9   |
| Re             | lative vapor density                           | :   | No data available                        | 9   |
| De             | nsity  | :   | No data available                        | 9   |
|                | lubility(ies)<br>Water solubility              | :   | No data available                        | 9   |
|                | rtition coefficient: n-                        | :   | No data available                        | 9   |
|                | anol/water<br>toignition temperature           | :   | No data available                        | 9   |
| De             | composition temperature                        | :   | No data available                        | 9   |
| Vis            | cosity<br>Viscosity, kinematic                 | :   | No data available                        | e   |
| Ex             | plosive properties                             | :   | Not explosive                            |   |
|                |  |     |  |   |



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|-------------------|--|-------------|---|---|
| Ox                | idizing properties   | :           | The substance o   | r mixture is not classified as oxidizing.                         |
| Мо                | lecular weight   | :           | No data available   | e   |
| Pa                | rticle size  | :           | No data available   | 9   |
| SECTIC            | ON 10. STABILITY AND RE  | EAC         | TIVITY  |   |
| Ch                | activity<br>emical stability<br>ssibility of hazardous reac-<br>ns         | :           | Stable under nor<br>May form explos<br>handling or other                    | ive dust-air mixture during processing,                           |
| Inc<br>Ha         | nditions to avoid<br>ompatible materials<br>zardous decomposition<br>ducts | :<br>:<br>: | Heat, flames and<br>Avoid dust forma<br>Oxidizing agents<br>No hazardous de | ition.  |
| Inh<br>Ski<br>Ing | ormation on likely routes<br>alation<br>n contact<br>estion<br>e contact   | ofe         | exposure  |   |
| Ac                | <b>ute toxicity</b><br>y be harmful if swallowed.                          |             |   |   |
|                   | oduct:<br>ute oral toxicity  | :           | Acute toxicity esti<br>Method: Calculati                                    | mate: 4,026 mg/kg<br>on method                                    |
| <u>Co</u>         | mponents:  |             |   |   |
|                   | Itegravir:<br>ute oral toxicity  | :           | LD50 (Mouse, ma   | ale and female): > 2,000 mg/kg                                    |
|                   | Ilulose:<br>ute oral toxicity  | :           | LD50 (Rat): > 5,0   | 00 mg/kg  |
|                   | ute inhalation toxicity  | :           | LC50 (Rat): > 5.8<br>Exposure time: 4<br>Test atmosphere:                   | mg/l<br>h   |

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



| ersion<br>1 | Revision Date:<br>30.09.2023                  | SDS Number:<br>741579-00017      | Date of last issue: 04.04.2023<br>Date of first issue: 06.06.2016  |
|-------------|---|----------------------------------|--|
| Magn        | esium stearate:                               |                                  |  |
| -           | oral toxicity                                 | Assessment: T<br>icity           | 2,000 mg/kg<br>D Test Guideline 423<br>The substance or mixture has no acute oral tox<br>ed on data from similar materials |
| Acute       | dermal toxicity                               | : LD50 (Rabbit):<br>Remarks: Bas | : > 2,000 mg/kg<br>ed on data from similar materials   |
| Skin        | corrosion/irritation                          |                                  |  |
| Not cl      | assified based on av                          | ailable information.             |  |
| <u>Comp</u> | oonents:                                      |                                  |  |
| Ralte       | gravir:                                       |                                  |  |
| Speci       |   | : Rabbit                         |  |
| Resul       | t   | : No skin irritatio              | n  |
| Magn        | esium stearate:                               |                                  |  |
| Speci       | es  | : Rabbit                         |  |
| Resul       |   | : No skin irritatio              |  |
| Rema        |   | . Dased on data                  | from similar materials   |
|             | us eye damage/eye                             |                                  |  |
|             | es serious eye damag                          | je.                              |  |
|             | <u>oonents:</u>                               |                                  |  |
|             | gravir:                                       |                                  |  |
| Speci       |   | : Bovine cornea                  |  |
| Resul       | t   | : Severe irritatio               | 'n   |
| Magn        | esium stearate:                               |                                  |  |
| Speci       |   | : Rabbit                         |  |
| Resul       |   | : No eye irritatio               |  |
| Rema        |   |                                  | from similar materials   |
| -           | iratory or skin sens                          | itization                        |  |
|             | sensitization<br>assified based on av         | ailable information.             |  |
| -           | iratory sensitization<br>assified based on av |                                  |  |
| <u>Com</u>  | oonents:                                      |                                  |  |
| Ralte       | gravir:                                       |                                  |  |
| Test 1      | Гуре  | : Local lymph no                 | ode assay (LLNA)   |



| Magnesium stearate:         Test Type       ::::::::::::::::::::::::::::::::::::  | Version<br>4.1                          | Revision Date:<br>30.09.2023             | SDS Number:<br>741579-00017                                 | Date of last issue: 04.04.2023<br>Date of first issue: 06.06.2016 |
|---|---|--|---|---|
| Test Type       :       Maximization Test         Routes of exposure       :       Skin contact         Species       :       Survey and the second and th | Magr                                    | esium stearate:                          |   |   |
| 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         Genotoxicity in vivo       : Test Type: Chromosomal aberration<br>Method: OECD Test Guideline 475<br>Result: negative         Cellulose:       : Test Type: Chromosomal aberration<br>Method: OECD Test Guideline 475<br>Result: negative         Cellulose:       : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative         Genotoxicity in vitro       : Test Type: In vitro mammalian cell gene mutation test<br>Result: negative         Genotoxicity in vitro       : Test Type: Mammalian erythrocyte micronucleus test (in vivo<br>cytogenetic assay)  | Test<br>Route<br>Speci<br>Metho<br>Resu | Type<br>es of exposure<br>es<br>od<br>It | : Skin contact<br>: Guinea pig<br>: OECD Test<br>: negative | Guideline 406   |
| Raitegravir:       Genotoxicity in vitro       : Test Type: reverse mutation assay Result: negative         Test Type: Alkaline elution assay Test system: rat hepatocytes Result: negative       Test Type: Chromosomal aberration Method: OECD Test Guideline 473 Result: negative         Genotoxicity in vivo       : Test Type: In vivo micronucleus test Species: Mouse Result: negative         Genotoxicity in vivo       : Test Type: Chromosomal aberration Method: OECD Test Guideline 473 Result: negative         Genotoxicity in vivo       : Test Type: In vivo micronucleus test Species: Mouse Result: negative         Cellulose:       Test Type: Chromosomal aberration Method: OECD Test Guideline 475 Result: negative         Cellulose:       : Test Type: Bacterial reverse mutation assay (AMES) Result: negative         Genotoxicity in vitro       : Test Type: In vitro mammalian cell gene mutation test Result: negative         Genotoxicity in vivo       : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  |   |  | ilable information.   |   |
| 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         Cellulose:       :         Genotoxicity in vitro       : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative         Cellulose:       :         Genotoxicity in vitro       : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative         Cellulose:       :         Genotoxicity in vitro       : Test Type: Mammalian cell gene mutation test<br>Result: negative         Genotoxicity in vitro       : Test Type: Mammalian erythrocyte micronucleus test (in vivo<br>cytogenetic assay)  | <u>Com</u>                              | oonents:                                 |   |   |
| Result: negative         Test Type: Alkaline elution assay         Test Type: Alkaline elution assay         Result: negative         Test Type: Chromosomal aberration         Method: OECD Test Guideline 473         Result: negative         Genotoxicity in vivo         :       Test Type: In vivo micronucleus test         Species: Mouse         Result: negative         Test Type: Chromosomal aberration         Method: OECD Test Guideline 475         Result: negative         Test Type: Chromosomal aberration         Method: OECD Test Guideline 475         Result: negative         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)   | Ralte                                   | gravir:                                  |   |   |
| Test system: rat hepatocytes         Result: negative         Test Type: Chromosomal aberration         Method: OECD Test Guideline 473         Result: negative         Genotoxicity in vivo         :       Test Type: In vivo micronucleus test         Species: Mouse         Result: negative         Test Type: Chromosomal aberration         Method: OECD Test Guideline 475         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       :         Genotoxicity in vivo       :         Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)   | Geno                                    | toxicity in vitro                        |   |   |
| 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         Test Type: In vitro mammalian cell gene mutation test<br>Result: negative         Genotoxicity in vivo       : Test Type: Mammalian erythrocyte micronucleus test (in vivo<br>cytogenetic assay)   |   |  | Test system   | : rat hepatocytes   |
| 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         Test Type: In vitro mammalian cell gene mutation test<br>Result: negative         Genotoxicity in vivo       :         Genotoxicity in vivo       :         Test Type: In vitro mammalian cell gene mutation test<br>Result: negative         Genotoxicity in vivo       :         Test Type: Mammalian erythrocyte micronucleus test (in vivo<br>cytogenetic assay)  |   |  | Method: OE  | CD Test Guideline 473   |
| 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)  | Geno                                    | toxicity in vivo                         | Species: Mo   | use   |
| Genotoxicity in vitro       : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative         Test Type: In vitro mammalian cell gene mutation test<br>Result: negative         Genotoxicity in vivo       : Test Type: Mammalian erythrocyte micronucleus test (in vivo<br>cytogenetic assay)   |   |  | Method: OE  | CD Test Guideline 475   |
| 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)   | Cellu                                   | lose:                                    |   |   |
| Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)   | Geno                                    | toxicity in vitro                        |   |   |
| cytogenetic assay)  |   |  |   |   |
| Species: Mouse<br>Application Route: Ingestion<br>Result: negative  | Geno                                    | toxicity in vivo                         | cytogenetic a<br>Species: Mo<br>Application F               | assay)<br>use<br>Route: Ingestion                                 |
| Magnesium stearate:   | Magn                                    | esium stearate:                          |   |   |
| Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test<br>Result: negative<br>Remarks: Based on data from similar materials  | Geno                                    | toxicity in vitro                        | Result: nega  | itive   |
| Test Type: Chromosome aberration test in vitro<br>Method: OECD Test Guideline 473   |   |  | Test Type: C<br>Method: OE                                  | Chromosome aberration test in vitro<br>CD Test Guideline 473      |



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|  |   |   | Result: negative<br>Remarks: Based   | on data from similar materials   |
|  |   |   | Result: negative   | erial reverse mutation assay (AMES)<br>on data from similar materials  |
|  | <b>nogenicity</b><br>assified based on availa   | ahla                                    | information  |  |
|  | oonents:  | 1010                                    |  |  |
| Speci  | sure time   | :                                       | Mouse, male and<br>104 weeks<br>negative   | d female   |
|  | es<br>cation Route<br>sure time   | : | Rat<br>Ingestion<br>72 weeks<br>negative   |  |
| Resul  | ·   | •                                       |  |  |
| <b>Repro</b><br>Suspe                            | bductive toxicity<br>ected of damaging the u  | nbo                                     | rn child.  |  |
| Repro<br>Suspe<br><u>Comp</u>                    | oductive toxicity<br>ected of damaging the u  | nbo                                     | rn child.  |  |
| Repro<br>Suspe<br><u>Comp</u><br>Ralte           | oductive toxicity<br>ected of damaging the u<br>conents:  | nbo<br>:                                | Test Type: Fertili<br>Species: Rat, ma<br>Application Route  |  |
| Repro<br>Suspe<br><u>Comp</u><br>Ralte<br>Effect | oductive toxicity<br>ected of damaging the u<br><u>conents:</u><br>gravir:  | nbo<br>:                                | Test Type: Fertili<br>Species: Rat, ma<br>Application Route<br>General Toxicity<br>Result: negative<br>Species: Rat<br>Application Route<br>General Toxicity<br>Teratogenicity: L  | ale and female<br>e: Oral<br>Parent: NOAEL: 600 mg/kg body weight<br>e: Oral   |
| Repro<br>Suspe<br><u>Comp</u><br>Ralte<br>Effect | oductive toxicity<br>ected of damaging the un<br><u>ponents:</u><br>gravir:<br>s on fertility                           | nbo                                     | Test Type: Fertili<br>Species: Rat, ma<br>Application Route<br>General Toxicity<br>Result: negative<br>Species: Rat<br>Application Route<br>General Toxicity<br>Teratogenicity: L<br>Symptoms: Skele<br>Result: positive<br>Species: Rabbit<br>General Toxicity<br>weight  | ale and female<br>e: Oral<br>Parent: NOAEL: 600 mg/kg body weight<br>e: Oral<br>Maternal: NOAEL: >= 600 mg/kg body weig<br>OAEL F1: 300 mg/kg body weight  |
| Repro<br>Suspe<br>Comp<br>Raite<br>Effect        | oductive toxicity<br>ected of damaging the un<br><u>ponents:</u><br>gravir:<br>s on fertility<br>s on fetal development | nbo<br>:<br>:                           | Test Type: Fertili<br>Species: Rat, ma<br>Application Route<br>General Toxicity<br>Result: negative<br>Species: Rat<br>Application Route<br>General Toxicity<br>Teratogenicity: L<br>Symptoms: Skele<br>Result: positive<br>Species: Rabbit<br>General Toxicity<br>weight<br>Teratogenicity: N<br>Result: negative                     | ale and female<br>e: Oral<br>Parent: NOAEL: 600 mg/kg body weight<br>e: Oral<br>Maternal: NOAEL: >= 600 mg/kg body weight<br>OAEL F1: 300 mg/kg body weight<br>etal malformations.<br>Maternal: NOAEL: >= 1,000 mg/kg body<br>IOAEL: >= 1,000 mg/kg body weight<br>of adverse effects on development, based of |
| Repro<br>Suspe<br>Comp<br>Raites<br>Effect       | oductive toxicity<br>ected of damaging the un<br><u>conents:</u><br>gravir:<br>s on fertility<br>s on fetal development | nbo<br>:<br>:                           | Test Type: Fertili<br>Species: Rat, ma<br>Application Route<br>General Toxicity<br>Result: negative<br>Species: Rat<br>Application Route<br>General Toxicity<br>Teratogenicity: L<br>Symptoms: Skele<br>Result: positive<br>Species: Rabbit<br>General Toxicity<br>weight<br>Teratogenicity: N<br>Result: negative<br>Some evidence of | ale and female<br>e: Oral<br>Parent: NOAEL: 600 mg/kg body weight<br>e: Oral<br>Maternal: NOAEL: >= 600 mg/kg body weig<br>OAEL F1: 300 mg/kg body weight<br>etal malformations.<br>Maternal: NOAEL: >= 1,000 mg/kg body<br>IOAEL: >= 1,000 mg/kg body weight<br>of adverse effects on development, based of   |



## **Raltegravir Formulation**

Target Organs

| Version<br>4.1               | Revision Date:<br>30.09.2023                      |      | )S Number:<br>1579-00017   | Date of last issue: 04.04.2023<br>Date of first issue: 06.06.2016  |  |  |
|------------------------------|---|------|--|--|--|--|
|                              |   |      | Species: Rat<br>Application Rout<br>Result: negative   | e: Ingestion   |  |  |
| Effec                        | Effects on fetal development :                    |      | : Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |  |  |  |
| Maqi                         | nesium stearate:                                  |      |  |  |  |  |
| -                            | ets on fertility                                  | :    | reproduction/dev<br>Species: Rat<br>Application Rout<br>Method: OECD   | bined repeated dose toxicity study with the<br>velopmental toxicity screening test<br>e: Ingestion<br>Test Guideline 422 |  |  |
| Effec                        | ts on fetal development                           | :    | Species: Rat<br>Application Rout<br>Result: negative   | ryo-fetal development<br>e: Ingestion<br>I on data from similar materials  |  |  |
|                              | T-single exposure<br>cause respiratory irritatio  | n.   |  |  |  |  |
| <u>Com</u>                   | ponents:  |      |  |  |  |  |
| Ralte                        | egravir:  |      |  |  |  |  |
| Targ                         | es of exposure<br>et Organs<br>ssment             | :    | Inhalation<br>Respiratory Trac<br>May cause respi  |  |  |  |
|                              | T-repeated exposure<br>classified based on availa | able | information.   |  |  |  |
| Repe                         | eated dose toxicity                               |      |  |  |  |  |
| <u>Com</u>                   | ponents:  |      |  |  |  |  |
| Ralte                        | egravir:  |      |  |  |  |  |
| Spec<br>NOA<br>Appli<br>Expo | cies  | :    | Dog<br>90 mg/kg<br>Oral<br>371 d<br>Vomiting   |  |  |  |
| Expo                         | EL  |      | Rat<br>30 mg/kg<br>120 mg/kg<br>Oral<br>189 d<br>Stomach   |  |  |  |

:

Stomach



| Version<br>4.1 | Revision Date:<br>30.09.2023                                     | SDS Number:<br>741579-00017   | Date of last issue: 04.04.2023<br>Date of first issue: 06.06.2016             |
|----------------|--|---|---|
|                |  |   |   |
| Expo           | EL   | : Mouse<br>: 50 mg/kg<br>: 500 mg/kg<br>: Oral<br>: 14 Weeks<br>: Stomach |   |
| Expo           | EL   | : Rat<br>: 50 mg/kg<br>: 200 mg/kg<br>: Oral<br>: 8 Weeks<br>: Stomach    |   |
| Cellu          | lose:  |   |   |
|                |  | : Rat<br>: >= 9,000 mg/k<br>: Ingestion<br>: 90 Days                      | g   |
| Magn           | nesium stearate:   |   |   |
|                | EL<br>cation Route<br>sure time                                  | : Rat<br>: > 100 mg/kg<br>: Ingestion<br>: 90 Days<br>: Based on data     | from similar materials  |
| Not c          | ration toxicity<br>lassified based on ava<br>rience with human e |   |   |
| Com            | ponents:   |   |   |
| Ralte<br>Inges | <b>gravir:</b><br>tion   | : Symptoms: Na<br>irritation  | ausea, Diarrhea, Headache, Fever, Rash, Skin                                  |
| SECTION        | 12. ECOLOGICAL IN  | IFORMATION  |   |
| Ecoto          | oxicity  |   |   |
| Com            | ponents:   |   |   |
| Ralte          | gravir:  |   |   |
| Toxic          | ity to fish  | Exposure time   | ales promelas (fathead minnow)): > 100 mg/l<br>: 96 h<br>D Test Guideline 203 |
|                |  | LC50 (Cyprino<br>mg/l<br>Exposure time                                    | don variegatus (sheepshead minnow)): > 100<br>: 96 h                          |



| Versio<br>4.1 | on               | Revision Date:<br>30.09.2023                         |   | 9S Number:<br>1579-00017   | Date of last issue: 04.04.2023<br>Date of first issue: 06.06.2016                          |
|---------------|------------------|--|---|--|--|
|               |                  |  |   | Method: OECD Te  | est Guideline 203  |
|               |                  | to daphnia and other invertebrates                   | : | EC50 (Daphnia m<br>Exposure time: 48<br>Method: OECD Te                      |  |
|               | oxicity<br>ants  | to algae/aquatic                                     | : | EC50 (Pseudokiro<br>Exposure time: 96<br>Method: OECD Te                     |  |
|               |                  |  |   | NOEC (Pseudokir<br>mg/l<br>Exposure time: 96<br>Method: OECD Te              |  |
|               | oxicity<br>city) | to fish (Chronic tox-                                | : | NOEC (Pimephale<br>Exposure time: 33<br>Method: OECD Te                      |  |
| а             |                  | to daphnia and other<br>invertebrates (Chron-<br>ty) | : | NOEC (Daphnia r<br>Exposure time: 21<br>Method: OECD Te                      |  |
| Т             | oxicity          | to microorganisms                                    | : | EC50: > 1,000 mg<br>Exposure time: 3<br>Test Type: Respir<br>Method: OECD Te | h<br>ation inhibition  |
|               |                  |  |   | NOEC: 1,000 mg/<br>Exposure time: 3<br>Test Type: Respir<br>Method: OECD Te  | h<br>ation inhibition  |
| c             | Cellulo          | se:  |   |  |  |
| Т             | oxicity          | to fish  | : | Exposure time: 48  | ipes (Japanese medaka)): > 100 mg/l<br>3 h<br>on data from similar materials               |
| Ν             | lagnes           | sium stearate:                                       |   |  |  |
| Т             | oxicity          | to fish  | : | Exposure time: 48<br>Method: DIN 384   |  |
|               |                  | to daphnia and other invertebrates                   | : | Exposure time: 47<br>Test substance: V<br>Method: Directive                  | Vater Accommodated Fraction<br>67/548/EEC, Annex V, C.2.<br>on data from similar materials |
|               | oxicity<br>ants  | to algae/aquatic                                     | : | EL50 (Pseudokirc<br>mg/l   | hneriella subcapitata (green algae)): > 1  |



| rsion   | Revision Date:<br>30.09.2023                      |       | OS Number:<br>1579-00017  | Date of last issue: 04.04.2023<br>Date of first issue: 06.06.2016   |
|---------|---|-------|---|---|
|         |   |       | Method: OECD<br>Remarks: Base   | 72 h<br>: Water Accommodated Fraction<br>Test Guideline 201<br>d on data from similar materials<br>e limit of solubility.                         |
|         |   |       | mg/l<br>Exposure time:<br>Test substance<br>Method: OECD                | okirchneriella subcapitata (green algae)): > 7<br>72 h<br>: Water Accommodated Fraction<br>Test Guideline 201<br>d on data from similar materials |
| Toxici  | ty to microorganisms                              | :     | Exposure time:<br>Test substance  | nonas putida): > 100 mg/l<br>16 h<br>: Water Accommodated Fraction<br>d on data from similar materials  |
| Persi   | stence and degradab                               | ility |   |   |
| Comp    | oonents:  |       |   |   |
| Ralte   | gravir:   |       |   |   |
| Biode   | gradability                                       | :     | Result: rapidly of<br>Biodegradation:<br>Exposure time:<br>Method: OECD | 50 %  |
| Stabil  | ity in water                                      | :     | Hydrolysis: < 10<br>Method: OECD  | ) %(5 d)<br>Test Guideline 111  |
| Cellu   | lose:   |       |   |   |
| Biode   | gradability                                       | :     | Result: Readily   | biodegradable.  |
| Magn    | esium stearate:                                   |       |   |   |
| Biode   | gradability                                       | :     |   | legradable<br>d on data from similar materials  |
| Bioac   | cumulative potential                              |       |   |   |
| Comp    | oonents:  |       |   |   |
| Partiti | <b>gravir:</b><br>on coefficient: n-<br>ol/water  | :     | log Pow: -0.328   |   |
| Partiti | esium stearate:<br>on coefficient: n-<br>ol/water | :     | log Pow: > 4  |   |
|         | i <b>ty in soil</b><br>ıta available              |       |   |   |



## **Raltegravir Formulation**

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|--|---|--------------------------------------|---|--|--|--|--|--|
| ••   | r adverse effects<br>ata available  |                                      |   |  |  |  |  |  |
| SECTION  | 13. DISPOSAL CONS   | IDERATIONS                           |   |  |  |  |  |  |
| Dispo  | osal methods  |                                      |   |  |  |  |  |  |
| Wast   | e from residues   |                                      | se of waste into sewer.   |  |  |  |  |  |
| Contaminated packaging<br>Contaminated packaging |   |                                      |   |  |  |  |  |  |
| SECTION  | 14. TRANSPORT INF   | ORMATION                             |   |  |  |  |  |  |
| Interi   | national Regulations  |                                      |   |  |  |  |  |  |
| UNR <sup>-</sup><br>Not re   | <b>FDG</b><br>egulated as a dangerou  | ıs good                              |   |  |  |  |  |  |
|  | -DGR<br>egulated as a dangerou  | is good                              |   |  |  |  |  |  |
| -  | <b>-Code</b><br>egulated as a dangerou  | is good                              |   |  |  |  |  |  |
|  | sport in bulk accordir<br>pplicable for product as                              | -                                    | ARPOL 73/78 and the IBC Code                                      |  |  |  |  |  |
| Dom  | Domestic regulation   |                                      |   |  |  |  |  |  |
| -  | -002-SCT<br>egulated as a dangerou  | ıs good                              |   |  |  |  |  |  |
| -  | ial precautions for us<br>pplicable   | er                                   |   |  |  |  |  |  |
| SECTION  | 15. REGULATORY IN   | FORMATION                            |   |  |  |  |  |  |
| Safet<br>mixtu   |   | mental regulations                   | /legislation specific for the substance or                        |  |  |  |  |  |
| esser  | ral Law for the control on<br>tial chemical products<br>ucing capsules, tablets | and machinery for                    | ors, : Not applicable   |  |  |  |  |  |
| <b>The i</b><br>AICS   | -   | duct are reported<br>: not determine | in the following inventories:                                     |  |  |  |  |  |
| DSL  |   | : not determine                      | ed  |  |  |  |  |  |
|  |   |                                      |   |  |  |  |  |  |

IECSC : not determined

#### **SECTION 16. OTHER INFORMATION**



#### Raltegravir Formulation

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|----------------|--|-----|---------------------------------------|--|
|                | vision Date<br>e format                  | :   | 30.09.2023<br>dd.mm.yyyy              |  |
| Ful            | I text of other abbreviati               | ons |                                       |  |
|                | GIH<br>M-010-STPS-2014                   |     | Mexico. Norm NC the Work Environ      | eshold Limit Values (TLV)<br>DM-010-STPS-2014 on Chemicals Polluting<br>ment - Identification, Assessment and Con-<br>Occupational Exposure Limits |
| -              | GIH / TWA<br>M-010-STPS-2014 / VLE-<br>T | :   | 8-hour, time-weig<br>Time weighted av | hted 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, 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; 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

Sources of key data used to compile the Material Safety Data Sheet

: Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8