

## **Raltegravir Formulation**

| Version<br>3.1                 | Revision Date:<br>30.09.2023  |        | S Number:<br>1584-00020 | Date of last issue: 04.04.2023<br>Date of first issue: 06.06.2016 |  |  |  |  |
|--------------------------------|---|--------|-------------------------|---|--|--|--|--|
| SECTIO                         | SECTION 1: Identification of the substance/mixture and of the company/undertaking |        |                         |   |  |  |  |  |
| 1.1 Prod                       | uct identifier  |        |                         |   |  |  |  |  |
| Trac                           | le name   | :      | Raltegravir Formu       | lation  |  |  |  |  |
| 1.2 Relev                      | vant identified uses of   | the s  | ubstance or mixt        | ure and uses advised against                                      |  |  |  |  |
|                                | of the Sub-<br>ce/Mixture   | :      | Pharmaceutical          |   |  |  |  |  |
| Rec<br>on u                    | ommended restrictions<br>se   | :      | Not applicable          |   |  |  |  |  |
| 1.3 Detai                      | ils of the supplier of the  | e safe | ety data sheet          |   |  |  |  |  |
|                                | npany   | :      | MSD<br>117 16th Road    | use, Midrand, South Africa  |  |  |  |  |
| Tele                           | phone   | :      | +27 11 655 3000         |   |  |  |  |  |
|                                | ail address of person<br>onsible for the SDS                                      | :      | EHSDATASTEW             | ARD@msd.com   |  |  |  |  |
| 1.4 Emergency telephone number |   |        |                         |   |  |  |  |  |
| +1-9                           | 008-423-6000  |        |                         |   |  |  |  |  |
|                                |   |        |                         |   |  |  |  |  |

## **SECTION 2: Hazards identification**

### 2.1 Classification of the substance or mixture

### Classification (REGULATION (EC) No 1272/2008)

Serious eye damage, Category 1 Reproductive toxicity, Category 2 Specific target organ toxicity - single exposure, Category 3

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

#### 2.2 Label elements

### Labelling (REGULATION (EC) No 1272/2008)

| Hazard pictograms | : |  |
|-------------------|---|--|
| Signal word       | : | Danger   |
| Hazard statements | : | <ul><li>H318 Causes serious eye damage.</li><li>H335 May cause respiratory irritation.</li><li>H361d Suspected of damaging the unborn child.</li></ul> |



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|----------------|------------------------------|---|--|
| Preca          | autionary statements         | P261 Avoid bre  | pecial instructions before use.<br>eathing dust.<br>tective gloves/ protective clothing/ eye protec-<br>on.  |
|                |                              | air and keep com<br>CENTER/ doctor<br>P305 + P351 + P<br>with water for sev<br>sent and easy to<br>POISON CENTE | <ul> <li>312 IF INHALED: Remove person to fresh fortable for breathing. Call a POISON if you feel unwell.</li> <li>338 + P310 IF IN EYES: Rinse cautiously veral minutes. Remove contact lenses, if predo. Continue rinsing. Immediately call a R/ doctor.</li> <li>F exposed or concerned: Get medical advice/</li> </ul> |

Hazardous components which must be listed on the label:

Raltegravir

## 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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**

#### 3.2 Mixtures

#### Components

| Chemical name | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number | Classification  | Concentration<br>(% w/w) |
|---------------|---|---|--------------------------|
| Raltegravir   | 871038-72-1   | Eye Dam. 1; H318<br>Repr. 2; H361d<br>STOT SE 3; H335 | >= 50 - < 70             |

For explanation of abbreviations see section 16.

## **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

| General advice             | : | In the case of accident or if you feel unwell, seek medical ad-<br>vice immediately.<br>When symptoms persist or in all cases of doubt seek medical<br>advice. |
|----------------------------|---|--|
| Protection of first-aiders | : | First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment  |



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|----------------|-----------------------------------|------|---|--|--|
|                |                                   |      | when the potentia   | I for exposure exists (see section 8).   |  |
| If inf         | naled                             | :    | If inhaled, remove<br>Get medical atten   |  |  |
| In ca          | ase of skin contact               | :    | of water.<br>Remove contamin<br>Get medical atten<br>Wash clothing be   |  |  |
| In ca          | ase of eye contact                | :    | In case of contact, immediately flush eyes with plenty of w<br>for at least 15 minutes.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention immediately. |  |  |
| lf sw          | vallowed                          | :    | Get medical atten   | NOT induce vomiting.<br>tion.<br>oughly with water.  |  |
| 4.2 Most       | important symptoms ar             | nd e | effects, both acute   | e and delayed  |  |
| Risk           | S                                 | :    | Causes serious e<br>May cause respira<br>Suspected of dan   |  |  |
|                |                                   |      | Contact with dust the skin.   | can cause mechanical irritation or drying of   |  |
| 4.3 Indic      | ation of any immediate            | med  | dical attention and   | special treatment needed   |  |
| Trea           | atment                            | :    | Treat symptomati  | cally and supportively.  |  |
| SECTIO         | N 5: Firefighting meas            | sur  | es  |  |  |
| 5.1 Extin      | guishing media                    |      |   |  |  |
|                | able extinguishing media          | :    | Water spray<br>Alcohol-resistant<br>Carbon dioxide (C<br>Dry chemical   |  |  |
| Uns<br>med     | uitable extinguishing<br>ia       | :    | None known.   |  |  |
| 5.2 Spec       | ial hazards arising from          | the  | e substance or mi   | xture  |  |
| Spe<br>fight   | cific hazards during fire-<br>ing | :    | 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. |  |
| Haz<br>ucts    | ardous combustion prod-           | :    | Carbon oxides<br>Nitrogen oxides (l   | NOx)   |  |



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|--|------|------------------------------|--|----------------------------------|---|
|  |      |                              |  | Fluorine compour<br>Metal oxides | nds   |
| <ul> <li>5.3 Advice for firefighters</li> <li>Special protective equipment for firefighters</li> <li>Specific extinguishing meth-</li> <li>Use extinguishing measures that are appropriate to the sector of the se</li></ul> |      |                              |  |                                  | ective equipment.   |
|  | ods  |                              |  | Use water spray t                | he surrounding environment.<br>o cool unopened containers.<br>ged containers from fire area if it is safe to do |

## **SECTION 6:** Accidental release measures

| 6.1 | Personal precautions, protect<br>Personal precautions | tive<br>: | e equipment and emergency procedures<br>Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal pro-<br>tective equipment recommendations (see section 8).   |
|-----|---|-----------|---|
| 6.2 | Environmental precautions                             |           |   |
|     | 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.<br>Local authorities should be advised if significant spillages<br>cannot be contained.  |
| 6.3 | Methods and material for cor                          | ntai      | nment and cleaning up   |
|     | Methods for cleaning up                               | :         | Surround spill with absorbents and place a damp covering<br>over the area to minimise entry of the material into the air.<br>Add excess liquid to allow the material to enter into solution.<br>Soak up with inert absorbent material.<br>Avoid dispersal of dust in the air (i.e., clearing dust surfaces<br>with compressed air).<br>Dust deposits should not be allowed to accumulate on surfac-<br>es, as these may form an explosive mixture if they are re-<br>leased into the atmosphere in sufficient concentration.<br>Clean up remaining materials from spill with suitable absor-<br>bent.<br>Local or national regulations may apply to releases and dis-<br>posal of this material, as well as those materials and items<br>employed in the cleanup of releases. You will need to deter- |

employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

## 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.



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# SECTION 7: Handling and storage

| 7.1 Precautions for safe handling                  |   |
|--|---|
| 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 :                          |   |
| 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 as-<br>sessment<br>Keep container tightly closed.<br>Already sensitised individuals, and those susceptible<br>to asthma, allergies, chronic or recurrent respiratory disease,<br>should consult their physician regarding working with respira-<br>tory irritants or sensitisers.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Take care to prevent spills, waste and minimize release to the<br>environment. |
| Hygiene measures :                                 | If exposure to chemical is likely during typical use, provide eye<br>flushing systems and safety showers close to the working<br>place. When using do not eat, drink or smoke. Wash contami-<br>nated clothing before re-use.   |
| 7.2 Conditions for safe storage, inc               | cluding any incompatibilities   |
| Requirements for storage :<br>areas and containers | Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations.  |
| Advice on common storage :                         | Do not store with the following product types:<br>Strong oxidizing agents   |
| 7.3 Specific end use(s)                            |   |
| Specific use(s) :                                  | No data available   |

## **SECTION 8: Exposure controls/personal protection**

## 8.1 Control parameters

### **Occupational Exposure Limits**

| Components  | CAS-No.         | Value type (Form of exposure) | Control parameters | Basis    |
|-------------|-----------------|-------------------------------|--------------------|----------|
| Raltegravir | 871038-72-<br>1 | TWA                           | 1000 µg/m3 (OEB 1) | Internal |



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|---------------------------------|--|---------------------------------|--|---|----------------------|
| Cellulose                       |  | 9004-34-6   OEL-RL              |  | 10 mg/m3  | ZA OEL               |
|                                 |  | Further inform<br>Hazardous C   |  | ational Exposure Limits - R<br>is                     | estricted Limits For |

#### **8.2 Exposure controls**

#### **Engineering measures**

Minimize workplace exposure concentrations.

Apply measures to prevent dust explosions.

Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

If sufficient ventilation is unavailable, use with local exhaust ventilation.

### Personal protective equipment

| Eye/face 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   |
|--------------------------|---|--|
| Hand protection          |   |  |
| 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<br>applications, we recommend clarifying the resistance to<br>chemicals of the aforementioned protective gloves with the<br>glove manufacturer. Wash hands before breaks and at the<br>end of workday. |
| Skin and body protection | : | Select appropriate protective clothing based on chemical re-<br>sistance data and an assessment of the local exposure poten-<br>tial.  |
| Respiratory protection   | : | Skin contact must be avoided by using impervious protective<br>clothing (gloves, aprons, boots, etc).<br>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              | : | Particulates type (P)  |

## **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

| Appearance<br>Colour<br>Odour<br>Odour Threshold | : | powder<br>No data available<br>No data available<br>No data available |
|--|---|---|
| рН   | : | No data available   |
| Melting point/freezing point                     | : | No data available   |
| Initial boiling point and boiling                | : | No data available   |



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|------------|--------------------|--|---|---|---|
|            | range<br>Flash p   | point                                    | : | Not applicable  |   |
|            | Evapor             | ation rate                               | : | No data available   | e   |
|            | Flamm              | ability (solid, gas)                     | : | May form explos dling or other me                           | ive dust-air mixture during processing, han-<br>ans.              |
|            |                    | explosion limit / Upper<br>ability limit | : | No data available   | 9   |
|            |                    | explosion limit / Lower<br>ability limit | : | No data available   | 9   |
|            | Vapou              | - pressure                               | : | No data available   | 9   |
|            | Relativ            | e vapour density                         | : | No data available   | 9   |
|            | Density            | /  | : | No data available   | 9   |
|            | Partitio<br>octano | ter solubility<br>n coefficient: n-      | : | No data available<br>No data available<br>No data available | 9   |
|            | -                  | position temperature                     | : | No data available   |   |
|            | Viscos             |  | : | No data available   |   |
|            | Explos             | ive properties                           | : | Not explosive   |   |
|            | Oxidizi            | ng properties                            | : | The substance o   | r mixture is not classified as oxidizing.                         |
| 9.2        |                    | n <b>formation</b><br>ability (liquids)  | : | No data available   | e   |
|            | Molecu             | ılar weight                              | : | No data available   | e   |
|            | Particle           | e size                                   | : | No data available   | 9   |
|            |                    |  |   |   |   |

## **SECTION 10: Stability and reactivity**

## 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

Hazardous reactions

: May form explosive dust-air mixture during processing, han-



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|----------------|---|--------|--|---|
|                |   |        | dling or other<br>Can react with         | means.<br>n strong oxidizing agents.                              |
| 10.4 Cond      | litions to avoid                                    |        |  |   |
| Condi          | tions to avoid                                      | :      | Heat, flames a Avoid dust for            |   |
| 0.5 Incor      | npatible materials                                  |        |  |   |
| Mater          | ials to avoid                                       | :      | Oxidizing agents                         |   |
|                | rdous decomposition<br>Izardous decompositio        | -      |  | ı.  |
|                | I 11: Toxicological i                               | •      |  |   |
| 14 4 Inform    | nation on toxicologic                               |        | faata                                    |   |
|                | mation on toxicologic<br>nation on likely routes of |        | Inhalation                               |   |
| expos          | -   |        | Skin contact<br>Ingestion<br>Eye contact |   |
| Acute          | e toxicity  |        |  |   |
| Not cl         | assified based on avai                              | lable  | information.                             |   |
| Comp           | oonents:  |        |  |   |
| Ralte          | gravir:   |        |  |   |
| Acute          | oral toxicity                                       | :      | LD50 (Mouse,                             | male and female): > 2.000 mg/kg                                   |
| Skin           | corrosion/irritation                                |        |  |   |
| Not cl         | assified based on avai                              | lable  | information.                             |   |
| <u>Comp</u>    | oonents:  |        |  |   |
| Ralte          | gravir:   |        |  |   |
| Speci          |   | :      | Rabbit                                   |   |
| Resul          | t   | :      | No skin irritatio                        | 5n  |
|                | us eye damage/eye ir                                |        | on                                       |   |
| Cause          | es serious eye damage                               | Э.     |  |   |
| <u>Comp</u>    | oonents:  |        |  |   |
|                | gravir:   |        |  |   |
| Speci<br>Resul |   | :      | Bovine cornea<br>Severe irritatio        |   |
| Resp           | iratory or skin sensiti                             | isatio | n  |   |
|                | sensitisation                                       |        |  |   |

Not classified based on available information.



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|------------------------------------|---|--|--|
| •                                  | iratory sensitisatior<br>lassified based on av    |  |  |
| <u>Com</u>                         | ponents:  |  |  |
| Ralte                              | gravir:   |  |  |
| Test <sup>-</sup><br>Speci<br>Resu | ies   | : Local lymph no<br>: Mouse<br>: negative              | ode assay (LLNA)   |
|                                    | <b>cell mutagenicity</b><br>lassified based on av | ailable information.                                   |  |
| Com                                | ponents:  |  |  |
| Ralte                              | gravir:   |  |  |
| Geno                               | toxicity in vitro                                 | : Test Type: reve<br>Result: negativ                   | erse mutation assay<br>e   |
|                                    |   | Test Type: Alka<br>Test system: ra<br>Result: negativ  |  |
|                                    |   |  | omosomal aberration<br>Test Guideline 473<br>e                     |
| Geno                               | toxicity in vivo                                  | : Test Type: In v<br>Species: Mouse<br>Result: negativ |  |
|                                    |   |  | omosomal aberration<br>Test Guideline 475<br>e                     |
|                                    | i <b>nogenicity</b><br>lassified based on av      | ailable information                                    |  |
|                                    | ponents:  |  |  |
| Ralte                              | gravir:   |  |  |
| Speci                              | ies<br>sure time                                  | : Mouse, male a<br>: 104 weeks<br>: negative           | nd female  |
| -                                  | oductive toxicity<br>ected of damaging the        | e unborn child   |  |
|                                    | ponents:  |  |  |
|                                    | gravir:   |  |  |
|                                    | ts on fertility                                   |  | tility/early embryonic development<br>nale and female<br>ute: Oral |
|                                    |   | 0/45   |  |



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|----------------|--|-------------------------------|---|
|                |  | General Toxi<br>Result: nega  | city - Parent: NOAEL: 600 mg/kg body weight<br>tive   |
| Effe<br>men    | cts on foetal develop-<br>t                              | Teratogenicit                 | Route: Oral<br>city Maternal: NOAEL: >= 600 mg/kg body weight<br>y: LOAEL F1: 300 mg/kg body weight<br>Skeletal malformations |
|                |  | weight                        | city Maternal: NOAEL: >= 1.000 mg/kg body<br>y: NOAEL: >= 1.000 mg/kg body weight   |
| -              | roductive toxicity - As-<br>ment                         | : Some eviden<br>animal exper | ice of adverse effects on development, based on iments.   |
|                | <b>T - single exposure</b><br>cause respiratory irritati | on.                           |   |
|                | ponents:   | -                             |   |

### Raltegravir:

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

### STOT - repeated exposure

Not classified based on available information.

## Repeated dose toxicity

#### **Components:**

| Raltegravir:<br>Species<br>NOAEL<br>Application Route<br>Exposure time<br>Symptoms | : | Dog<br>90 mg/kg<br>Oral<br>371 d<br>Vomiting             |
|--|---|--|
| Species<br>NOAEL<br>LOAEL<br>Application Route<br>Exposure time<br>Target Organs   | : | Rat<br>30 mg/kg<br>120 mg/kg<br>Oral<br>189 d<br>Stomach |
| Species<br>NOAEL<br>LOAEL<br>Application Route<br>Exposure time                    | : | Mouse<br>50 mg/kg<br>500 mg/kg<br>Oral<br>14 Weeks       |



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|--|-----|---|---|
| Target Organs  | :   | Stomach   |   |
| Species<br>NOAEL<br>LOAEL<br>Application Route<br>Exposure time<br>Target Organs |     | Rat<br>50 mg/kg<br>200 mg/kg<br>Oral<br>8 Weeks<br>Stomach                  |   |
| Aspiration toxicity<br>Not classified based on availa                            |     |   |   |
| Experience with human exp  | osi | ire   |   |
| Components:  |     |   |   |
| Raltegravir:<br>Ingestion  | :   | Symptoms: Nause irritation  | ea, Diarrhoea, Headache, Fever, Rash, Skin                        |
| 12.1 Toxicity  |     |   |   |
| Components:  |     |   |   |
| Raltegravir:   |     |   |   |
| Toxicity to fish   | :   | Exposure time: 96<br>Method: OECD T   |   |
|  |     | mg/I<br>Exposure time: 96<br>Method: OECD T                                 |   |
| Toxicity to daphnia and other aquatic invertebrates                              | :   | EC50 (Daphnia m<br>Exposure time: 48<br>Method: OECD T                      |   |
| Toxicity to algae/aquatic plants   | :   | EC50 (Pseudokiro<br>Exposure time: 96<br>Method: OECD T                     |   |
|  |     | NOEC (Pseudokin<br>mg/l<br>Exposure time: 96<br>Method: OECD T              |   |
| Toxicity to microorganisms   | :   | EC50 : > 1.000 m<br>Exposure time: 3<br>Test Type: Respir<br>Method: OECD T | h<br>ration inhibition  |
|  |     | NOEC : 1.000 mg   | /I  |



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|                |   |     | Exposure time: 3<br>Test Type: Respir<br>Method: OECD T   |  |
| To»<br>icity   | ticity to fish (Chronic tox-<br>/)                                  | :   | NOEC: 9,3 mg/l<br>Exposure time: 33 d<br>Species: Pimephales promelas (fathead minnow)<br>Method: OECD Test Guideline 210 |  |
| aqu            | cicity to daphnia and other natic invertebrates (Chron-<br>pxicity) | :   | NOEC: 9,5 mg/l<br>Exposure time: 21 d<br>Species: Daphnia magna (Water flea)<br>Method: OECD Test Guideline 211           |  |
| 12.2 Pe        | sistence and degradabil   | ity |   |  |
| Co             | mponents:   | -   |   |  |
| Ra             | tegravir:   |     |   |  |
| Bio            | degradability   | :   | Result: rapidly de<br>Biodegradation: 4<br>Exposure time: 9<br>Method: OECD T   | 50 %   |
| Sta            | bility in water   | :   | Hydrolysis: < 10 9<br>Method: OECD T  | %(5 d)<br>rest Guideline 111   |
| 12.3 Bic       | accumulative potential  |     |   |  |
| Co             | mponents:   |     |   |  |
| Par            | <b>tegravir:</b><br>tition coefficient: n-<br>anol/water            | :   | log Pow: -0,328   |  |
|                | <b>bility in soil</b><br>data available                             |     |   |  |
| 12.5 Re        | sults of PBT and vPvB as  | sse | ssment  |  |
|                | essment   | :   | to be either persis   | nixture contains no components considered stent, bioaccumulative and toxic (PBT), or nd very bioaccumulative (vPvB) at levels of   |
| 12.6 Otl       | ner adverse effects   |     |   |  |
| Pro            | duct:   |     |   |  |
|                | docrine disrupting poten-   | :   | ered to have endo<br>REACH Article 57   | ixture does not contain components consid-<br>ocrine disrupting properties according to<br>7(f) or Commission Delegated regulation<br>or Commission Regulation (EU) 2018/605 at<br>higher. |
|                |   |     |   |  |



# Raltegravir Formulation

| Version | Revision Date: | SDS Number:  | Date of last issue: 04.04.2023  |
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## **SECTION 13:** Disposal considerations

#### 13.1 Waste treatment methods

| Product                | <ul> <li>Dispose of in accordance with local regulations.<br/>According to the European Waste Catalogue, Waste Codes<br/>are not product specific, but application specific.<br/>Waste codes should be assigned by the user, preferably in<br/>discussion with the waste disposal authorities.<br/>Do not dispose of waste into sewer.</li> </ul> |
|------------------------|---|
| Contaminated packaging | : Empty containers should be taken to an approved waste han-<br>dling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product.  |

## **SECTION 14: Transport information**

#### 14.1 UN number

|                                 | ADN              | : | Not regulated as a dangerous good |
|---------------------------------|------------------|---|-----------------------------------|
|                                 | ADR              | : | Not regulated as a dangerous good |
|                                 | RID              | : | Not regulated as a dangerous good |
|                                 | IMDG             | : | Not regulated as a dangerous good |
|                                 | ΙΑΤΑ             | : | Not regulated as a dangerous good |
| 14.2 UN proper shipping name    |                  |   |                                   |
|                                 | ADN              | : | Not regulated as a dangerous good |
|                                 | ADR              | : | Not regulated as a dangerous good |
|                                 | RID              | : | Not regulated as a dangerous good |
|                                 | IMDG             | : | Not regulated as a dangerous good |
|                                 | ΙΑΤΑ             | : | Not regulated as a dangerous good |
| 14.3 Transport hazard class(es) |                  |   |                                   |
|                                 | ADN              | : | Not regulated as a dangerous good |
|                                 | ADR              | : | Not regulated as a dangerous good |
|                                 | RID              | : | Not regulated as a dangerous good |
|                                 | IMDG             | : | Not regulated as a dangerous good |
|                                 | ΙΑΤΑ             | : | Not regulated as a dangerous good |
| 14.4 Packing group              |                  |   |                                   |
|                                 | ADN              | : | Not regulated as a dangerous good |
|                                 | ADR              | : | Not regulated as a dangerous good |
|                                 | RID              | : | Not regulated as a dangerous good |
|                                 | IMDG             | : | Not regulated as a dangerous good |
|                                 | IATA (Cargo)     | : | Not regulated as a dangerous good |
|                                 | IATA (Passenger) | : | Not regulated as a dangerous good |
|                                 |                  |   |                                   |



## **Raltegravir Formulation**

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|--|------------------------------------|-----------------------------|---|--|--|--|--|
|  | onmental hazards                   |                             |   |  |  |  |  |
| Not re   | egulated as a dangero              | us good                     |   |  |  |  |  |
| -  | ial precautions for u<br>pplicable | ser                         |   |  |  |  |  |
| <b>4.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b><br>Remarks : Not applicable for product as supplied.   |                                    |                             |   |  |  |  |  |
| SECTION  | 15: Regulatory in                  | formation                   |   |  |  |  |  |
| 15.1 Safet<br>ture   | y, health and enviro               | nmental regulatior          | s/legislation specific for the substance or mix-  |  |  |  |  |
| The c  | omponents of this p                | roduct are reporte          | d in the following inventories:   |  |  |  |  |
| AICS   |                                    | : not determin              | led   |  |  |  |  |
| DSL  |                                    | : not determin              | led   |  |  |  |  |
| IECS   | С                                  | : not determin              | led   |  |  |  |  |
| 15.2 Chemical safety assessment         A Chemical Safety Assessment has not been carried out.         SECTION 16: Other information |                                    |                             |   |  |  |  |  |
| Other  | information                        |                             | changes have been made to the previous version<br>ed in the body of this document by two vertical   |  |  |  |  |
| Full t   | ext of H-Statements                |                             |   |  |  |  |  |
| H318   |                                    | : Causes serie              | ous eye damage.   |  |  |  |  |
| H335   |                                    |                             | espiratory irritation.  |  |  |  |  |
| H361   | d                                  | : Suspected c               | f damaging the unborn child.  |  |  |  |  |
| Full to  | Full text of other abbreviations   |                             |   |  |  |  |  |
| Eye D  |                                    | : Serious eye               |   |  |  |  |  |
| Repr.  |                                    | : Reproductiv               | e toxicity<br>et organ toxicity - single exposure   |  |  |  |  |
| STOT SE :<br>ZA OEL :  |                                    |                             | . The Regulations for Hazardous Chemical  |  |  |  |  |
| 2/10/  |                                    |                             | Agents, Occupational Exposure Limits  |  |  |  |  |
| ZA OI  | EL / OEL-RL                        | : Occupationa               | al Exposure Limit Restricted limit - 8- hour expo-<br>valent (12 hour shifts)   |  |  |  |  |
| Water  | rways; ADR - Agreer                | ment concerning th          | ternational Carriage of Dangerous Goods by Inlan<br>e International Carriage of Dangerous Goods b<br>Chemicals; ASTM - American Society for the Tes |  |  |  |  |

Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration as-



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sociated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association: IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

### Further information

| compile the Safety Data eCher  |     | eChem Portal | al technical data, data from raw material SDSs, OECD<br>m Portal search results and European Chemicals Agen-<br>p://echa.europa.eu/ |  |
|--------------------------------|-----|--------------|---|--|
| Classification of the mixture: |     |              | Classification procedure:   |  |
| Eye Dam. 1                     | H31 | 8            | Calculation method  |  |
| Repr. 2                        | H36 | 61d          | Calculation method  |  |

Calculation method

H335

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.

ZA / EN

STOT SE 3