



| Version 3.1 | Revision Date: 2023/09/26 | | S Number: 231-00025 | Date of last issue: 2023/03/20 Date of first issue: 2014/09/16 |
|----------------|--|-----|----------------------------------|---|
| | | | | |
| 1. PROD | UCT AND COMPANY IDE | ENT | IFICATION | |
| Prod | luct name | : | Raltegravir Adult | Formulation |
| Man | ufacturer or supplier's d | eta | ils | |
| Com | pany | : | MSD | |
| Addı | ess | : | | n KM. 48 Timur - Indonesia |
| Tele | phone | : | 908-740-4000 | |
| Eme | rgency telephone number | : | 1-908-423-6000 | |
| E-ma | ail address | : | EHSDATASTEW | /ARD@msd.com |
| Rec | ommended use of the ch | nem | ical and restriction | ons on use |
| | Recommended use Restrictions on use | | Pharmaceutical Not applicable | |

2. HAZARDS IDENTIFICATION

| GHS Classification Serious eye damage/eye irri- tation | : | Category 1 |
|--|---|--|
| Reproductive toxicity | : | Category 2 |
| Specific target organ toxicity - single exposure | : | Category 3 |
| GHS label elements | | |
| Hazard pictograms | : | |
| Signal word | : | Danger |
| Hazard statements | : | H318 Causes serious eye damage. H335 May cause respiratory irritation. H361d Suspected of damaging the unborn child. |
| Precautionary statements | : | Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read |



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and understood.

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.

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 |

4. FIRST AID MEASURES

| General advice | : | In the case of accident or if you feel unwell, seek medical ad- 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. |

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| In c | In case of eye contact | | In case of contact for at least 15 min | shoes before reuse. t, immediately flush eyes with plenty of water nutes. ove contact lens, if worn. | |
| lf sv | vallowed | : | Get medical atter If swallowed, DO Get medical atter | ition immediately. NOT induce vomiting. ition. | |
| and | et important symptoms effects, both acute and ayed | : | May cause respiratory irritation. Suspected of damaging the unborn child. Contact with dust can cause mechanical irritation or drying | | |
| Prot | ection of first-aiders | : | and use the recor | ers should pay attention to self-protection, nmended personal protective equipment al for exposure exists (see section 8). | |
| | es to physician | : | Treat symptomati | cally and supportively. | |
| | | | | | |
| | able extinguishing media | : | Water spray Alcohol-resistant Carbon dioxide (C Dry chemical None known. | | |
| med | uitable extinguishing lia | · | NOTIC KHOWH. | | |
| Spe figh | cific hazards during fire- ting | Avoid generating dust; fine dust dispersed in air in su concentrations, and in the presence of an ignition sou potential dust explosion hazard. Exposure to combustion products may be a hazard to | | | |
| Haz ucts | ardous combustion prod- | : | Carbon oxides Metal oxides Oxides of phosph Nitrogen oxides (Fluorine compour | NOx) | |
| Spe ods | cific extinguishing meth- | : | cumstances and Use water spray f Remove undama so. | g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to do | |
| | cial protective equipment irefighters | : | | e, wear self-contained breathing apparatus. tective equipment. | |
| 6. ACCII | DENTAL RELEASE MEAS | SUF | RES | | |
| tive | sonal precautions, protec- equipment and emer- cy procedures | Use personal protective equipment. Follow safe handling advice (see section 7) and personal pe | | ling advice (see section 7) and personal pro- | |
| Env | ironmental precautions | : Avoid release to the environment. | | | |





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| Methods and materials for containment and cleaning up | | : | Retain and dis Local authoriti cannot be com Surround spill over the area Add excess lic Soak up with i Avoid dispersa with compress Dust deposits es, as these m leased into the Clean up rema bent. Local or nation | with absorbents and place a damp covering to minimise entry of the material into the air. quid to allow the material to enter into solution. nert absorbent material. al of dust in the air (i.e., clearing dust surfaces sed air). should not be allowed to accumulate on surfac- nay form an explosive mixture if they are re- e atmosphere in sufficient concentration. aining materials from spill with suitable absor- nal regulations may apply to releases and dis- |
| | | | employed in the mine which re Sections 13 and | naterial, as well as those materials and items ne cleanup of releases. You will need to deter- gulations are applicable. Ind 15 of this SDS provide information regarding r national requirements. |
| 7. HANDI | ING AND STORAGE | | | |
| | | | | |
| Techi | nical measures | : | causing an ex Provide adequ | ty may accumulate and ignite suspended dust plosion. ate precautions, such as electrical grounding or inert atmospheres. |
| Local | /Total ventilation | : | | ntilation is unavailable, use with local exhaust |
| Advic | e on safe handling | : | Handle in according practice, base sessment Keep container Already sensiti to asthma, alle | w. eyes. ed or repeated contact with skin. ordance with good industrial hygiene and safety d on the results of the workplace exposure as- er tightly closed. ised individuals, and those susceptible ergies, chronic or recurrent respiratory disease, t their physician regarding working with respira- |

tory irritants or sensitisers. Minimize dust generation and accumulation.

Keep container closed when not in use.

- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labelled containers.
 - Store locked up. Keep tightly closed.



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| | Keep in a cool, well-ventilated place. |
|--------------------|---|
| | Store in accordance with the particular national regulations. |
| Materials to avoid | : Do not store with the following product types: |
| | Strong oxidizing agents |

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

| Components | CAS-No. | Value type (Form of exposure) | Control parame- ters / Permissible concentration | Basis |
|--------------------|-------------|--|--|----------|
| Raltegravir | 871038-72-1 | TŴA | 1000 µg/m3 (OEB 1) | Internal |
| Cellulose | 9004-34-6 | NAB | 10 mg/m3 | ID OEL |
| | | TWA | 10 mg/m3 | ACGIH |
| Magnesium stearate | 557-04-0 | NAB | 10 mg/m3 | ID OEL |
| | | classify these | fied as carcinogenic t materials as carcinog | |
| | | TWA (Inhal- able particu- late matter) | 10 mg/m3 | ACGIH |
| | | TWA (Res- pirable par- ticulate mat- ter) | 3 mg/m3 | ACGIH |

Components with workplace control parameters

| 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 de- signed 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 equipme | ent | | |
| Respiratory protection | : | If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. | |
| Filter type Hand protection | : | Particulates type | |
| Material | : | Chemical-resistant gloves | |
| Remarks | : | Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous sub- stance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to | |



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| Eye ç | protection | : | glove manufact end of workday Wear the follow Chemical resist | e aforementioned protective gloves with the turer. Wash hands before breaks and at the ving personal protective equipment: tant goggles must be worn. likely to occur, wear: | | |
| | Skin and body protection Hygiene measures | | Face-shield Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc). If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the work ing place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. | | | |
| . PHYSIC | | ROF | PERTIES | | | |
| Appe | arance | : | powder | | | |
| Colou | ır | : | No data available | | | |
| Odou | ır | : | No data availa | ble | | |
| Odou | ır Threshold | : | No data availa | ble | | |
| pН | | : | No data availa | ble | | |
| Meltir | ng point/freezing point | : | No data availa | ble | | |
| Initial range | boiling point and boiling | : | No data availa | ble | | |
| Flash | n point | : | No data availa | ble | | |
| Evap | oration rate | : | Not applicable | | | |
| Flam | mability (solid, gas) | : | May form expl dling or other r | osive dust-air mixture during processing, han- means. | | |
| Flam | mability (liquids) | : | No data availa | ble | | |
| Self-i | gnition | : | No data availa | ble | | |
| | er explosion limit / Upper nability limit | : | No data availa | ble | | |
| | er explosion limit / Lower nability limit | : | No data availa | ble | | |
| Vara | | | | h la | | |

SAFETY DATA SHEET



Raltegravir Adult Formulation

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| | | | |
| Relat | ive vapour density | : No data ava | ilable |
| Dens | ity | : No data ava | ilable |
| | ility(ies) ater solubility | : No data ava | ilable |
| | ion coefficient: n- ol/water | : No data ava | ilable |
| | ignition temperature | : No data ava | ilable |
| Deco | mposition temperature | : No data ava | ilable |
| Visco Vi | sity scosity, dynamic | : No data ava | ilable |
| Vi | scosity, kinematic | : No data ava | ilable |
| Flow | time | : No data ava | ilable |
| Explo | sive properties | : Not explosiv | /e |
| Oxidi | zing properties | : The substar | nce or mixture is not classified as oxidizing. |
| Moleo | cular weight | : No data ava | ilable |
| Partic | cle size | : No data ava | ilable |
| | | | |

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

| Information on likely routes of | : | Inhalation |
|---------------------------------|---|--------------|
| exposure | | Skin contact |
| | | Ingestion |
| | | Eye contact |





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| | | | | |
| Acute | toxicity | | | |
| Not cl | assified based on ava | ailable | information. | |
| <u>Comp</u> | oonents: | | | |
| Ralte | gravir: | | | |
| Acute | oral toxicity | : | LD50 (Mouse, | male and female): > 2,000 mg/kg |
| Cellul | lose: | | | |
| Acute | oral toxicity | : | LD50 (Rat): > 9 | 5,000 mg/kg |
| Acute | inhalation toxicity | : | LC50 (Rat): > \$ | |
| | | | Exposure time Test atmosphe | |
| Acute | dermal toxicity | : | LD50 (Rabbit): | > 2,000 mg/kg |
| Magn | esium stearate: | | | |
| - | oral toxicity | : | Assessment: T icity | 2,000 mg/kg) Test Guideline 423 The substance or mixture has no acute oral to ed on data from similar materials |
| Acute | dermal toxicity | : | LD50 (Rabbit): | |
| Skin d | corrosion/irritation | | | |
| Not cl | assified based on ava | ailable | information. | |
| Comp | oonents: | | | |
| Ralte | gravir: | | | |
| Specie Resul | es | : | Rabbit No skin irritatic | n |
| Magn | esium stearate: | | | |
| Speci | | : | Rabbit | |
| Resul [:] Rema | | : | No skin irritation Based on data | n from similar materials |
| | u s eye damage/eye i es serious eye damag | | on | |
| | oonents: | | | |
| Ralte | gravir: | | | |
| Specie Resul | es | : | Bovine cornea Severe irritatio | |
| | | | | |



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Magnesium stearate:

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

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Raltegravir:

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

Magnesium stearate:

| Maximisation Test |
|--------------------------------------|
| Skin contact |
| Guinea pig |
| OECD Test Guideline 406 |
| negative |
| Based on data from similar materials |
| |

Germ cell mutagenicity

Not classified based on available information.

Components:

Raltegravir:

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



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| | | | |
| | | Result: neg | ative |
| Cellulo | ose: | | |
| Genoto | oxicity in vitro | : Test Type: Result: neg | Bacterial reverse mutation assay (AMES) ative |
| | | Test Type: Result: neg | In vitro mammalian cell gene mutation test ative |
| Genoto | oxicity in vivo | cytogenetic Species: M | ouse Route: Ingestion |
| Magne | sium stearate: | | |
| Genoto | oxicity in vitro | Result: neg | In vitro mammalian cell gene mutation test ative Based on data from similar materials |
| | | | Chromosome aberration test in vitro ECD Test Guideline 473 ative |
| | | Remarks: E | Based on data from similar materials |
| | | Result: neg | Bacterial reverse mutation assay (AMES) ative Based on data from similar materials |
| | ogenicity | | based on data from similar materials |
| Not cla | ssified based on av | ailable information. | |

Components:

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

Cellulose:

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

Reproductive toxicity

Suspected of damaging the unborn child.



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| Ralte | ponents: gravir: | | | |
| Effect | ts on fertility | Specie Applica Genera | s: Rat, male ation Route: | /early embryonic development and female Oral Parent: NOAEL: 600 mg/kg body weight |
| Effect ment | ts on foetal develop- | Genera Teratog Sympto | ation Route: al Toxicity M genicity: LO | Oral aternal: NOAEL: >= 600 mg/kg body weight AEL F1: 300 mg/kg body weight al malformations |
| | | Genera weight Teratog | - | aternal: NOAEL: >= 1,000 mg/kg body AEL: >= 1,000 mg/kg body weight |
| Repro sessr | oductive toxicity - As- nent | | evidence of experiments | adverse effects on development, based on s. |
| Cellu | lose: | | | |
| Effect | ts on fertility | Specie: Applica | | neration reproduction toxicity study |
| Effect ment | ts on foetal develop- | Specie: Applica | | early embryonic development |
| Magn | nesium stearate: | | | |
| Effect | ts on fertility | reprodu Species Applica Methoo Result: | uction/develo s: Rat ation Route: d: OECD Tes negative | ed repeated dose toxicity study with the opmental toxicity screening test Ingestion st Guideline 422 n data from similar materials |
| Effect ment | ts on foetal develop- | Specie Applica Result: | s: Rat ation Route: negative | e-foetal development Ingestion n data from similar materials |



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STOT - single exposure

May cause respiratory irritation.

Components:

Raltegravir:

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

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

| Raltegravir: | | |
|--|---|---|
| Species NOAEL Application Route Exposure time Symptoms | : | Dog 90 mg/kg Oral 371 d Vomiting |
| Species NOAEL LOAEL Application Route Exposure time Target Organs | | Rat 30 mg/kg 120 mg/kg Oral 189 d Stomach |
| Species NOAEL LOAEL Application Route Exposure time Target Organs | | Mouse 50 mg/kg 500 mg/kg Oral 14 Weeks Stomach |
| Species NOAEL LOAEL Application Route Exposure time Target Organs | | Rat 50 mg/kg 200 mg/kg Oral 8 Weeks Stomach |
| Cellulose: Species NOAEL Application Route Exposure time | : : | Rat >= 9,000 mg/kg Ingestion 90 Days |



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| Speci NOAI Applie | EL cation Route sure time | : | Rat > 100 mg/kg Ingestion 90 Days Based on data | from similar materials |
| - | ration toxicity lassified based on availa | ble | information. | |
| Expe | rience with human exp | osı | ıre | |
| Com | oonents: | | | |
| Ralte Inges | gravir: tion | : | Symptoms: Na irritation | usea, Diarrhoea, Headache, Fever, Rash, Skir |
| 2. ECOL | OGICAL INFORMATION | N | | |
| Fcot | oxicity | | | |
| | oonents: | | | |
| | gravir: | | | |
| | ity to fish | : | Exposure time: | ales promelas (fathead minnow)): > 100 mg/l 96 h 9 Test Guideline 203 |
| | | | mg/l Exposure time: | don variegatus (sheepshead minnow)): > 100 96 h 9 Test Guideline 203 |
| | ity to daphnia and other ic invertebrates | : | Exposure time: | a magna (Water flea)): > 100 mg/l : 48 h 9 Test Guideline 202 |
| Toxic plants | ity to algae/aquatic | : | Exposure time: | kirchneriella subcapitata (green algae)): 66 mg 96 h 9 Test Guideline 201 |
| | | | mg/l Exposure time: | okirchneriella subcapitata (green algae)): 3.8 96 h 9 Test Guideline 201 |
| Toxic icity) | ity to fish (Chronic tox- | : | Exposure time: | nales promelas (fathead minnow)): 9.3 mg/l 33 d) Test Guideline 210 |
| | | | | |



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| | | | | | |
| | aquatic ir ic toxicity | nvertebrates (Chron- | | Exposure time: 21 Method: OECD Te | |
| - | Toxicity to | o microorganisms | : | EC50: > 1,000 mg Exposure time: 3 Test Type: Respir Method: OECD Te | h ation inhibition |
| | | | | NOEC: 1,000 mg/ Exposure time: 3 Test Type: Respir Method: OECD Te | h ation inhibition |
| (| Cellulos | e: | | | |
| | Toxicity to | | : | Exposure time: 48 | pes (Japanese medaka)): > 100 mg/l h on data from similar materials |
| r | Magnesi | um stearate: | | | |
| | Toxicity to | | : | Exposure time: 48 Method: DIN 3841 | |
| | Toxicity to daphnia and other aquatic invertebrates | | : | Exposure time: 47 Test substance: W Method: Directive | Vater Accommodated Fraction 67/548/EEC, Annex V, C.2. on data from similar materials |
| | Toxicity to plants | o algae/aquatic | : | mg/l Exposure time: 72 Test substance: W Method: OECD Te | Vater Accommodated Fraction est Guideline 201 on data from similar materials |
| | | | | mg/l Exposure time: 72 Test substance: V Method: OECD Te | Vater Accommodated Fraction |
| - | Toxicity t | o microorganisms | : | Exposure time: 16 Test substance: V | nas putida): > 100 mg/l 5 h Vater Accommodated Fraction on data from similar materials |



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| | | | | | | |
| D | | | | | | |
| | stence and degrada | DIIITY | | | | |
| <u>Com</u> | ponents: | | | | | |
| | gravir: | | | | | |
| Biode | gradability | | Result: rapidly Biodegradatio Exposure time Method: OEC | n: 50 % | | |
| Stabil | lity in water | | Hydrolysis: < Method: OEC | 10 %(5 d) D Test Guideline 111 | | |
| Cellu | lose: | | | | | |
| Biode | egradability | : | Result: Readi | ly biodegradable. | | |
| Magn | nesium stearate: | | | | | |
| Biode | egradability | | Result: Not bi Remarks: Bas | odegradable sed on data from similar materials | | |
| Bioad | ccumulative potentia | al | | | | |
| <u>Com</u> | ponents: | | | | | |
| Ralte | gravir: | | | | | |
| | ion coefficient: n- ol/water | : | log Pow: -0.32 | 28 | | |
| Magn | nesium stearate: | | | | | |
| | ion coefficient: n- ol/water | : | log Pow: > 4 | | | |
| Mobi | lity in soil | | | | | |
| No da | ata available | | | | | |
| Othe | r adverse effects | | | | | |
| No da | ata available | | | | | |

| 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. |

14. TRANSPORT INFORMATION

International Regulations



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|-----------------|------------------------------|------|----------------------------------|---|
| | | | | |
| UNR | IDG | | | |
| - | umber | : | Not applicable | |
| | er shipping name | : | Not applicable | |
| Class | | : | Not applicable | |
| | diary risk | : | Not applicable | |
| | ng group | : | Not applicable | |
| Label | S | : | Not applicable | |
| IATA | DGR | | | |
| UN/IE |) No. | : | Not applicable | |
| | er shipping name | : | Not applicable | |
| Class | | : | Not applicable | |
| | diary risk | : | Not applicable | |
| | ng group | : | Not applicable | |
| Label | | : | Not applicable | |
| | ng instruction (cargo | • | Not applicable | |
| aircra Packi | ng instruction (passen- | : | Not applicable | |
| | rcraft) | • | | |
| 0 | , | | | |
| | -Code | | Not oppliaable | |
| - | umber | ÷ | Not applicable | |
| Class | er shipping name | : | Not applicable Not applicable | |
| | diary risk | : | Not applicable | |
| | ng group | ÷ | Not applicable | |
| Label | | ÷ | Not applicable | |
| EmS | Code | : | Not applicable | |
| Marin | e pollutant | : | Not applicable | |
| Trans | sport in bulk according | g to | Annex II of MAR | POL 73/78 and the IBC Code |
| Not a | pplicable for product as | sup | plied. | |
| Spec | ial precautions for use | er | | |
| Not a | pplicable | | | |
| DEOU | | | | |

Safety, health and environmental regulations/legislation specific for the substance or mixture

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

| Hazardous substances approve | ed for use |
|------------------------------|------------|
|------------------------------|------------|

: Not applicable



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Raltegravir Adult Formulation

| Version 3.1 | Revision Date: 2023/09/26 | - | 0S Number: 231-00025 | | | of last issue: 2023/03/20 of first issue: 2014/09/16 | | |
|----------------|--|------|-------------------------|------|-----|---|--|--|
| | | | | | | | | |
| | | | | | | | | |
| Prohit | oited substances | | | | : | Not applicable | | |
| Restri | cted substances | | | | : | Not applicable | | |
| Regul Mater | | f Tr | ade No. 7 of 2022 | on | Dis | stribution and Control of Hazardous | | |
| | of hazardous materials s I, Annex I | subj | ect to distribution a | and | : | Not applicable | | |
| | Type of hazardous materials subject to distribution and : Not applicable control, Annex II | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| Revisi | on Date | | 2023/09/26 | | | | | |
| | er information | | | | | | | |
| | es of key data used to le the Safety Data | : | | arch | res | lata from raw material SDSs, OECD sults and European Chemicals Agen- 』/ | | |
| Date f | ormat | : | yyyy/mm/dd | | | | | |
| Full te | ext of other abbreviation | ons | | | | | | |
| ACGI | 4 | : | USA. ACGIH Thre | esho | bld | Limit Values (TLV) | | |

| | 8-hour, time-weighted average Long term exposure limit |
|--|---|

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

: Indonesia. Occupational Exposure Limits

SAFETY DATA SHEET



Raltegravir Adult Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 2023/03/20 |
|---------|----------------|-------------|---------------------------------|
| 3.1 | 2023/09/26 | 13231-00025 | Date of first issue: 2014/09/16 |

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

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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