according to the OSHA Hazard Communication Standard



Raltegravir Formulation

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SECTION 1. IDENTIFICATION

Product name : Raltegravir Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Hazards for the product as supplied

Serious eye damage : Category 1

Reproductive toxicity : Category 2

Other hazards

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

Hazards associated with a change in physical form:

Conditions	Hazards
If small particles are generated during further processing, handling or by other means.	May form combustible dust concentrations in air.

GHS label elements

Hazard pictograms :







Signal Word : Danger

Hazard Statements : H318 Causes serious eye damage.

H361d Suspected of damaging the unborn child.

Supplemental Hazard State-

ments

Corrosive to the respiratory tract.

Precautionary Statements

Prevention:

according to the OSHA Hazard Communication Standard



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		P202 Do not h and understoo P261 Avoid br P271 Use only	eathing dust. outdoors or in a well-ventilated area. otective gloves, protective clothing, eye protection
	Response: P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a doctor if you feel unwell. P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously wit water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER. P308 + P313 IF exposed or concerned: Get medical attention.		
		Storage: P405 Store loc	sked up.
		Disposal:	

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
Raltegravir	871038-72-1*	>= 45 - <= 70	TSC
Cellulose	9004-34-6*	>= 10 - <= 30	TSC
Magnesium stearate	557-04-0*	>= 0.5 - <= 1.5	TSC

^{*} Indicates that the identifier is a CAS No.

TSC- the actual concentration or concentration range is withheld as a trade secret

disposal plant.

SECTION 4. FIRST AID MEASURES

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

advice immediately.

When symptoms persist or in all cases of doubt seek medical

P501 Dispose of contents and container to an approved waste

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.

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Get medical attention.

Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of contact, immediately flush eyes with plenty of water In case of eye contact

for at least 15 minutes.

If easy to do, remove contact lens, if worn.

Get medical attention immediately.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

delayed

Causes serious eye damage. May cause respiratory irritation.

Suspected of damaging the unborn child.

Corrosive to the respiratory tract.

Contact with dust can cause mechanical irritation or drying of

the skin.

Protection of first-aiders First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Treat symptomatically and supportively. Notes to physician

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire

fighting

Avoid generating dust; fine dust dispersed in air in sufficient

concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx) Fluorine compounds

Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment :

for fire-fighters

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

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

according to the OSHA Hazard Communication Standard



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Personal precautions, protective equipment and emergency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Surround spill with absorbents and place a damp covering over the area to minimize entry of the material into the air. Add excess liquid to allow the material to enter into solution.

Soak up with inert absorbent material.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Clean up remaining materials from spill with suitable

absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to

determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

Advice on safe handling : Avoid breathing dust.

Do not swallow. Do not get in eyes.

Avoid prolonged or repeated contact with skin.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure

assessment

Keep container tightly closed.

Already sensitized individuals, and those susceptible

to asthma, allergies, chronic or recurrent respiratory disease,

should consult their physician regarding working with

respiratory irritants or sensitizers.

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges.

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Take care to prevent spills, waste and minimize release to the

environment.

Conditions for safe storage : Keep in properly labeled containers.

Store locked up. Keep tightly closed.

Keep in a cool, well-ventilated place.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

inert or nuisance dust 50 Million particles per cubic foot

Value type (Form of exposure): TWA (total dust)

Basis: OSHA Z-3

15 mg/m³

Value type (Form of exposure): TWA (total dust)

Basis: OSHA Z-3

5 mg/m³

Value type (Form of exposure): TWA (respirable fraction)

Basis: OSHA Z-3

15 Million particles per cubic foot

Value type (Form of exposure): TWA (respirable fraction)

Basis: OSHA Z-3

Dust, nuisance dust and par-

ticulates

10 mg/m³

Value type (Form of exposure): PEL (Total dust)

Basis: CAL PEL

5 mg/m³

Value type (Form of exposure): PEL (respirable dust fraction)

Basis: CAL PEL

Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	
Raltegravir	871038-72-1	TWA	1000 (µg/m3)	Internal
			(OEB 1)	
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
		TWA (Res-	5 mg/m ³	NIOSH REL
		pirable)		
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total	15 mg/m ³	OSHA Z-1
		dust)		
		TWA (respir-	5 mg/m ³	OSHA Z-1
		able fraction)		
Magnesium stearate	557-04-0	TWA (Inhal-	10 mg/m ³	ACGIH
		able particu-	-	

according to the OSHA Hazard Communication Standard



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II	late matter)		
	TWA (Res-	3 mg/m³	ACGIH
	pirable par-		
	ticulate mat-		
	ter)		

Engineering measures Use feasible engineering controls to minimize exposure to

compound.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Personal protective equipment

Respiratory protection General and local exhaust ventilation is recommended to

> maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided

by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other

circumstance where air purifying respirators may not provide

adequate protection.

Hand protection

Material Chemical-resistant gloves

Eye protection Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection

Work uniform or laboratory coat.

Hygiene measures If exposure to chemical is likely during typical use, provide

eye flushing systems and safety showers close to the

working place.

When using do not eat, drink or smoke.

Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance powder

Color No data available

No data available Odor

according to the OSHA Hazard Communication Standard



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Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : Not applicable

Evaporation rate : No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing,

handling or other means.

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle characteristics

Particle size : No data available

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SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac- :

tions

May form explosive dust-air mixture during processing,

handling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

: Oxidizing agents

Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: 4,026 mg/kg

Method: Calculation method

Components:

Raltegravir:

Acute oral toxicity : LD50 (Mouse, male and female): > 2,000 mg/kg

Acute inhalation toxicity : Assessment: Not corrosive to the respiratory tract.

Cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

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

Magnesium stearate:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 423

Assessment: The substance or mixture has no acute oral tox-

icity

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

Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

Components:

Raltegravir:

Species : Rabbit

Result : No skin irritation

Magnesium stearate:

Species : Rabbit

Result : No skin irritation

Remarks : Based on data from similar materials

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

Raltegravir:

Species : Bovine cornea
Result : Severe irritation

Magnesium stearate:

Species : Rabbit

Result : No eye irritation

Remarks : Based on data from similar materials

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Raltegravir:

Test Type : Local lymph node assay (LLNA)

Species : Mouse Result : negative

Magnesium stearate:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig

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Method : OECD Test Guideline 406

Result : negative

Remarks : 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

Result: negative

Cellulose:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Ingestion

Result: negative

Magnesium stearate:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Result: negative

Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

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Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

Components:

Raltegravir:

Species : Mouse, male and female

Exposure time : 104 weeks Result : negative

Cellulose:

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

IARC No ingredient of this product present at levels greater than or equal to 0.1% is

identified as probable, possible or confirmed human carcinogen by IARC.

OSHANo component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Suspected of damaging the unborn child.

Components:

Raltegravir:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat, male and female

Application Route: Oral

General Toxicity Parent: NOAEL: 600 mg/kg body weight

Result: negative

Effects on fetal development : Species: Rat

Application Route: Oral

General Toxicity Maternal: NOAEL: >= 600 mg/kg body weight

Teratogenicity: LOAEL F1: 300 mg/kg body weight

Symptoms: Skeletal malformations.

Result: positive

Species: Rabbit

General Toxicity Maternal: NOAEL: >= 1,000 mg/kg body

weight

Teratogenicity: NOAEL: >= 1,000 mg/kg body weight

Result: negative

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Reproductive toxicity - As-

sessment

: Some evidence of adverse effects on development, based on

animal experiments.

Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Effects on fetal development : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

Magnesium stearate:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

Application Route: Ingestion

Method: OECD Test Guideline 422

Result: negative

Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

STOT-single exposure

May cause respiratory irritation. Corrosive to the respiratory tract.

Components:

Raltegravir:

Routes of exposure : Inhalation Target Organs : Respiratory Tract

Assessment : May cause respiratory irritation.

STOT-repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Raltegravir:

Species : Dog NOAEL : 90 mg/kg Application Route : Oral

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Exposure time 371 d Symptoms Vomiting

Species NOAEL LOAEL Application Route Exposure time Target Organs Species Rat 30 mg/kg 120 mg/kg Oral 189 d Target Organs Stomach

Species Mouse NOAEL LOAEL Application Route Exposure time NOAEL 50 mg/kg 500 mg/kg : Oral : 14 Weeks Target Organs : Stomach

Species : Rat Species
NOAEL
LOAEL
Application Route
Exposure time 50 mg/kg 200 mg/kg : Oral : 8 Weeks Target Organs : Stomach

Cellulose:

Species : Rat

NOAEL >= 9,000 mg/kg

Application Route : Ingestion : 90 Days Exposure time

Magnesium stearate:

Species : Rat

NOAEL : > 100 mg/kg

Application Route : Ingestion

Exposure time : 90 Days

Remarks : Rased on day

Remarks : Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Raltegravir:

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

irritation

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SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Raltegravir:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

LC50 (Cyprinodon variegatus (sheepshead minnow)): > 100

mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 66 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 3.8

mg/l

Exposure time: 96 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 9.3 mg/l

Exposure time: 33 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 9.5 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50: > 1,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

NOEC: 1,000 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l

Exposure time: 48 h

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Magnesium stearate:

Toxicity to fish LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l

> Exposure time: 48 h Method: DIN 38412

Remarks: Based on data from similar materials

aquatic invertebrates

Toxicity to daphnia and other : EL50 (Daphnia magna (Water flea)): > 1 mg/l

Exposure time: 47 h

Test substance: Water Accommodated Fraction Method: Directive 67/548/EEC, Annex V, C.2. Remarks: Based on data from similar materials

No toxicity at the limit of solubility.

Toxicity to algae/aquatic

plants

EL50 (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

No toxicity at the limit of solubility.

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

EC10 (Pseudomonas putida): > 100 mg/l Toxicity to microorganisms

Exposure time: 16 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Persistence and degradability

Components:

Raltegravir:

Biodegradability Result: rapidly degradable

Biodegradation: 50 % Exposure time: 9 d

Method: OECD Test Guideline 302B

Hydrolysis: < 10 %(5 d) Stability in water

Method: OECD Test Guideline 111

Cellulose:

Biodegradability Result: Readily biodegradable.

Magnesium stearate:

Biodegradability Result: Not biodegradable

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П

Bioaccumulative potential

Components:

Raltegravir:

Partition coefficient: n-

octanol/water

: log Pow: -0.328

Magnesium stearate:

Partition coefficient: n-

: log Pow: > 4

octanol/water

Mobility in soil
No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Domestic regulation

49 CFR

Not regulated as a dangerous good

Special precautions for user

Not applicable

according to the OSHA Hazard Communication Standard



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SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

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

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Reproductive toxicity

Serious eye damage or eye irritation

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

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

California Permissible Exposure Limits for Chemical Contaminants

Cellulose 9004-34-6 Magnesium stearate 557-04-0

The ingredients of this product are reported in the following inventories:

AICS : not determined

CA. DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

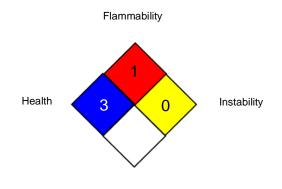
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NFPA 704:



Special hazard

HMIS® IV:



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

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

CAL PEL : California permissible exposure limits for chemical contami-

nants (Title 8, Article 107)

NIOSH REL : USA. NIOSH Recommended Exposure Limits

OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Lim-

its for Air Contaminants

OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Min-

eral Dusts

ACGIH / TWA : 8-hour, time-weighted average CAL PEL / PEL : Permissible exposure limit

NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour

workday during a 40-hour workweek

OSHA Z-1 / TWA : 8-hour time weighted average OSHA Z-3 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardization; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC -International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organization 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 Pre-

according to the OSHA Hazard Communication Standard



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vention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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 Agen-

cy, http://echa.europa.eu/

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

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