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## SECTION 1. IDENTIFICATION

Substance name : SYMTUZA oral film-coated tablets  
DARUNAVIR/COBICISTAT/EMTRICITABINE/TENOFOVIR  
ALAFENAMIDE eq. 800mg/150mg/200mg/10mg  
Darunavir single tablet regimen (STR)

### Manufacturer or supplier's details

Company name of supplier : Janssen Pharmaceuticals, Inc.

Address : 1125 Trenton-Harbourton Rd  
Titusville NJ 08560  
US

Telephone : (609) 730-2000

E-mail address Responsible/issuing person : SDSJanssen@its.jnj.com

**Emergency telephone number** : **CHEMTREC US: 1-800-424-9300**  
**CHEMTREC International: +1 703-527-3887**

### Recommended use of the chemical and restrictions on use

Recommended use : Finished Pharmaceutical Product  
This SDS is only intended for occupational use and not for consumer use (see patient packaging insert for consumer use). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished pharmaceutical product. For health and safety information during manufacturing of this product we refer to the appropriate SDS for each component.  
This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).

## SECTION 2. HAZARDS IDENTIFICATION

### GHS classification in accordance with 29 CFR 1910.1200

Not a hazardous substance or mixture.

### GHS label elements

Not a hazardous substance or mixture.

Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

### Other hazards

This Finished Pharmaceutical Product is non-hazardous based on chemical classification rules.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

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Chemical nature : Solid

Substance name : SYMTUZA oral film-coated tablets

### Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
DARUNAVIR ETHANOLATE	635728-49-3	>= 50 - < 70
COBICISTAT	1004316-88-4	>= 10 - < 20
Emtricitabine	143491-57-0	>= 10 - < 20
CELLULOSE	9004-34-6	>= 5 - < 10
Octadecanoic acid, magnesium salt	557-04-0	>= 1 - < 5
TITANDIOXIDE	13463-67-7	>= 1 - < 5
Tenofovir Alafenamide Fumarate (TAF)	1392275-56-7	>= 0.1 - < 1

### SECTION 4. FIRST AID MEASURES

If inhaled : Health injuries are not known or expected under normal use. Consult a physician.

In case of skin contact : Take off contaminated clothing and shoes immediately. Wash off with soap and water. If symptoms persist, call a physician.

In case of eye contact : Rinse immediately with plenty of water, also under the eyelids, for at least 5 minutes. Remove contact lenses. If eye irritation persists, consult a specialist.

If swallowed : If swallowed, rinse mouth with water (only if the person is conscious). Call a physician immediately.

Most important symptoms and effects, both acute and delayed : Abdominal pain  
Diarrhoea  
nausea  
headache  
Fatigue  
Dizziness  
asthenia  
insomnia  
Rash  
Allergic reactions  
Cough  
Liver disorders  
Vomiting

Notes to physician : Treat symptomatically.

### SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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Hazardous combustion products : No information available.

Further information : No information available.

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

## SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Avoid breathing dust.  
Evacuate personnel to safe areas.  
In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate.

Environmental precautions : Should not be released into the environment.  
Do not allow material to contaminate ground water system.

Methods and materials for containment and cleaning up : Large spills: Sweep up (intact) or vacuum with HEPA filter (broken or crushed) or via wet cleaning into suitable containers for disposal. Pick up and arrange without creating dust. Keep in properly labelled containers.  
Small spills: Moisten a towel, cover the spill, pick up the spill or use HEPA vacuum.  
Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".

## SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : No data available

Advice on safe handling : Do not break, crush or spill this Finished Pharmaceutical Product.  
To avoid thermal decomposition, do not overheat.  
Keep away from heat and sources of ignition.  
Avoid inhalation, ingestion and contact with skin and eyes.  
Use personal protective equipment as required.

Conditions for safe storage : To maintain product quality, do not store in heat or direct sunlight.  
Store in original container.  
Keep containers tightly closed in a dry, cool and well-ventilated place.  
Keep away from heat and sources of ignition.  
Store at room temperature.

Recommended storage temperature : 15 - 25 °C

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**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Components with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
DARUNAVIR ETHANOLATE	635728-49-3	TWA	1.6 mg/m <sup>3</sup>	J&J OEL/PBOEL HHC
		PBOEL-HHC	1 A	J&J OEL/PBOEL HHC
	Further information: J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 1A.			
COBICISTAT	1004316-88-4	TWA	0.060 mg/m <sup>3</sup>	J&J OEL/PBOEL HHC
Emtricitabine	143491-57-0	PEL	5 mg/day	
CELLULOSE	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Total dust)	15 mg/m <sup>3</sup>	OSHA P0
		TWA (respirable dust fraction)	5 mg/m <sup>3</sup>	OSHA P0
Octadecanoic acid, magnesium salt	557-04-0	TWA (Inhalable fraction)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable fraction)	3 mg/m <sup>3</sup>	ACGIH
TITANDIOXIDE	13463-67-7	TWA	2.4 mg/m <sup>3</sup>	J&J OEL/PBOEL HHC
		TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Total dust)	10 mg/m <sup>3</sup>	OSHA P0
		TWA	10 mg/m <sup>3</sup> (Titanium dioxide)	ACGIH
Tenofovir Alafenamide Fumarate (TAF)	1392275-56-7	TWA	0.015 mg/m <sup>3</sup>	J&J OEL/PBOEL HHC

**Engineering measures** : All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if

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necessary.

#### Personal protective equipment

- Respiratory protection : Engineering controls should always be the primary method of controlling exposures.  
If respiratory protective equipment is needed for certain activities, the type as well as the corresponding protection factor will depend upon the risk assessment and air concentrations, hazards, physical and warning properties of substances present.  
No personal respiratory protective equipment normally required.
- Hand protection
- Remarks : No special precautions required.
- Eye protection : No special precautions required.
- Skin and body protection : No special precautions required.
- Protective measures : The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Consult a Environmental Health and Safety expert if necessary.
- Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

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#### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : Coated, tablet
- Colour : yellow

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#### SECTION 10. STABILITY AND REACTIVITY

- Reactivity : None reasonably foreseeable.
- Chemical stability : Stable under recommended storage conditions.
- Possibility of hazardous reactions : No dangerous reaction known under conditions of normal use.
- Conditions to avoid : To avoid thermal decomposition, do not overheat.  
Heat, flames and sparks.
- Incompatible materials : None known.
- Hazardous decomposition products : None known.

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**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity****Product:**

Acute oral toxicity : Acute toxicity estimate: 3,755 mg/kg  
Method: Calculation method

**Components:****DARUNAVIR ETHANOLATE:**

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

LD50 (Dog): > 320 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

**COBICISTAT:**

Acute oral toxicity : (Rat): Remarks: No adverse effect has been observed in acute toxicity tests.

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : Remarks: No data available

**Emtricitabine:**

Acute oral toxicity : LD50 (Rat): > 4,000 mg/kg

LD50 (Mouse): > 4,000 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : LD50 (Rat): > 200 mg/kg  
Application Route: intravenous injection

LC50 (Mouse): > 200 mg/kg  
Application Route: intravenous injection

**Tenofovir Alafenamide Fumarate (TAF):**

Acute oral toxicity : Remarks: No data available

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

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Acute toxicity (other routes of administration) :  
Remarks: No data available

#### **Skin corrosion/irritation**

##### **Components:**

##### **DARUNAVIR ETHANOLATE:**

Result: No skin irritation  
Remarks: Based on Animal Evidence

##### **COBICISTAT:**

Species: Rabbit  
Remarks: Substance caused a mild irritation of eyes and skin in animal experiments.

##### **Emtricitabine:**

Remarks: No data available

##### **Tenofovir Alafenamide Fumarate (TAF):**

Remarks: No data available

#### **Serious eye damage/eye irritation**

##### **Components:**

##### **DARUNAVIR ETHANOLATE:**

Remarks: May irritate eyes.

##### **COBICISTAT:**

Remarks: No data available

##### **Emtricitabine:**

Remarks: No data available

##### **Tenofovir Alafenamide Fumarate (TAF):**

Remarks: No data available

#### **Respiratory or skin sensitisation**

##### **Components:**

##### **DARUNAVIR ETHANOLATE:**

Method: Local Lymph Node Assay (LLNA) in mice  
Result: Not a sensitizer

##### **COBICISTAT:**

Remarks: Not a sensitizer

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**Emtricitabine:**

Remarks: No data available

**Tenofovir Alafenamide Fumarate (TAF):**

Remarks: No data available

**Germ cell mutagenicity****Components:****DARUNAVIR ETHANOLATE:**

Genotoxicity in vitro : Test Type: Ames test  
Result: negative

: Test Type: Chromosome aberration test in vitro  
Result: negative

Genotoxicity in vivo : Test Type: in vivo assay  
Cell type: Bone marrow  
Method: Mutagenicity (micronucleus test)

Germ cell mutagenicity - Assessment : Did not show mutagenic effects in animal experiments.

**COBICISTAT:**

Genotoxicity in vitro : Remarks: No data available

Germ cell mutagenicity - Assessment : Did not show mutagenic effects in animal experiments.

**Emtricitabine:**

Genotoxicity in vitro : Test Type: Ames test  
Result: negative

: Test Type: A mouse lymphoma test  
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test  
Species: Mouse  
Application Route: Oral  
Result: In vivo tests did not show any chromosomal changes.

**Tenofovir Alafenamide Fumarate (TAF):**

Genotoxicity in vitro : Test Type: Ames test  
Result: negative

: Test Type: A mouse lymphoma test  
Result: negative



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Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse  
Cell type: Bone marrow  
Dose: 2000 mg/kg  
Result: negative

Germ cell mutagenicity - Assessment : Did not show mutagenic or teratogenic effects in animal experiments.

### **Carcinogenicity**

#### **Components:**

##### **DARUNAVIR ETHANOLATE:**

Carcinogenicity - Assessment : No information available.

##### **COBICISTAT:**

Species: Mouse  
Exposure time: 2 years  
Result: No evidence of carcinogenicity in animal studies.

Species: Rat, (males)  
Exposure time: 2 years  
50  
Remarks: Did not show carcinogenic effects in animal experiments.

Species: Rat, (females)  
Exposure time: 2 years  
30  
Remarks: Did not show carcinogenic effects in animal experiments.

##### **Emtricitabine:**

Species: Rat  
Dose: 600 mg/kg/day  
Result: No evidence of carcinogenicity in animal studies.

Species: Mouse  
Dose: 750 mg/kg/day  
Result: No evidence of carcinogenicity in animal studies.

Carcinogenicity - Assessment : Did not show carcinogenic, teratogenic or mutagenic effects in animal experiments.

##### **Tenofovir Alafenamide Fumarate (TAF):**

Species: Rat  
Dose: 300 mg/kg/day  
Result: negative  
Remarks: Information given is based on data obtained from similar substances.

Species: Mouse  
Dose: 300 mg/kg/day

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Result: negative

Remarks: Information given is based on data obtained from similar substances.

Carcinogenicity - Assessment : Did not show carcinogenic effects in animal experiments.

**IARC**

Group 2B: Possibly carcinogenic to humans

TITANDIOXIDE 13463-67-7

**OSHA**

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP**

No component 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**

**Components:**

**DARUNAVIR ETHANOLATE:**

Reproductive toxicity - Assessment : No information available.

Teratogenicity - Assessment : No information available.

**COBICISTAT:**

Effects on fertility : Species: Rat  
General Toxicity - Parent: NOAEL: 100 mg/kg  
Remarks: Fertility and developmental toxicity tests did not reveal any effect on reproduction.

Effects on foetal development : Species: Rat  
Teratogenicity: NOAEL: 50 mg/kg  
Remarks: Did not show teratogenic effects in animal experiments.

Species: Rabbit  
Teratogenicity: NOAEL: 100 mg/kg  
Remarks: Did not show teratogenic effects in animal experiments.

**Emtricitabine:**

Effects on fertility : Species: Rat, male  
Dose: 200 mg/day  
Remarks: Fertility and developmental toxicity tests did not reveal any effect on reproduction.

Species: Mouse, female  
Dose: 200 mg/day  
Remarks: Fertility and developmental toxicity tests did not reveal any effect on reproduction.

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Effects on foetal development : Species: Rabbit, female  
Dose: 1000 mg/kg/day  
Remarks: Did not show teratogenic effects in animal experiments.

Reproductive toxicity - Assessment : No evidence of adverse effects on sexual function and fertility, or on development, based on animal experiments.

### **Tenofovir Alafenamide Fumarate (TAF):**

Effects on fertility : Species: Rat, females  
Application Route: Oral  
Dose: 25, 100, 250 mg/kg/day  
General Toxicity - Parent: NOAEL: 100 mg/kg  
Remarks: Fertility and developmental toxicity tests did not reveal any effect on reproduction.

Species: Rabbit, females  
Application Route: Oral  
Dose: 10, 30, 100 mg/kg/day  
General Toxicity - Parent: NOAEL: 100 mg/kg  
Remarks: Fertility and developmental toxicity tests did not reveal any effect on reproduction.

Effects on foetal development : Remarks: No data available

Reproductive toxicity - Assessment : No evidence of reprotoxicity.

### **STOT - single exposure**

#### **Components:**

#### **DARUNAVIR ETHANOLATE:**

Assessment: No information available.

#### **COBICISTAT:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

#### **Emtricitabine:**

Remarks: No data available

#### **Tenofovir Alafenamide Fumarate (TAF):**

Remarks: No data available

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**STOT - repeated exposure****Components:****DARUNAVIR ETHANOLATE:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

**COBICISTAT:**

Remarks: No data available

**Repeated dose toxicity****Components:****DARUNAVIR ETHANOLATE:**

Species: Rat  
NOAEL: 19 mg/kg  
Exposure time: 6 months

Species: Dog  
NOAEL: 30 mg/kg  
Exposure time: 12 months

**COBICISTAT:**

Species: Rat  
Target Organs: Liver  
Remarks: No adverse effect has been observed in chronic toxicity tests.

**Emtricitabine:**

Species: Mouse  
NOAEL: 500 mg/kg  
Exposure time: 6 months  
Dose: 3000 mg/kg/day

Species: Rat  
NOAEL: 600 mg/kg  
Exposure time: 3 months  
Dose: 1500 mg/kg/day

Species: Monkey  
NOAEL: 200 mg/kg  
Exposure time: 12 months  
Dose: 2000 mg/kg/day

**Tenofovir Alafenamide Fumarate (TAF):**

Species: Mouse  
Exposure time: 13 weeks  
Dose: 10, 30, 100 mg/kg  
Remarks: No significant adverse effects were reported

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Species: Rat  
NOAEL: 25 mg/kg  
Exposure time: 26 weeks  
Dose: 100 mg/kg  
Target Organs: Bone, Kidney

Species: Dog  
NOAEL: 2 mg/kg  
Application Route: Oral  
Exposure time: 9 months  
Dose: 18 mg/kg/day  
Target Organs: Bone, Kidney

Species: Monkey  
NOAEL:  $\geq$  30 mg/kg  
Exposure time: 28 days  
Dose: 30 mg/kg/day

### Aspiration toxicity

No data available

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## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### **DARUNAVIR ETHANOLATE:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 38 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

NOEC (Oncorhynchus mykiss (rainbow trout)): 38 mg/l  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 44 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

NOEC (Daphnia magna (Water flea)): 2.6 mg/l  
Method: OECD Test Guideline 202

Toxicity to algae : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 43 mg/l  
Exposure time: 72 h  
Test Type: Growth inhibition  
Method: FDA 4.01

NOECr (Pseudokirchneriella subcapitata (green algae)): 43 mg/l  
Exposure time:  
Test Type: Growth inhibition  
Method: FDA 4.01

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EbC50 (Pseudokirchneriella subcapitata (green algae)): > 43 mg/l  
Exposure time: 72 h  
Test Type: Cell multiplication inhibition test  
Method: FDA 4.01

NOECb (Pseudokirchneriella subcapitata (green algae)): 43 mg/l  
Exposure time:  
Test Type: Cell multiplication inhibition test  
Method: FDA 4.01

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): > 9.4 mg/l  
Method: OECD Test Guideline 210

LOEC (Pimephales promelas (fathead minnow)): 9.4 mg/l  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 19 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

LOEC (Daphnia magna (Water flea)): 38 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

EC50 (Daphnia magna (Water flea)): > 38 mg/l  
Method: OECD Test Guideline 211

NOEC (Midge emergence (Chironomus riparius)): 80 mg/kg  
Method: OECD Test Guideline 218

LOEC (Midge emergence (Chironomus riparius)): > 80 mg/kg  
Method: OECD Test Guideline 218

EC50 (Midge emergence (Chironomus riparius)): > 80 mg/kg  
Exposure time: 28 d  
Method: OECD Test Guideline 218

Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

**COBICISTAT:**

Toxicity to fish : NOEC (Daphnia magna (Water flea)): 17.5 mg/l  
NOEC (Pimephales promelas (fathead minnow)): 4.84 mg/l

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae : NOEC (Pseudokirchneriella subcapitata (green algae)): 29.3 mg/l

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Toxicity to microorganisms : NOEC (activated sludge): > 1,000 mg/l

### **Emtricitabine:**

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae : Remarks: No data available

### **Tenofovir Alafenamide Fumarate (TAF):**

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae : Remarks: No data available

### **Persistence and degradability**

#### **Product:**

Biodegradability : Result: rapidly biodegradable

#### **Components:**

#### **DARUNAVIR ETHANOLATE:**

Biodegradability : Result: Not readily biodegradable.  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

#### **COBICISTAT:**

Biodegradability : Concentration: 1.0 mg/l  
Result: Not readily biodegradable.  
Exposure time: 28 d  
Kinetic:  
: 35.5 %  
Remarks: According to the results of tests of biodegradability this product is not readily biodegradable.

Concentration: 4.5 mg/l  
Result: Not readily biodegradable.  
Exposure time: 28 d  
Kinetic:  
: 8 %

#### **Emtricitabine:**

Biodegradability : Remarks: No data available

#### **Tenofovir Alafenamide Fumarate (TAF):**

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Biodegradability : Remarks: No data available

## Bioaccumulative potential

### Components:

#### **COBICISTAT:**

Bioaccumulation : Species: Fish  
Bioconcentration factor (BCF): 2  
Remarks: Does not bioaccumulate.

Partition coefficient: n-octanol/water : log Pow: 4.2  
Remarks: No data available

#### **Emtricitabine:**

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : Remarks: No data available

#### **Octadecanoic acid, magnesium salt:**

Partition coefficient: n-octanol/water : Remarks: No data available

#### **TITANDIOXIDE:**

Partition coefficient: n-octanol/water : Remarks: No data available

#### **Tenofovir Alafenamide Fumarate (TAF):**

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : Remarks: No data available

## Mobility in soil

### Components:

#### **DARUNAVIR ETHANOLATE:**

Distribution among environmental compartments : Adsorption/Soil  
Koc: > 265 Method: OECD Test Guideline 106

Adsorption/Soil  
Koc: < 993 Method: OECD Test Guideline 106

#### **COBICISTAT:**

Distribution among environmental compartments : Medium: Soil  
Koc: 3.624 - 9.012

Stability in soil : Dissipation time: 171 - 241 d



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Percentage dissipation: > 10 % (DT50)

## Other adverse effects

### Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances  
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : In accordance with National, Federal, State and Local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

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## 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 Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### National Regulations

#### 49 CFR

Not regulated as a dangerous good

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## SECTION 15. REGULATORY INFORMATION

### Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

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This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM1 Intermediate or Final VOC's (40 CFR 60.489).

**Clean Water Act**

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

**US State Regulations****Massachusetts Right To Know**

CELLULOSE	9004-34-6
TITANDIOXIDE	13463-67-7

**Pennsylvania Right To Know**

DARUNAVIR ETHANOLATE	635728-49-3
COBICISTAT	1004316-88-4
Emtricitabine	143491-57-0
CELLULOSE	9004-34-6
	74811-65-7
TITANDIOXIDE	13463-67-7

**New Jersey Right To Know**

DARUNAVIR ETHANOLATE	635728-49-3
COBICISTAT	1004316-88-4
Emtricitabine	143491-57-0
CELLULOSE	9004-34-6
	74811-65-7
TITANDIOXIDE	13463-67-7

**New York City Hazardous Substances**

TITANDIOXIDE	13463-67-7
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**California Prop 65**

WARNING! This product contains a chemical known to the State of California to cause cancer.

TITANDIOXIDE	13463-67-7
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**Other regulations**

: Restricted to professional users.

This product is not subject to TSCA and TSCA 12(b) Export notification because Food, Drugs and cosmetic products are exempt.

**California Permissible Exposure Limits for Chemical Contaminants**

CELLULOSE	9004-34-6
Octadecanoic acid, magnesium salt	557-04-0
TITANDIOXIDE	13463-67-7

**TSCA list**

Not relevant

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			Date of first issue: 2015/02/12

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**SECTION 16. OTHER INFORMATION****Full text of other abbreviations**

AICS - Australian Inventory of Chemical Substances; 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 Standardisation; 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 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; 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, Authorisation 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; 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

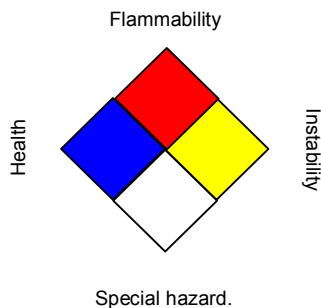
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## Further information

### NFPA:



### HMIS® IV:

HEALTH		
FLAMMABILITY		
PHYSICAL HAZARD		

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.

Revision Date : 2018/07/30

### Date and Number Formats

This document uses the following notation for printing dates and numbers:

**Date:** Dec 31th, 2012 as 2012/12/31  
**Numbers:** 123456,78 as 123,456.78

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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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