

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Janssen

PHARMACEUTICAL COMPANIES
of Johnson & Johnson

Version 1.20 Revision Date: 2016-12-06 SDS Number: 100000011734 Date of last issue: 2016-07-04
Date of first issue: 2015-08-28

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product Identifier**

Substance name : DARUNAVIR
TMC114
CAS-No. : 635728-49-3
Reference number : JNJ-25875382-AAA
R319064

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Active substance, Pharmaceutical

1.3 Details of the supplier of the safety data sheet

Company : Janssen Pharmaceutica NV
Turnhoutseweg 30
2340 Beerse
Belgium
Telephone : +3214602111
Telefax : +3214602841
E-mail address : SDSJanssen@its.jnj.com
Responsible/issuing person

1.4 Emergency telephone number

CHEMTREC BE: +(32)-28083237
CHEMTREC International: +1 703-527-3887

SECTION 2: Hazards Identification**2.1 Classification of the substance or mixture**

Classification (REGULATION (EC) No 1272/2008)
Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

Supplemental Hazard Statements : Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

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2.3 Other hazards

Non-classified PBT substance

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

SECTION 3: Composition/Information on ingredients**3.1 Substances**

Substance name : DARUNAVIR

Chemical nature : Solid

Hazardous components

Chemical name	CAS-No. EC-No.	Concentration (%)
Substances with a workplace exposure limit :		
DARUNAVIR	635728-49-3	<= 100

SECTION 4: First aid measures**4.1 Description of first aid measures**

If inhaled : If breathed in, move person into fresh air.
If symptoms persist, call 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).
Consult a physician after significant exposure.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : Ingestion may provoke the following symptoms:
Nausea
Headache
Drowsiness
tingling



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4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Water mist
Dry powder
Foam
Carbon dioxide (CO2)
Sand

Unsuitable extinguishing media : Water spray jet

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : Nitrogen oxides (NOx)
Sulphur oxides
Carbon oxides

5.3 Advice for firefighters

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

Further information : In the event of fire, cool tanks with water spray. Avoid dust formation.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Evacuate personnel to safe areas.
Avoid breathing dust.
Avoid dust formation.
Keep away from open flames, hot surfaces and sources of ignition.

6.2 Environmental precautions

Environmental precautions : Should not be released into the environment.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Large spills: Sweep up (intact) or vacuum with HEPA filter



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(broken or crushed) or via wet cleaning into suitable containers for disposal. Pick up and arrange without creating dust. Keep in properly labeled 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".

6.4 Reference to other sections

For disposal information, see section 13, Refer to protective measures listed in sections 7 and 8.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Ensure all equipment is electrically grounded before beginning transfer operations.
To avoid thermal decomposition, do not overheat.
Keep away from heat and sources of ignition.
Avoid inhalation, ingestion and contact with skin and eyes.
Avoid formation of dust and aerosols.

Advice on protection against fire and explosion : Avoid dust formation.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

Dust explosion class : SI2

7.2 Conditions for safe storage, including any incompatibilities

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

7.3 Specific end use(s)

Specific use(s) : Consult the technical guidelines for the use of this substance/mixture.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
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DARUNAVIR	635728-49-3	TWA	1,6 mg/m ³	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.			

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Fresh water
Value: 0,940 mg/l

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

8.2 Exposure controls

Engineering measures

Engineering controls should be used as the primary means to control possible exposures. Use process enclosures, local exhaust ventilation or other engineering controls to keep exposure levels below recommended exposure limits.

All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.

Personal protective equipment

Eye protection : Safety glasses with side-shields

Skin and body protection : closed work clothing
Long sleeved clothingRespiratory 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.

Suitable mask with particle filter P3

Protective measures : The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : powder

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Colour	: white, slight, beige
Odour	: odourless
Odour Threshold	: No data available
Melting point/range	: 103 - 105 °C
Boiling point/boiling range	: No data available
Burning number	: 2, 20 °C, Air 2, 100 °C, Air
Upper explosion limit	: No data available
Lower explosion limit	: 30 g/m ³
Relative vapour density	: No data available
Density	: No data available
Solubility(ies) Water solubility	: 0,16 g/l
Partition coefficient: n-octanol/water	: log Pow: 2,47 GLP: no
Auto-ignition temperature	: 410 °C Method: M.I.T. Dust Cloud BAM METHOD
Decomposition temperature	: 265 °C Minimum T

9.2 Other Information

Impact sensitivity : Not impact sensitive.
39 J

Molecular weight : 547,66 g/mol



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SECTION 10: Stability and reactivity

10.1 Reactivity

None reasonably foreseeable.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : No dangerous reaction known under conditions of normal use.

10.4 Conditions to avoid

Conditions to avoid : To avoid thermal decomposition, do not overheat.
Heat, flames and sparks.

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition products

Nitrogen oxides (NOx), Carbon oxides, Sulphur oxides, toxic smoke in case of fire

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product:

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

Skin corrosion/irritation

Product:

Result: No skin irritation
Remarks: Based on Animal Evidence

Serious eye damage/eye irritation

Product:

Remarks: May irritate eyes.



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Respiratory or skin sensitisation

Product:

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

Germ cell mutagenicity

Product:

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.

Carcinogenicity

Product:

Carcinogenicity - Assessment : No information available.

Reproductive toxicity

Product:

Reproductive toxicity - Assessment : No information available.

Teratogenicity - Assessment : No information available.

STOT - single exposure

Product:

Assessment: No information available.

STOT - repeated exposure

Product:

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



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Repeated dose toxicity

Product:

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

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

Aspiration toxicity
No data available

SECTION 12: Ecological information

12.1 Toxicity

Product:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 38 mg/l
Exposure time: 96 h
Test Type: static test
Method: OECD Test Guideline 203
GLP: yes
Remarks: No toxicity at the limit of solubility

NOEC (Oncorhynchus mykiss (rainbow trout)): 38 mg/l
Exposure time: 96 h
Test Type: static test
Method: OECD Test Guideline 203
GLP: yes

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 44 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202
GLP: yes
Remarks: No toxicity at the limit of solubility

NOEC (Daphnia magna (Water flea)): 2,6 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202
GLP: yes

Toxicity to algae : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 43 mg/l
End point: Growth rate
Exposure time: 72 h



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Test Type: Growth inhibition
Method: OECD Test Guideline 201
GLP: yes
Remarks: No toxicity at the limit of solubility

NOEC (Pseudokirchneriella subcapitata (green algae)): 43 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: Growth inhibition
Method: OECD Test Guideline 201
GLP: yes

EbC50 (Pseudokirchneriella subcapitata (green algae)): > 43 mg/l
End point: Biomass
Exposure time: 72 h
Test Type: Growth inhibition
Method: OECD Test Guideline 201
GLP: yes
Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity) : NOEC: 9,4 mg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)
Test Type: Fish early-life stage (FELS) toxicity test (OECD 210)
Method: OECD Test Guideline 210
GLP: yes

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

EC50: > 38 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Test Type: Daphnia reproduction test
Method: OECD Test Guideline 211
GLP: yes

NOEC: 80 mg/kg
Exposure time: 28 d
Species: Chironomus riparius (Midge larvae)
Test Type: Toxicity to sediment dwelling organisms
Method: OECD Test Guideline 218
GLP: yes

EC50: > 80 mg/kg



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Exposure time: 28 d
Species: *Chironomus riparius* (Midge larvae)
Test Type: Toxicity to sediment dwelling organisms
Method: OECD Test Guideline 218
GLP: yes

- Toxicity to bacteria :
- EC50 (activated sludge): > 1 000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
GLP: yes
 - NOEC (activated sludge): 1 000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
GLP: yes

12.2 Persistence and degradability

Product:

- Biodegradability :
- Test Type: aerobic
Inoculum: activated sludge
Result: Not readily biodegradable.
Exposure time: 28 d
Method: OECD Test Guideline 301B
GLP: yes
- Stability in water :
- Test Type: anaerobic
Degradation half life (DT50): 106,6 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: total system 2
 - Test Type: anaerobic
Degradation half life (DT50): 202,1 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: total system 1
 - Test Type: anaerobic
Degradation half life (DT50): 790,9 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: sediment 2
 - Test Type: anaerobic
Degradation half life (DT50): 27,5 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: sediment 1



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Test Type: anaerobic
Degradation half life (DT50): 33,9 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: Fresh water 1

Test Type: aerobic
Degradation half life (DT50): 37,1 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: total system 2

Test Type: aerobic
Degradation half life (DT50): 38,9 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: total system 1

Test Type: aerobic
Degradation half life (DT50): 65,6 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: sediment 2

Test Type: aerobic
Degradation half life (DT50): 73,7 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: sediment 1

Test Type: aerobic
Degradation half life (DT50): 17,4 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: Fresh water 1

Test Type: anaerobic
Degradation half life (DT50): 76,3 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: Fresh water 2

Test Type: aerobic
Degradation half life (DT50): 19,4 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: Fresh water 2

Test Type: anaerobic
Degradation half life (DT50): 161 d pH: 9
Method: OECD Test Guideline 111
GLP: yes

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Test Type: anaerobic
Degradation half life (DT50): > 300 d pH: 4
Method: OECD Test Guideline 111
GLP: yes

12.3 Bioaccumulative potential
No data available

12.4 Mobility in soil

Product:

Distribution among environmental compartments : Adsorption/Soil
Koc: 265 - 993 Method: OECD Test Guideline 106

12.5 Results of PBT and vPvB assessment

Product:

Assessment : Non-classified PBT substance.

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

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Must be incinerated in a suitable incineration plant holding a permit delivered by the competent authorities.
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.

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

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14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable for product as supplied.

SECTION 15: Regulatory Information

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

Svesvo III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

Other regulations : For professional users only.

15.2 Chemical safety assessment

A Chemical Safety Assessment is not required for this substance.

SECTION 16: Other information

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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