Version	Revision Date:	SDS Number:	Date of last issue: 2016/11/22
1.31	2017/03/28	100000002777	Date of first issue: 2015/04/16

SECTION 1. IDENTIFICATION

Substance name : ETRAVIRINE
TMC125
Substance No. : 269055-15-4
Reference number : JNJ-4371315-AAA
R165335

Manufacturer or supplier's details

Company name of supplier : Janssen Pharmaceutica NV

Address : Turnhoutseweg 30
Beerse 2340
Belgium
Telephone : +3214602111
Telefax : +3214602841

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 : Active Pharmaceutical Ingredient

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Acute toxicity (Oral) : Category 4

Chronic aquatic toxicity : Category 4

GHS label elements

Hazard pictograms :

Signal word : Warning

Hazard statements : H302 Harmful if swallowed.
H413 May cause long lasting harmful effects to aquatic life.

Precautionary statements : **Prevention:**
P264 Wash hands thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.

Response:
P330 Rinse mouth.
P301 + P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

Warning! May form combustible dust concentrations in air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Substance

Chemical nature : Solid

Hazardous components

Chemical name	CAS-No.	Concentration (%)
ETRAVIRINE	269055-15-4	>= 90 - <= 100

SECTION 4. 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 : Remove contact lenses.
Rinse immediately with plenty of water, also under the eyelids, for at least 5 minutes.
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 : Ingestion may provoke the following symptoms:
Headache
Nausea
Rash
Blood disorders
Diarrhoea
Kidney disorders

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. Water mist Dry powder Foam Carbon dioxide (CO2) Sand
Specific hazards during firefighting	:	Dust may form explosive mixture in air.
Hazardous combustion products	:	Nitrogen oxides (NOx) Carbon oxides
Further information	:	In the event of fire, cool tanks with water spray. Avoid dust formation.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Firefighters must wear fire resistant personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Evacuate personnel to safe areas. Avoid breathing dust. Avoid dust formation. Keep away from open flames, hot surfaces and sources of ignition.
Environmental precautions	:	Should not be released into the environment. Do not flush into surface water or sanitary sewer 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	:	Avoid dust formation. Keep away from heat and sources of ignition.
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 formation of dust and aerosols.

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.
Store at room temperature.
Keep containers tightly closed in a dry, cool and well-ventilated place.
Keep away from heat and sources of ignition.

Recommended storage temperature : 15 - 25 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
ETRAVIRINE	269055-15-4	TWA	3 mg/m3	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.			

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

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.
Use only respiratory protection that conforms to international/national standards.

Suitable mask with particle filter P100

Hand protection
Material : Nitrile rubber

Remarks	:	Impervious gloves Take note of the information given by the producer concerning permeability and break through times, and of special workplace conditions (mechanical strain, duration of contact).
Eye protection	:	Safety glasses with side-shields
Skin and body protection	:	closed work clothing disposable one-piece overall with integral hood
Protective measures	:	The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Hygiene measures	:	Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Colour	:	white
Odour	:	odourless
Odour Threshold	:	No data available
Melting point/range	:	240 °C
Boiling point/boiling range	:	No data available
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Relative vapour density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	< 0.001 g/l
Partition coefficient: n-octanol/water	:	Pow: 3.4Method: OECD Test Guideline 117 GLP: yes
Auto-ignition temperature	:	> 570 °C Method: M.I.T. Dust Cloud BAM METHOD
Decomposition temperature	:	220 °C Minimum T

Impact sensitivity	:	Not impact sensitive. 39 J Method: Lutolf Method Mechanical sensitivity (shock)
Molecular weight	:	435.29 g/mol

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	None reasonably foreseeable.
Chemical stability	:	Stable under recommended storage conditions.
Possibility of hazardous reactions	:	No data available
Conditions to avoid	:	To avoid thermal decomposition, do not overheat. Heat, flames and sparks.
Incompatible materials	:	Strong oxidizing agents
Hazardous decomposition products	:	Carbon monoxide Nitrogen oxides (NOx) Halogenated compounds Bromine

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity	:	LD50 (Rat, male and female): > 640 mg/kg Target Organs: Liver

Skin corrosion/irritation

Product:

Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation

Product:

Result: Mild eye irritation
Method: In vitro BCOP (Bovine Corneal Opacity and Permeability) assay

Respiratory or skin sensitisation

Product:

Result: Not expected to cause skin sensitization

Germ cell mutagenicity

Product:

Genotoxicity in vitro : Test Type: in vitro assay
Result: negative

Genotoxicity in vivo : Test Type: in vivo assay
Result: negative

Carcinogenicity

Product:

Remarks: No data available

IARC	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
OSHA	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.
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

Product:

Effects on fertility : Species: Rat
Dose: 506 mg/kg
Application Route: Oral

Remarks: Fertility and developmental toxicity tests did not reveal any effect on reproduction.

Species: Rat
Dose: 1000 mg/kg
Application Route: Oral
NOAEL: 1,000 mg/kg

Species: Rabbit
Dose: 375 mg/kg
Application Route: Oral
NOAEL: 125 mg/kg

Effects on foetal development : Remarks: Did not show teratogenic effects in animal experiments.

STOT - single exposure

Product:

Remarks: No data available

STOT - repeated exposure

Product:

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

Repeated dose toxicity

Product:

Species: Rat
NOAEL: 320 mg/kg
Application Route: Oral
Exposure time: 1 month
Number of exposures: 24h

Aspiration toxicity

No data available

Further information

Product:

Remarks: Not phototoxic

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Toxicity to algae	:	EC50 (Scenedesmus subspicatus (fresh water algae)): > 4.9 µg/lExposure time: 72 h Method: OECD Test Guideline 201 NOEC (Scenedesmus subspicatus (fresh water algae)): 4.9 µg/lExposure time: 72 h Method: OECD Test Guideline 201 ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0.0049 mg/lEnd point: Growth rate Exposure time: 72 h Test Type: Growth inhibition Method: OECD Test Guideline 201 GLP: yes EbC50 (Pseudokirchneriella subcapitata (green algae)): > 0.0049 mg/lEnd point: Growth rate

Exposure time: 72 h
Test Type: Growth inhibition
Method: OECD Test Guideline 201
GLP: yes

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.0049 mg/lEnd point: Growth rate
Exposure time: 72 h
Test Type: Growth inhibition
Method: OECD Test Guideline 201
GLP: yes

Toxicity to fish (Chronic toxicity) : NOEC (Danio rerio (zebra fish)): 0.01 mg/l
Exposure time: 35 Days
Method: OECD Test Guideline 210

NOEC (Brachydanio rerio (zebrafish)): 0.01 mg/l
Exposure time: 28 d
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 (Daphnia magna (Water flea)): 0.0091 mg/l
Exposure time: 21 Days
Test Type: Daphnia reproduction test
Method: OECD Test Guideline 211
GLP: yes

NOEC (Chironomus riparius (Midge larvae)): 0.02 mg/l
Exposure time: 28 d
Test Type: Toxicity to sediment dwelling organisms
Method: OECD Test Guideline 219
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

: NOEC (Soil microorganisms): 100 mg/kg
Exposure time: 28 d
Test Type: Nitrogen transformation
Method: OECD Test Guideline 216
GLP: yes

Toxicity to soil dwelling organisms : Test Type: Reproduction Test
NOEC (Springtail (Collembola)): > 1,000 mg/kg

Exposure time: 28 d
Method: ISO 11267
GLP: yes

LC50 (Eisenia fetida (earthworms)): > 1,000 mg/kg
Exposure time: 14 d
Method: OECD TG 207

Test Type: Acute toxicity
EC50 (Eisenia fetida (earthworms)): > 1,000 mg/kg
Exposure time: 14 d
Method: OECD Test Guideline 207
GLP: yes

Test Type: Acute toxicity
NOEC (Eisenia fetida (earthworms)): 1,000 mg/kg
Exposure time: 14 d
Method: OECD Test Guideline 207
GLP: yes

Plant toxicity : NOEC (Terestrial plants): 76 mg/kg
Method: OECD Test Guideline 208
GLP: yes

Persistence and degradability

Product:

Stability in water : Test Type: aerobic
Degradation half life (DT50): 0.6 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: Fresh water 1

Degradation half life (DT90): 1.1 d
Method: OECD Test Guideline 308
Remarks: aerobic

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

Degradation half life (DT90): 3.6 d
Method: OECD Test Guideline 308
Remarks: aerobic

Test Type: anaerobic
Degradation half life (DT50): 3.2 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: Fresh water 1

Bioaccumulative potential

Product:

Bioaccumulation : Species: Oncorhynchus mykiss (rainbow trout)
Bioconcentration factor (BCF): 370.3
Exposure time: 14 d
Method: OECD Test Guideline 305
GLP: yes

Species: Oncorhynchus mykiss (rainbow trout)
Bioconcentration factor (BCF): 476.9
Exposure time: 14 d
Method: OECD Test Guideline 305
GLP: yes

Mobility in soil

Product:

Distribution among environmental compartments : Adsorption/HPLC
Koc: 16617Method: OECD Test Guideline 121

Stability in soil : Test Type: Aerobic transformation in soil
Method: OECD Test Guideline 307
GLP: yes

Other adverse effects

Product:

Results of PBT and vPvB assessment : Non-classified PBT substance

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).

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Must be incinerated in a suitable incineration plant holding a permit delivered by the competent authorities.
Uncontrolled disposal or recycling of this packaging is not permitted and can be dangerous.In accordance with local and national regulations.

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

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

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know Act

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).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI 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.

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

ETRAVIRINE	269055-15-4	90 - 100 %

New Jersey Right To Know

ETRAVIRINE	269055-15-4	90 - 100 %

California Prop 65

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

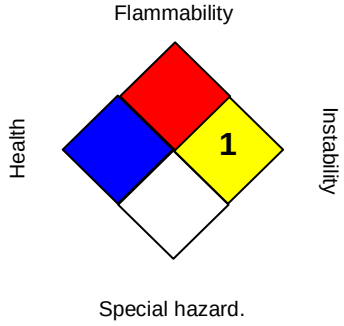
Other regulations : For professional users only.

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

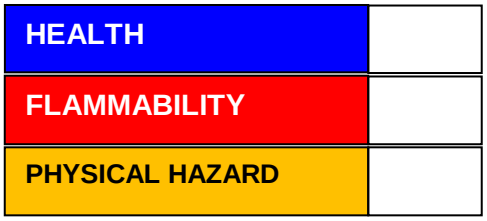
SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS III:



0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

Revision Date : 2017/03/28

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

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