

Aptivus® Oral Solution

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000030837 Date of last issue: -
Date of first issue: 06/03/2015

SECTION 1. IDENTIFICATION

Product name : Aptivus® Oral Solution

Synonyms : Active ingredient: Tipranavir <= 10 %
Aptivus® oral Solution 100mg/m (Bulk)

Product code : 000000030837

Manufacturer or supplier's details

Company name of supplier : Boehringer-Ingelheim Pharmaceuticals, Incorporated

Address : 900 Ridgebury Road
Ridgefield, Connecticut
06877-0368

Emergency telephone number : +1-800-424-9300 CHEMTREC Emergency Phone Number
CHEMTREC – 24 Hours

Routine Contact Number : (203) 778-7759

Recommended use of the chemical and restrictions on use

Recommended use : Solution for production of finished medicinal products.

Prepared by : Corp. Div. EHS & Sustainability / Global EHS Services
EHS-service@boehringer-ingelheim.com

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification (Hazard Communication Standard (HCS) 29 CFR 1910.1200)**

Not a hazardous substance or mixture.

GHS Label element (Hazard Communication Standard (HCS) 29 CFR 1910.1200)

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
Tipranavir	174484-41-4	<= 10

No hazardous ingredients

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000030837 Date of last issue: -
Date of first issue: 06/03/2015

SECTION 4. FIRST AID MEASURES

- General advice : Remove from exposure, lie down.
Take off immediately all contaminated clothing.
Victim to lie down in the recovery position, cover and keep him warm.
First Aid responders should pay attention to self-protection and use the recommended protective clothing
- If inhaled : Keep patient calm, remove to fresh air, seek medical attention.
- In case of skin contact : Wash off thoroughly with ample water.
Seek medical attention.
- In case of eye contact : Immediately wash affected eyes for at least 15 minutes under running water with eyelids held open, consult an eye specialist.
- If swallowed : Rinse mouth immediately and then drink plenty of water, seek medical attention.
- Most important symptoms and effects, both acute and delayed : Causes skin and eye irritation.
- Notes to physician : Observe the summary of product characteristics of proprietary medicinal products
-

SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Water
Dry chemical
Foam
Carbon dioxide (CO₂)
- Specific hazards during fire-fighting : In case of fire and/or explosion do not breathe fumes.
Can be released in case of fire:
Carbon oxides
Nitrogen oxides (NO_x)
Sulphur oxides
Hydrogen fluoride
- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
- Special protective equipment for firefighters : Wear self-contained breathing apparatus and chemical-protective clothing.

Aptivus® Oral Solution

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000030837 Date of last issue: -
Date of first issue: 06/03/2015

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Wear protective equipment. Keep unprotected persons away. Ensure adequate ventilation. High risk of slipping due to leakage/spillage of product.
- Environmental precautions : Do not flush into surface water or sanitary sewer system.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : No hazards which require special first aid measures.
- Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms. Keep container closed when not in use.
- Conditions for safe storage : Protect from heat and direct sunlight. Keep container tightly closed. Jointless smooth floor
- Materials to avoid : Keep away from food, drink and animal feedingstuffs. Advice on Segregation

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

Components	Basis	Factor	Cateryory	Values	Remark
(R-(R*,R*))-N-(3-(1-(5,6-Dihydro-4-hydroxy-2-oxo-6-(2-phenylethyl)-6-propyl-2H-pyran-3-yl)propyl)phenyl-5-(trifluoromethyl)-2-pyridyl)-2-pyridyl-1,4-diazepine-5-carboxamide trihydrate	ECL		2	120 µg/m ³	
	BIPC		1b		
ECL (BIPI Exposure Control Limit)					

Contains no substances with occupational exposure limit values.

Engineering measures : Local exhaust

Personal protective equipment

Respiratory protection : Not required; except in case of aerosol formation.

Hand protection Material : Chemical resistant gloves made of butyl rubber or nitrile rubber

Aptivus® Oral Solution

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	06/03/2015	000000030837	Date of first issue: 06/03/2015

Directive	: ber category III according to EN 374. : Protective gloves against chemicals and micro-organisms
Eye protection	: Safety glasses with side-shields
Skin and body protection	: Laboratory: laboratory coat; factory: disposable Overall.
Protective measures	: Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing.
Hygiene measures	: General industrial hygiene practice. Wash hands and face before breaks and immediately after handling the product. Keep working clothes separately.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: liquid
Colour	: No data available
Odour	: No data available
Odour Threshold	: No data available
pH	: No data available
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: Not applicable
Evaporation rate	: No data available
Flammability (solid, gas)	: does not ignite
Upper explosion limit	: Not applicable
Lower explosion limit	: Not applicable
Vapour pressure	: No data available
Relative vapour density	: No data available
Relative density	: No data available
Density	: No data available
Solubility(ies)	

Aptivus® Oral Solution

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	06/03/2015	000000030837	Date of first issue: 06/03/2015

Water solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: Not applicable
Decomposition temperature	: No data available
Viscosity	
Viscosity, dynamic	: No data available
Explosive properties	: No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: No dangerous reaction known under conditions of normal use.
Chemical stability	: No decomposition if stored and applied as directed.
Possibility of hazardous reactions	: No dangerous reaction known under conditions of normal use.
Conditions to avoid	: Extremes of temperature and direct sunlight.
Incompatible materials	: No data available

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified based on available information.

Product:

Acute oral toxicity	: Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
---------------------	--

Components:**Tipranavir:**

Acute oral toxicity	: LD50 (Rat, male): > 5,000 mg/kg LD0 (Rat): = 1,000 mg/kg LD50 (Mouse): > 3,000 mg/kg
---------------------	--

Acute inhalation toxicity	: Remarks: No data available
---------------------------	------------------------------

Acute dermal toxicity	: Remarks: No data available
-----------------------	------------------------------

Skin corrosion/irritation

Causes skin irritation.

Aptivus® Oral Solution

Version Revision Date: MSDS Number: Date of last issue: -
1.0 06/03/2015 000000030837 Date of first issue: 06/03/2015

Components:**Tipranavir:**

Species: Rabbit

Result: Slightly irritating.

Species: Rabbit

Result: Severe skin irritation

Serious eye damage/eye irritation

Causes eye irritation.

Components:**Tipranavir:**

Species: Rabbit

Result: Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Components:**Tipranavir:**

Method: DEREK

Result: No alert for skin sensitization

Germ cell mutagenicity

Not classified based on available information.

Components:**Tipranavir:**

Genotoxicity in vitro	:	Test Type: Ames-test Species: Salmonella typhimurium Result: negative
	:	Test Type: Chromosomal aberration test Species: Human lymphocytes Result: negative
	:	Test Type: Mammalian cell gene mutation assay Species: CHO (chinese hamster ovary) Result: negative
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse Result: negative

Carcinogenicity

Not classified based on available information.

Components:**Tipranavir:**

Remarks: No data available

Aptivus® Oral Solution

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	06/03/2015	000000030837	Date of first issue: 06/03/2015

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

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity**Components:****Tipranavir:**

Species: Rat

NOAEL: 40 mg/kg

Exposure time: 28-day

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Tipranavir:**

Toxicity to fish : LC50 (Onchorhynchus mykiss): = 15.4 mg/l

Exposure time: 96 h

Test Type: static test

Method: OECD Test Guideline 203

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): = 5.0 mg/l

aquatic invertebrates

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae : EC50 (Desmodesmus subspicatus): > 40.4 mg/l

End point: Biomass

Exposure time: 96 h

Method: OECD Test Guideline 201

EC50 (Desmodesmus subspicatus): > 40.4 mg/l

Aptivus® Oral Solution

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000030837 Date of last issue: -
Date of first issue: 06/03/2015

End point: Growth rate
Exposure time: 96 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: No data available

Toxicity to bacteria : EC50 (bacterium): > 1,000 mg/l
Exposure time: 3 h

Persistence and degradability

No data available

Bioaccumulative potential**Components:****Tipranavir:**

Partition coefficient: n-octanol/water : log Pow: 4.0 (ca. 25 °C)
Method: OECD Test Guideline 117

Mobility in soil**Product:**

Distribution among environmental compartments : Remarks: No data available

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).

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.
Must not be disposed off together with household garbage. Do not allow product to reach sewage system.

Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents.
Uncontaminated packaging can be recycled.

SECTION 14. TRANSPORT INFORMATION**International Regulation**

Aptivus® Oral Solution

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	06/03/2015	000000030837	Date of first issue: 06/03/2015

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations**SECTION 15. REGULATORY INFORMATION****EPCRA - Emergency Planning and Community Right-to-Know Act****SARA 311/312 Hazards** : Acute Health Hazard**SARA 302** : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.**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.**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 12 (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 SOCM 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

Massachusetts Right To Know

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

Pennsylvania Right To Know

Non-hazardous galenic excipients	Not Assigned	90 - 100 %
Tipranavir	174484-41-4	10 - 20 %

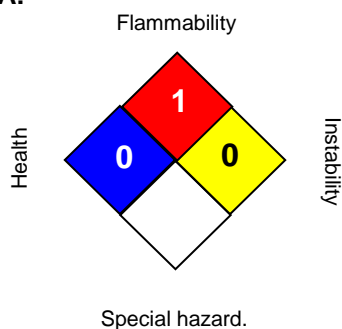
New Jersey Right To Know

Non-hazardous galenic excipients	Not Assigned	90 - 100 %
Tipranavir	174484-41-4	10 - 20 %

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.

Aptivus® Oral Solution

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000030837 Date of last issue: -
Date of first issue: 06/03/2015

SECTION 16. OTHER INFORMATION**Further information****NFPA:****HMIS III:**

HEALTH	0
FLAMMABILITY	1
PHYSICAL HAZARD	0

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

Vertical lines in the left hand margin indicate an amendment from the previous version.
Sources of key data used to compile the Safety Data Sheet : The specifications are based on own tests and/or literature data.
Revision Date : 06/03/2015

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.