

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING**Product Identifier****Material Name: Atazanavir Sulfate Capsules (Greenstone LLC)****Trade Name:** Not applicable
Chemical Family: Not determined**Relevant Identified Uses of the Substance or Mixture and Uses Advised Against****Intended Use:** Pharmaceutical product used for Treatment of HIV-1 Infections**Details of the Supplier of the Safety Data Sheet**Greenstone LLC
100 Route 206 North
Peapack, NJ 07977
800-435-7095**Emergency telephone number:**
CHEMTREC (24 hours): 1-800-424-9300**2. HAZARDS IDENTIFICATION****Classification of the Substance or Mixture****GHS - Classification**Serious Eye Damage/Eye Irritation: Category 1
Specific target organ systemic toxicity (repeated exposure): Category 2**Label Elements****Signal Word:** Danger
Hazard Statements: H318 - Causes serious eye damage
H372 - Causes damage to organs through prolonged or repeated exposure**Precautionary Statements:** P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTRE or doctor/physician
P314 - Get medical attention/advice if you feel unwell
P501 - Dispose of contents/container in accordance with all local and national regulations**Other Hazards**

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Ammonium hydroxide	1336-21-6	215-647-6	Skin Corr. 1B (H314) Aquatic Acute 1 (H400)	<1.0
Atazanavir sulfate	229975-97-7	Not Listed	STOT RE.2 (H373) Eye Dam. 1 (H318)	63.2
Ferric oxide red	1309-37-1	215-168-2	Not Listed	*
Isopropyl alcohol	67-63-0	200-661-7	STOT SE 3 (H336) Flam. Liq. 2 (H225) Eye Irrit. 2A (H319)	<1.0
Magnesium Stearate	557-04-0	209-150-3	Not Listed	*
N-BUTYL ALCOHOL	71-36-3	200-751-6	Acute Tox. 4 (H302) STOT SE 3 (H335) STOT SE 3 (H336) Skin Irrit. 2 (H315) Flam. Liq. 3 (H226) Eye Dam. 1 (H318)	<1.0
Propylene glycol	57-55-6	200-338-0	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Black Iron Oxide	1317-61-9	215-277-5	Not Listed	*
Crospovidone	9003-39-8	Not Listed	Not Listed	*
FD&C Blue No. 2	860-22-0	212-728-8	Not Listed	*
Ferric oxide yellow	51274-00-1	257-098-5	Not Listed	*
Gelatin	9000-70-8	232-554-6	Not Listed	*
Lactose NF, monohydrate	64044-51-5	Not Listed	Not Listed	*
Shellac	9000-59-3	232-549-9	Not Listed	*
Simethicone	8050-81-5	Not Listed	Not Listed	*

Additional Information: * Proprietary
 Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

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Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: No data available

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

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Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Ferric oxide red

ACGIH Threshold Limit Value (TWA)	5 mg/m ³
Australia TWA	5 mg/m ³ 10 mg/m ³
Austria OEL - MAKs	5 mg/m ³ 10 mg/m ³
Belgium OEL - TWA	5 mg/m ³
Bulgaria OEL - TWA	5.0 mg/m ³
Denmark OEL - TWA	3.5 mg/m ³
Estonia OEL - TWA	3.5 mg/m ³
Finland OEL - TWA	5 mg/m ³
France OEL - TWA	5 mg/m ³
Greece OEL - TWA	10 mg/m ³
Hungary OEL - TWA	6 mg/m ³
Ireland OEL - TWAs	5 mg/m ³ 10 mg/m ³ 4 mg/m ³
Lithuania OEL - TWA	3.5 mg/m ³
OSHA - Final PELs - TWAs:	10 mg/m ³ 15 mg/m ³
Poland OEL - TWA	5 mg/m ³
Portugal OEL - TWA	5 mg/m ³
Romania OEL - TWA	5 mg/m ³
Slovakia OEL - TWA	1.5 mg/m ³
Spain OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	3.5 mg/m ³

Isopropyl alcohol

ACGIH Threshold Limit Value (TWA)	200 ppm
ACGIH Threshold Limit Value (STEL)	400 ppm
ACGIH - Biological Exposure Limit:	40 mg/L
Australia STEL	500 ppm 1230 mg/m ³
Australia TWA	400 ppm 983 mg/m ³
Austria OEL - MAKs	200 ppm 500 mg/m ³
Belgium OEL - TWA	200 ppm 500 mg/m ³
Bulgaria OEL - TWA	980.0 mg/m ³
Czech Republic OEL - TWA	500 mg/m ³
Denmark OEL - TWA	200 ppm 490 mg/m ³
Estonia OEL - TWA	150 ppm 350 mg/m ³
Finland OEL - TWA	200 ppm 500 mg/m ³
Germany - TRGS 900 - TWAs	200 ppm 500 mg/m ³

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Germany (DFG) - MAK	200 ppm
	500 mg/m ³
Germany - Biological Exposure Limit:	25 mg/L
Greece OEL - TWA	400 ppm
	980 mg/m ³
Hungary OEL - TWA	500 mg/m ³
Ireland OEL - TWAs	200 ppm
Japan - OELs - Ceilings	400 ppm
	980 mg/m ³
Latvia OEL - TWA	350 mg/m ³
Lithuania OEL - TWA	150 ppm
	350 mg/m ³
OSHA - Final PELs - TWAs:	400 ppm
	980 mg/m ³
Poland OEL - TWA	900 mg/m ³
Portugal OEL - TWA	200 ppm
Romania OEL - TWA	81 ppm
	200 mg/m ³
Romania - Biological Exposure Limit:	50 mg/L
Slovakia OEL - TWA	200 ppm
	500 mg/m ³
Slovenia OEL - TWA	200 ppm
	500 mg/m ³
Spain OEL - TWA	200 ppm
	500 mg/m ³
Spain - Biological Exposure Limit:	40 mg/L
Sweden OEL - TWAs	150 ppm
	350 mg/m ³
Magnesium Stearate	
Lithuania OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	5 mg/m ³
N-BUTYL ALCOHOL	
ACGIH Threshold Limit Value (TWA)	20 ppm
Australia PEAK	50 ppm
	152 mg/m ³
Austria OEL - MAKs	50 ppm
	150 mg/m ³
Belgium OEL - TWA	20 ppm
	62 mg/m ³
Bulgaria OEL - TWA	100 mg/m ³
Czech Republic OEL - TWA	300 mg/m ³
Estonia OEL - TWA	15 ppm
	45 mg/m ³
Finland OEL - TWA	50 ppm
	150 mg/m ³
Germany - TRGS 900 - TWAs	100 ppm
	310 mg/m ³
Germany (DFG) - MAK	100 ppm
	310 mg/m ³
Germany - Biological Exposure Limit:	10 mg/g
	2 mg/g
Greece OEL - TWA	100 ppm
	300 mg/m ³

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Hungary OEL - TWA	45 mg/m ³
Ireland OEL - TWAs	20 ppm
Japan - OELs - Ceilings	50 ppm
	150 mg/m ³
Latvia OEL - TWA	10 mg/m ³
Lithuania OEL - TWA	15 ppm
	45 mg/m ³
OSHA - Final PELs - TWAs:	100 ppm
	300 mg/m ³
Poland OEL - TWA	50 mg/m ³
Portugal OEL - TWA	20 ppm
Romania OEL - TWA	33 ppm
	100 mg/m ³
Slovakia OEL - TWA	100 ppm
	310 mg/m ³
Slovak Republic - Biological Exposure Limit:	2 mg/g creatinine
	10 mg/g creatinine
Slovenia OEL - TWA	100 ppm
	310 mg/m ³
Spain OEL - TWA	20 ppm
	61 mg/m ³
Sweden OEL - TWAs	15 ppm
	45 mg/m ³
Propylene glycol	
Australia TWA	150 ppm
	474 mg/m ³
	10 mg/m ³
Ireland OEL - TWAs	150 ppm
	470 mg/m ³
	10 mg/m ³
Latvia OEL - TWA	7 mg/m ³
Lithuania OEL - TWA	7 mg/m ³
Titanium dioxide	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Austria OEL - MAKs	5 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Denmark OEL - TWA	6 mg/m ³
Estonia OEL - TWA	5 mg/m ³
France OEL - TWA	10 mg/m ³
Greece OEL - TWA	10 mg/m ³
	5 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
Latvia OEL - TWA	10 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Poland OEL - TWA	10.0 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Romania OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³
Sweden OEL - TWAs	5 mg/m ³

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Manufacturer OEB Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Atazanavir sulfate
Manufacturer OEB:

OEB2 (control exposure to the range of >100ug/m³ to < 1000ug/m³)

Exposure Controls
Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands:

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection:

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Capsule	Color:	Various
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water Solubility:	No data available		
pH:	No data available.		
Melting/Freezing Point (°C):	No data available		
Boiling Point (°C):	No data available.		
Partition Coefficient: (Method, pH, Endpoint, Value)			
Atazanavir sulfate	No data available		
Crospovidone	No data available		
Lactose NF, monohydrate	No data available		
Magnesium Stearate	No data available		

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9. PHYSICAL AND CHEMICAL PROPERTIES

Gelatin

No data available

FD&C Blue No. 2

No data available

Titanium dioxide

No data available

Ferric oxide red

No data available

Shellac

No data available

Isopropyl alcohol

No data available

Ammonium hydroxide

No data available

Propylene glycol

No data available

Simethicone

No data available

Black Iron Oxide

No data available

Ferric oxide yellow

No data available

N-BUTYL ALCOHOL

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

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11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Known Clinical Effects: Common adverse effects include nausea, yellowing of the skin, eyes, and mucous membranes (jaundice), headache skin rash. Severe effects could include inflammation of the pancreas (pancreatitis), liver failure, decreased red blood cell count (anemia), neutropenia, inflammation of the liver.

Acute Toxicity: (Species, Route, End Point, Dose)

Atazanavir sulfate

Rat Oral LD50 > 1600 mg/kg
Mouse Oral LD50 > 1600mg/kg

FD&C Blue No. 2

Rat Oral LD50 2 g/kg
Mouse Oral LD50 2500mg/kg

Titanium dioxide

Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD50 50 mg/kg

Isopropyl alcohol

Rat Oral LD50 > 2000 mg/kg
Mouse Oral LD50 3600 mg/kg
Rat Inhalation LC50-8h 16,000 ppm
Rabbit Dermal LD50 12800 mg/kg
Rat Inhalation LC50 30mg/L

Ammonium hydroxide

Rat Oral LD50 350 mg/kg

Propylene glycol

Rat Oral LD 50 22,000 mg/kg
Mouse Oral LD 50 24,900mg/kg
Rabbit Dermal LD 50 20,800mg/kg

Black Iron Oxide

Rat Oral LD50 >1000 mg/kg

N-BUTYL ALCOHOL

Rat Oral LD 50 2292 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Atazanavir sulfate

Eye Irritation Not specified Severe
Skin Irritation Not specified Non-irritating
Skin Sensitization Not specified Negative

Isopropyl alcohol

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11. TOXICOLOGICAL INFORMATION

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Ammonium hydroxide

Eye Irritation Rabbit Severe

Propylene glycol

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

N-BUTYL ALCOHOL

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Irritant

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Atazanavir sulfate

3 Month(s) Rat Oral 1000 mg/kg/day NOAEL None identified
9 Month(s) Dog Oral 10 mg/kg/day NOAEL Liver

Magnesium Stearate

13 Week(s) Rat Oral 1092 g/kg LOAEL Liver

Isopropyl alcohol

20 Week(s) Rat Inhalation 4000 ppm NOAEL Liver, Central nervous system
104 Week(s) Rat Inhalation 5000 ppm Kidney

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Atazanavir sulfate

Fertility and Embryonic Development Rat Oral 100 mg/kg/day LOAEL Maternal toxicity
Fertility and Embryonic Development Rat Oral 1400 mg/kg/day NOAEL No evidence of impaired fertility or harm to the fetus
Embryo / Fetal Development Rat Oral 200 mg/kg/day LOAEL Maternal Toxicity
Embryo / Fetal Development Rabbit Oral 15 mg/kg/day NOAEL Maternal Toxicity
Prenatal & Postnatal Development Rat Oral 50 mg/kg/day LOAEL Maternal Toxicity

Isopropyl alcohol

Prenatal & Postnatal Development Rat Inhalation 7,000 ppm LOAEL Maternal toxicity, Fetotoxicity, Embryotoxicity
2 Generation Reproductive Toxicity Rat Oral 1000 mg/kg/day LOAEL Maternal Toxicity, Fetal mortality
Prenatal & Postnatal Development Rat Oral 1200 mg/kg/day NOAEL No effects at maximum dose,

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Atazanavir sulfate

In Vitro Bacterial Mutagenicity (Ames) Not specified Negative
In Vitro Chromosome Aberration Not specified Positive
In Vivo Micronucleus Rat Negative
In Vivo Unscheduled DNA Synthesis Rat Negative

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11. TOXICOLOGICAL INFORMATION

FD&C Blue No. 2

Bacterial Mutagenicity (Ames) *Salmonella* Negative

Isopropyl alcohol

Bacterial Mutagenicity (Ames) *Salmonella* Negative
Mammalian Cell Mutagenicity HGPRT Chinese Hamster Ovary (CHO) cells Negative
In Vitro Sister Chromatid Exchange Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Atazanavir sulfate

2 Year(s) Rat Oral > 1200 mg/kg/day NOAEL Not carcinogenic
2 Year(s) Mouse Oral > 120 mg/kg/day NOAEL Liver, Tumors, Not carcinogenic

Carcinogen Status: See below

Crospovidone

IARC: Group 3 (Not Classifiable)

Titanium dioxide

IARC: Group 2B (Possibly Carcinogenic to Humans)

Ferric oxide red

IARC: Group 3 (Not Classifiable)

Isopropyl alcohol

IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been investigated. Releases to the environment should be avoided.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Atazanavir sulfate

Oncorhynchus mykiss (Rainbow Trout) LC50 96 Hours > 89 mg/L
Daphnia magna (Water Flea) EC50 48 Hours > 5.4 mg/L
Pseudokirchneriella subcapitata (Green Alga) EC50 72 Hours > 4.1 mg/L

Ammonium hydroxide

Daphnia magna (Water Flea) LC50 48 Hours 0.66 mg/L
Lepomis macrochirus (Bluegill Sunfish) LC50 48 Hours 0.024 mg/L
Pimephales promelas (Fathead Minnow) LC50 96 Hours 8.2 mg/L

Terrestrial Toxicity: (Species, Method, End Point, Duration, Result)

Atazanavir sulfate

Chironomus riparius (Midges) EC50 28 Days > 100 mg/kg

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Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

Atazanavir sulfate

Daphnia magna (Water Flea) 21 Day(s) NOEC 5.1 mg/L
Pimephales promelas (Fathead Minnow) 32 Day(s) NOEC > 8.6 mg/L

Persistence and Degradability:

Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

Atazanavir sulfate Ready 0% After 43 Day(s) Not readily biodegradable.

Photolysis: (Method, pH, Endpoint, Results)

Atazanavir sulfate 7 Half-Life 12.5 Day(s)

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

N-BUTYL ALCOHOL

RCRA - U Series Wastes

Listed

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

WHMIS hazard class:

None required

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15. REGULATORY INFORMATION

Ammonium hydroxide

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-647-6

Atazanavir sulfate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Black Iron Oxide

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	215-277-5

Crospovidone

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

FD&C Blue No. 2

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	212-728-8

Ferric oxide red

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	215-168-2

Ferric oxide yellow

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	257-098-5

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15. REGULATORY INFORMATION

Gelatin

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-554-6

Isopropyl alcohol

CERCLA/SARA 313 Emission reporting	1.0 %
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-661-7

Lactose NF, monohydrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Magnesium Stearate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

N-BUTYL ALCOHOL

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	200-751-6

Propylene glycol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-338-0

Shellac

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-549-9

SAFETY DATA SHEET

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15. REGULATORY INFORMATION

Simethicone

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Titanium dioxide

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen 9/2/2011 airborne, unbound particles of respirable size
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	236-675-5

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage
Specific target organ toxicity, repeated exposure-Cat.2; H372 - Causes damage to organs through prolonged or repeated exposure
Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Skin corrosion/irritation-Cat.2; H315 - Causes skin irritation
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation
Specific target organ toxicity, single exposure; Narcotic effects-Cat.3; H336 - May cause drowsiness and dizziness
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation
Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor
Flammable liquids-Cat.3; H226 - Flammable liquid and vapor
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life

Data Sources: The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: New data sheet.

Revision date: 19-Nov-2017

Prepared by: Product Stewardship Hazard Communication
Global Environment, Health, and Safety Operations

It is believed that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time

End of Safety Data Sheet