Issued: Jun-18-2013

SAFETY DATA SHEET

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product Identifier

Product Name: Azeotropica EtOAc/Eptano

Synonyms: Azeotropica Acetato di Etile/Eptano; Recovered Ethyl Acetate/Heptanes Azeotrope;

Recovered Ethyl Acetate/Heptanes from Lopinavir; Ethyl Acetate, Recovered;

Mixture Ethyl Acetate/Heptanes

Drug Code Number: 78634; 24739

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

Recommended use: Industrial use

Scientific research and development

1.3 Details of the supplier of the safety data sheet

Supplier: AbbVie Inc.

1 North Waukegan Road North Chicago, IL 60064

USA

1-800-255-5162 +1-847-937-7433

Manufacturer European: AbbVie Inc.

via Pontina, km 52 Campoverde - LT 04010

Italia

Customer Service Telephone: 1-800-255-5162 (US and Canada only)

+1-847-937-7433

E-mail Address: AbbVie.SDS@abbvie.com

1.4 Emergency telephone number

Emergency Telephone: CHEMTREC: 1(800) 424-9300 (in USA and Canada)

or +1-703-527-3887 (international)

Section 2. Hazards identification

2.1 Classification of the substance or mixture

Regulation (EC) No 1272/2008

Aspiration toxicityCategory 1Skin corrosion/irritationCategory 2Serious eye damage/eye irritationCategory 2Specific target organ systemicCategory 3

toxicity (single exposure)

Acute aquatic toxicity Acute 1

Chronic aquatic toxicity Chronic toxicity 1

Issued: Jun-18-2013

Section 2. Hazards identification

Flammable liquids Category 2

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Indication of danger: F - Highly flammable

Xi - Irritant Xn - Harmful

N - Dangerous for the environment

Risk Phrases: R11 - Highly flammable

R36 - Irritating to eyes R38 - Irritating to skin

R50 - Very toxic to aquatic organisms

R53 - May cause long-term adverse effects in the aquatic environment

R65 - Harmful: may cause lung damage if swallowed R67 - Vapors may cause drowsiness and dizziness

2.2 Label elements



Signal Word: Danger

Hazard Statements: H225 - Highly flammable liquid and vapor

H304 - May be fatal if swallowed and enters airways

H315 - Causes skin irritation

H319 - Causes serious eye irritation

H336 - May cause drowsiness or dizziness

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

P303 + P361 + P353 - IF ON SKIN (or hair): Remove/Take off immediately all

contaminated clothing. Rinse skin with water/shower

P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or

doctor/physician

P304 + P340 - IF INHALED: Remove to fresh air and keep at rest in a position

comfortable for breathing

P312 - Call a POISON CENTER or doctor/physician if you feel unwell

P403 + P233 - Store in a well-ventilated place. Keep container tightly closed

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing

2.3 Other hazards

Not determined

Issued: Jun-18-2013

Section 3. Composition/information on ingredients

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Ethyl Acetate 141-78-6	50-75	Present	F; R11 R66 R67 Xi; R36	Flam. Liq. 2 (H225) Eye Irrit. 2 (H319) STOT SE 3 (H336)	No data available
Heptane 142-82-5	25-45	Present	F; R11 N; R50-53 R67 Xi; R38 Xn, R65	STOT SE 3 (H336) Asp. Tox. 1 (H304) Skin Irrit. 2 (H315) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) Flam. Liq. 2 (H225)	No data available
Water 7732-18-5	0.1-1	Present		Not Hazardous*	No data available

Not Hazardous* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

For the full text of the R-phrases mentioned in this Section, see Section 16

For the full text of the H-Statements mentioned in this Section, see Section 16

Section 4. First aid measures

4.1 Description of first aid measures

Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation

persists or signs of toxicity occur, seek medical attention. Provide

symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation

persists or signs of toxicity occur, seek medical attention. Provide

symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention.

Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention.

Provide symptomatic/supportive care as necessary.

Protection of First-aiders: Use personal protective equipment

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms: This product may produce irritation to the skin, eyes, and upper respiratory tract.

Medical Conditions Medical conditions exacerbated due to exposure to the following organs: eyes, skin,

Aggravated by Exposure: lungs, kidney, liver.

4.3 Indication of any immediate medical attention and special treatment needed

Issued: Jun-18-2013

Notes To Physician: Treat symptomatically

Section 5. Firefighting measures

5.1 Extinguishing Media

Suitable Extinguishing Media: Use extinguishing agent suitable for type of surrounding fire

Unsuitable Extinguishing Media: Not determined

5.2 Special hazards arising from the substance or mixture

Special Exposure Hazards: Not determined

5.3 Advice for firefighters

Protective Equipment and

As in any fire, wear self-contained breathing apparatus and full protective gear

Precautions for Firefighters:

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal Precautions: For personal protection see section 8

6.2. Environmental precautions

Environmental Precautions: Contain material and prevent release to waterways or soil.

6.3. Methods and material for containment and cleaning up

Methods for Cleaning Up: Recover product and place in an appropriate container for disposal.

6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

Section 7. Handling and storage

7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice. Keep away from open flames, hot surfaces and sources of ignition.

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions

7.3. Specific end use(s)

Recommended use: Industrial use

Scientific research and development

Section 8. Exposure controls/personal protection

Issued: Jun-18-2013

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	Employee Exposure Limit	Skin Notation
Ethyl Acetate	Not Applicable	None
141-78-6		
Heptane	400 ppm (OSHA)	None
142-82-5		
Water	Not Applicable	None
7732-18-5		

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Ethyl Acetate	400 ppm TWA	TWA: 1400 mg/m ³	1500 mg/m ³ TWA	400 ppm (STEL)	
141-78-6				200 ppm (TWA)	
Heptane	500 ppm STEL	STEL: 2085 mg/m ³	2100 mg/m ³ TWA	500 ppm (TWA)	2085 mg/m ³ (TWA)
142-82-5	400 ppm TWA	TWA: 1668 mg/m ³		2085 mg/m ³ (TWA)	
				500 ppm (TWA)	

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Ethyl Acetate		1460 mg/m ³ (TWA)	1400 mg/m ³ (TWA)	400 ppm (STEL)
141-78-6			2800 mg/m ³ (STEL)	200 ppm (TWA)
Heptane	1600 mg/m ³ (STEL)	2085 mg/m ³ (TWA)	1600 mg/m ³ (TWA)	1500 ppm (STEL)
142-82-5	1200 mg/m³ (TWA)	_	1600 mg/m ³ (STEL)	6255 mg/m ³ (STEL)
				1500 ppm (STEL)
				500 ppm (TWA)
				$2085 \text{ mg/m}^3 \text{ (TWA)}$

8.2. Exposure controls

Engineering Controls: Local exhaust ventilation as necessary to maintain exposures to within applicable

limits.

Respiratory Protection: An approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are

expected to exceed the applicable limits.

Eyes: Wear eye protection appropriate to handling activities.

Gloves: Impervious gloves.

Other PPE Data: Wear appropriate body coverings if contact may occur.

Environmental Exposure

Controls:

Not determined

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance: Liquid

Odor:
Odor Threshold:
PH:
Not determined.

Issued: Jun-18-2013

Evaporation Rate at 20°C: Not determined. Flammability (Solid): Not determined. **Lower Explosive Limit:** Not determined. **Upper Explosive Limit:** Not determined. Vapor Pressure (mm Hg): Not determined. Vapor Density (Air = 1): Not determined. **Specific Gravity:** Not determined. **Solubility(ies):** Not determined. Partition coefficient: n-Not determined.

octanol/water

Autoignition Temp. (°C): Not determined.

Decomposition temperature (°C): Not determined.

Viscosity (centipoise): Not determined.

Explosion Severity: Not determined.

Oxidizer Properties: Not determined.

9.2. Other information

Not determined

Section 10. Stability and reactivity

10.1. Reactivity

Not determined

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Hazardous reactions: Not determined.

10.4. Conditions to avoid

Avoid contact with heat, sparks, open flame, and static discharge.

10.5 Incompatible materials

Strong oxidizing agents

10.6 Hazardous decompostion products

Carbon oxides

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Yes
Dermal: Yes
Inhalation: Unlikely

Acute Toxicity - Oral: Data for component (s) given below.

Page 6 of 11

Issued: Jun-18-2013

Chemical Name	Acute Test	Value	Units	Species
Ethyl Acetate 141-78-6	LD50 =	4100-4935	mg/kg	Mice Rats Rabbits
Heptane 142-82-5	LD50 >	260,000	mg/kg	Rats

Acute Toxicity - Dermal: Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Ethyl Acetate 141-78-6	LD50 >	20	ml/kg	Rabbits
	LD50 =	3400	mg/kg	Rabbits

Acute Toxicity - Inhalation: Data for component (s) given below.

Chemical Name	Test	Value	Units	Species
Ethyl Acetate 141-78-6	LC 50 =	200	g/m³	Rats
Heptane 142-82-5	LC 50 =	130,000	mg/m ³ , 4 hour	Rats

Other Toxicology Data: Data for component (s) given below:

Chemical Name	Test Type	Value	Units	Species	Comments
Heptane	LD50 (iv) =	222	mg/kg	Mice	
142-82-5					

Corrosivity: Not determined.

Dermal Irritation: A minor ingredient is a skin irritant.

Eye Irritation: A major ingredient is an eye irritant.

Not determined. **Sensitization:** Not determined.

Toxicokinetics/Metabolism:

Target Organ Effects: Target Organ Effects: blood, liver, kidneys, central nervous system.

Data for component (s) given below.

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Ethyl Acetate 141-78-6	Respiratory System Eyes	Humans	400	ppm	Inhalation	Not Specified

Not determined. **Reproductive Effects:**

Carcinogenicity: Not determined.

Mutagenicity: Not determined.

Aspiration hazard: Not determined

Notes:

1. ALD: Approximate lethal dosage

2. LC50: Concentration in air that produces 50% mortality

3. LD50: Oral or dermal dosage that produces 50% mortality

Issued: Jun-18-2013

Section 12. Ecological information

12.1. Toxicity

Data for component (s) given below.

Chemical Name	Percent	LC 50 (mg/l)	Species	Duration
Ethyl Acetate	50-75	350-600	Rainbow Trout	96 Hours
141-78-6		220-250	Fathead Minnow	
Heptane	25-45	4	Carassius auratus	24 hours
142-82-5				

Chemical Name	Percent	EC 50 (mg/l)	Species	Duration
Ethyl Acetate	50-75	560	Daphnia magna	24 hours
141-78-6				
Heptane	25-45	1.5	Daphnia magna	48 Hours
142-82-5			-	

12.2. Persistence and degradability

Not determined.

12.3. Bioaccumulative potential

Data for components given below.

Chemical Name	Percent	Log Po/w
Heptane	25-45	4.66
142-82-5		

12.4. Mobility in soil

Not determined.

12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

- 1. EC50: Concentration in water that produces 50% mortality in Daphnia sp.
- 2. LC50: Concentration in water that produces 50% mortality in fish.
- 3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

Section 13. Disposal considerations

13.1 Waste treatment methods

Waste Disposal Methods: Disposal should be made in accordance with country, federal, state and local

regulations.

Section 14. Transport information

Issued: Jun-18-2013

Section 14. Transport information

ADR, DOT, ICAO/IATA, IMDG/IMO

Status: Regulated

14.1. UN Number: UN1993

14.2. Proper shipping name: Flammable liquid, n.o.s. (Ethyl Acetate, Heptanes)

14.3. Hazard class: 3 14.4. Packing group: II

14.5. Environmental hazard: Not applicable14.6. Special Provisions: Not applicable14.7. Transport in bulk according Not applicable

to Annex II of MARPOL 73/78

and the IBC Code:

Section 15. Regulatory Information

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

International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Ethyl Acetate 141-78-6	Present	X	X	Not listed.	X
Heptane 142-82-5	Present	X	X	Not listed.	X
Water 7732-18-5	Present	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Ethyl Acetate 141-78-6	Present	-	X	X	Present	HSR001041
Heptane 142-82-5	Present	-	X	X	Present	HSR001164
Water 7732-18-5	-	2-(4)-1220	X	X	Present	

Legend

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

ISHL - Japan Industrial Safety and Health Law

IECSC - China Inventory of Existing Chemical Substances AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

Carcinogenicity Rating:

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Ethyl Acetate	50-75	Not Listed	Not Listed	Not Listed
Heptane	25-45	Not Listed	Not Listed	Not Listed
Water	0.1-1	Not Listed	Not Listed	Not Listed

SARA 313 Information

Issued: Jun-18-2013

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Ethyl Acetate	50-75	No	2270 kg	Not applicable
Heptane	25-45	No	Not Applicable	Not applicable
Water	0.1-1	No	Not Applicable	Not applicable

Immediate Health:YesDelayed Health:NoFire:YesSudden Pressure:NoReactivity:No

RCRA Status: Not determined.

Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or

reproductive harm.

WHMIS Hazard Class: Not determined.

NFPA Rating:

Health: 2 Fire: 3 Reactivity: 0

Notes:

- 1. SARA = Superfund Amendments and the Reauthorization Act.
- 2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
- 3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
- 4. TSCA = Toxic Substances Control Act.
- 5. EC = European Community.
- 6. WHMIS = Canadian Workplace Hazardous Materials Information System.
- 7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

Section 16. Other information

Risk Phrases: R11 - Highly flammable, R36 - Irritating to eyes, R38 - Irritating to skin, R50 - Very

toxic to aquatic organisms, R53 - May cause long-term adverse effects in the aquatic environment, R65 - Harmful: may cause lung damage if swallowed, R67 - Vapors

may cause drowsiness and dizziness

Full text of H-Statements referred to under sections 2 and 3

H225 - Highly flammable liquid and vapor, H319 - Causes serious eye irritation, H336 - May cause drowsiness or dizziness, H304 - May be fatal if swallowed and enters airways, H315 - Causes skin irritation, H400 - Very toxic to aquatic life, H410 - Very toxic to aquatic life with long lasting effects

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