

Product Name: Kaletra Oral Solution
Issued: Sep-24-2015

abbvie
SAFETY DATA SHEET

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

1.1 Product Identifier

Product Name: Kaletra Oral Solution

Synonyms: Kaletra Liquid; Kaletra 80 mg/20 mg/ml, solution buvable; Kaletra 80 mg/20 mg solucion; Kaletra Oral Liquid; Kaletra Jarabe; Kaletra Solucion Oral; Lopinavir/Ritonavir Oral Solution

Trade name: Kaletra

List Number: 3956

Drug Code Number: 10061759; 10066736; 20010043; 20010395; 20010407; 20010508; 20012932; 20013417; 20021969

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

Recommended use: Pharmaceuticals

1.3 Details of the supplier of the safety data sheet

Supplier: AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064
USA
+1-847-932-7900

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

Reproductive toxicity Category 2
Carcinogenicity Category 2
Flammable liquids Category 3

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

Indication of danger: F - Highly flammable
Xn - Harmful
Xi - Irritant

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2.2 Label elements



Signal Word:

Warning

Hazard Statements:

H225 - Highly flammable liquid and vapor
H302 - Harmful if swallowed
H319 - Causes serious eye irritation
H351 - Suspected of causing cancer
H361 - Suspected of damaging fertility or the unborn child
H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary Statements

P202 - Do not handle until all safety precautions have been read and understood
P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
P281 - Use personal protective equipment as required
P303 + P361 + P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P501 - Dispose of contents/container to an approved waste disposal plant

2.3 Other hazards

Not determined

Section 3. Composition/information on ingredients

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Ethyl Alcohol 64-17-5	30-50	Present	F; R11	Flam. Liq. 2 (H225)	No data available
Corn syrup	5-20	NA		Not Hazardous*	No data available
Propylene Glycol 57-55-6	5-20	Present		Not Hazardous*	No data available
Lopinavir 192725-17-0	1-10	NA		Acute Oral Cat 4 (H302); Repeat Chron Tox Cat 2 (H373)	No data available
Water 7732-18-5	1-10	Present		Not Hazardous*	No data available
Glycerol 56-81-5	1-10	Present		Not Hazardous*	No data available
Kollidon 9003-39-8	1-10	NA		Not Hazardous*	No data available
Magnasweet flavor	1-10	NA		Not classified	No data available

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Ritonavir 155213-67-5	1-9	NA	Xn, R22; Xi; R36; R40; R63	Eye Irrit. 2 (H319) Acute Tox. 4 (H302) Carc. 2 (H351) Repro 2 (H361D)	No data available
Vanilla flavor	1-10	NA		Not classified	No data available
Cotton candy flavor	1-10	NA		Not classified	No data available
Castor Oil 8001-79-4	1-10	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: None known from occupational exposure. Direct contact with the eyes could result in the following: eye irritation. Exposure may result in the following: vomiting, nausea, diarrhea, rash, abnormal liver function, abnormal thyroid function, gastrointestinal upset, incoordination, headaches, altered acid/ base balance, taste alterations, alterations in serum lipid concentrations. Ingestion of alcohol can cause: nausea, vomiting, flushing, depression, drowsiness, impaired perception, incoordination, stupor, death.

Medical Conditions Aggravated by Exposure: None known from occupational exposure. Available information suggest pre-existing ailments of the following organs: eyes, liver, or hematopoietic system, nervous system, gastrointestinal system, urinary bladder, testes, thyroid, A GLP-compliant embryo-fetal development study has been conducted with ABT-414 in mice resulting in post-implantation loss of all fetuses at a human equivalent dose near the anticipated clinical dose. This result is consistent with the pharmacology of ABT-414. Hypersensitivity to the material and/or similar materials.

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4.3 Indication of any immediate medical attention and special treatment needed

Notes To Physician: Treat symptomatically

Section 5. Firefighting measures

5.1 Extinguishing Media

Suitable Extinguishing Media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide

Unsuitable Extinguishing Media: Not determined

5.2 Special hazards arising from the substance or mixture

Special Exposure Hazards: Keep away from heat, sparks and flame.

5.3 Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus and full protective gear

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. Keep away from ignition sources.

Incompatibilities: Strong acids and bases.

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. Avoid sources of ignition: heat sparks, and open flames and ground all transfer equipment properly to prevent electrostatic discharge.

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions.

7.3. Specific end use(s)

Recommended use: Pharmaceuticals

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Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	Employee Exposure Limit	Skin Notation
Ethyl Alcohol 64-17-5	Not Applicable	None
Corn syrup	Not Applicable	None
Propylene Glycol 57-55-6	Not Applicable	None
Lopinavir 192725-17-0	1300 mcg/m ³ TWA	None
Water 7732-18-5	Not Applicable	None
Glycerol 56-81-5	Not Applicable	None
Kollidon 9003-39-8	Not Applicable	None
Magnasweet flavor	Not Applicable	None
Ritonavir 155213-67-5	160 mcg/m ³ TWA	None
Vanilla flavor	Not Applicable	None
Cotton candy flavor	Not Applicable	None
Castor Oil 8001-79-4	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Ethyl Alcohol 64-17-5	1000 ppm STEL	STEL: 5000 ppm STEL: 9500 mg/m ³ TWA: 1000 ppm TWA: 1900 mg/m ³	500 ppm TWA 960 mg/m ³ TWA 1000 ppm Peak 1920 mg/m ³ Peak	1000 ppm (STEL)	
Propylene Glycol 57-55-6				450 ppm (STEL) 1410 mg/m ³ (STEL) 30 mg/m ³ (STEL) 150 ppm (TWA) 470 mg/m ³ (TWA) 10 mg/m ³ (TWA)	
Glycerol 56-81-5	10 mg/m ³ (total mist)	TWA: 10 mg/m ³	50 mg/m ³ TWA 100 mg/m ³ Peak	30 mg/m ³ (STEL) 10 mg/m ³ (TWA)	
Kollidon 9003-39-8	10 mg/m ³ for nuisance dust; 3 mg/m ³ respirable particulate				

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Ethyl Alcohol 64-17-5	1900 mg/m ³ (STEL) 260 mg/m ³ (TWA)	1000 ppm (STEL) 1910 mg/m ³ (STEL)	500 ppm (TWA) 960 mg/m ³ (TWA) 1000 ppm (STEL) 1920 mg/m ³ (STEL)	3000 ppm (STEL) 5760 mg/m ³ (STEL) 1000 ppm (TWA) 1920 mg/m ³ (TWA)
Propylene Glycol 57-55-6				450 ppm (STEL) 1422 mg/m ³ (STEL) 30 mg/m ³ (STEL) 150 ppm (TWA) 474 mg/m ³ (TWA) 10 mg/m ³ (TWA)
Glycerol 56-81-5		10 mg/m ³ (TWA)	50 mg/m ³ (TWA) 100 mg/m ³ (STEL)	30 mg/m ³ (STEL) 10 mg/m ³ (TWA)

8.2. Exposure controls

Product Name:	Kaletra Oral Solution
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Engineering Controls:	No special provisions are required under normal product use conditions. When handling bulk formulation, use in a well-ventilated area.
Respiratory Protection:	Respiratory protection is not needed during normal product use. When handling the bulk formulation, an approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.
Eyes:	Eye protection not required during typical product use conditions. Wear eye protection appropriate to exposures when handling the product formulation.
Gloves:	Gloves not required during normal product use conditions. Wear impervious gloves when handling the product formulation.
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:	Yellow to orange Liquid
Odor:	Not determined.
Odor Threshold:	Not determined
pH:	Not determined.
Boiling Pt. @ 760 mm Hg (°C):	Not determined.
Melting/Freezing Point (°C):	Not determined
Flash Point (°C):	24
Flash Point Method:	Pensky-Martens Closed Cup (PMCC)
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:	1.006 - 1.035 at 25 deg. C
Solubility(ies):	Not determined.
Partition coefficient:	Not determined.
n-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

Product Name: Kaletra Oral Solution
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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

Keep away from open flames, hot surfaces and sources of ignition

10.5 Incompatible materials

Strong oxidizing agents, Strong acids, Strong bases

10.6 Hazardous decomposition products

Carbon oxides, Nitrogen oxides (NO_x)

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Clinical Route
Dermal: Unlikely
Inhalation: Unlikely

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

Chemical Name	Acute Test	Value	Units	Species
Ethyl Alcohol 64-17-5	LD50 =	3450-7060	mg/kg	Mice Rats
Propylene Glycol 57-55-6	LD50 =	10,000-33,700	mg/kg	Animals
Lopinavir 192725-17-0	LD50 >	2500	mg/kg	Rats
Glycerol 56-81-5	LD50 >	4090	mg/kg	Animals
Kollidon 9003-39-8	LD50 = LD50 >	100000 1040 40000	mg/kg	Rats Rabbits Mice
Ritonavir 155213-67-5	LD50 =	1030 - 1970	mg/kg	Mice

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

Chemical Name	Acute Test	Value	Units	Species
Ethyl Alcohol 64-17-5	LD50 =	20000	mg/kg	Rabbits
Propylene Glycol 57-55-6	LD50 =	20,800	mg/kg	Rabbits
Glycerol 56-81-5	LD50 >	10,000	mg/kg	Rabbits
Ritonavir 155213-67-5	LD50 >	2000	mg/kg	Rats

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

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Chemical Name	Test	Value	Units	Species
Ethyl Alcohol 64-17-5	LC 50 =	20000	ppm	Rats
Glycerol 56-81-5	LC 50 >	0.57	mg/L , 1 hour	Rats

Corrosivity: Not determined.

Dermal Irritation: Active Ingredient : Produced mild skin irritation in rabbits.

Eye Irritation: Active Ingredient : Produced mild eye irritation in animal testing. Recovery after 72 hours.

Sensitization: Active Ingredient : Negative in the maximization assay in guinea pigs at challenge concentrations.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: Data for component (s) given below.

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Lopinavir 192725-17-0	Liver Gastrointestinal Tract Blood	Rats Mice Dogs	50 - 100 co-dosed ritonavir	mg/kg	Oral	Variable exposure periods
Ritonavir 155213-67-5	Eyes Gastrointestinal Tract Liver Thyroid Kidney	Rats Dogs	25 50	mg/kg	Oral	Variable exposure periods 6 months 3 months

Reproductive Effects: Active Ingredient : In animals adverse reproductive effects include: testicular atrophy, fetal abnormalities. fetal toxicity, fetal behavior abnormalities.
Data for component (s) given below.

Chemical Name	Species	Dosage	Units	Route	Duration
Ritonavir 155213-67-5	Rats	35	mg/kg	Oral	During Gestation

Carcinogenicity: Data for component(s) given below.

Chemical Name	Site of Tumors	Species	Dosage	Route	Units	Duration
Ritonavir 155213-67-5	Liver	Mice	100	Oral	mg/kg	2 years

Mutagenicity: Data for component (s) given below.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Lopinavir 192725-17-0	Negative	Negative	Negative	Negative
Glycerol 56-81-5	No Data.	Negative	No Data.	No Data.
Ritonavir 155213-67-5	Negative	Negative	Negative	Negative

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

Section 12. Ecological information

12.1. Toxicity

Data for component (s) given below.

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Chemical Name	Percent	48h EC50 (daphnia - mg/l) (48HLCD)	Species	Duration
Propylene Glycol 57-55-6	5-20	1000		

12.2. Persistence and degradability

Not determined.

12.3. Bioaccumulative potential

Not determined

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

IMDG/IMO

Status: Regulated

14.1. UN Number: UN1170
14.2. Proper shipping name: Ethanol solution
14.3. Hazard class: 3
14.4. Packing group: III
14.5. Environmental hazard: Not applicable
14.6. Special Provisions: Not applicable
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

ADR

Status: Not regulated

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DOT

Status: Regulated
14.2. Proper shipping name: Consumer commodity
14.3. Hazard class: ORM-D

ICAO/IATA

Status: Regulated
14.1. UN Number: ID8000
14.2. Proper shipping name: Consumer commodity
14.3. Hazard Class: 9

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 Alcohol 64-17-5	Present	X	X	Not listed.	X
Corn syrup	-	-	-	Not listed.	-
Propylene Glycol 57-55-6	Present	X	X	Not listed.	X
Lopinavir 192725-17-0	-	-	-	Not listed.	-
Water 7732-18-5	Present	X	X	Not listed.	X
Glycerol 56-81-5	Present	X	X	Not listed.	X
Kollidon 9003-39-8	-	X	X	Not listed.	X
Magnasweet flavor	-	-	-	Not listed.	-
Ritonavir 155213-67-5	-	-	-	Not listed.	-
Vanilla flavor	-	-	-	Not listed.	-
Cotton candy flavor	-	-	-	Not listed.	-
Castor Oil 8001-79-4	Present	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Ethyl Alcohol 64-17-5	Present	-	X	X	Present	HSR001144
Corn syrup	-	-	-	-	-	
Propylene Glycol 57-55-6	Present	Present	X	X	Present	
Lopinavir 192725-17-0	-	-	-	-	-	
Water 7732-18-5	-	-	X	X	Present	
Glycerol 56-81-5	Present	-	X	X	Present	
Kollidon 9003-39-8	Present	-	X	X	Present	
Magnasweet flavor	-	-	-	-	-	
Ritonavir 155213-67-5	-	-	-	-	-	
Vanilla flavor	-	-	-	-	-	

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Cotton candy flavor	-	-	-	-	-	
Castor Oil 8001-79-4	-	-	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 Alcohol	30-50	Not Listed	Monograph 100E [2012] (in alcoholic beverages); Monograph 96 [2010] (in alcoholic beverages)	A3 - Confirmed Animal Carcinogen with Unknown Relevance to Humans
Corn syrup	5-20	Not Listed	Not Listed	Not Listed
Propylene Glycol	5-20	Not Listed	Not Listed	Not Listed
Lopinavir	1-10	Not Listed	Not Listed	Not Listed
Water	1-10	Not Listed	Not Listed	Not Listed
Glycerol	1-10	Not Listed	Not Listed	Not Listed
Kollidon	1-10	Not Listed	Not Listed	Not Listed
Magnasweet flavor	1-10	Not Listed	Not Listed	Not Listed
Ritonavir	1-9	Not Listed	Not Listed	Not Listed
Vanilla flavor	1-10	Not Listed	Not Listed	Not Listed
Cotton candy flavor	1-10	Not Listed	Not Listed	Not Listed
Castor Oil	1-10	Not Listed	Not Listed	Not Listed

SARA 313 Information

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Ethyl Alcohol	30-50	No	Not Applicable	Not applicable
Corn syrup	5-20	No	Not Applicable	Not applicable
Propylene Glycol	5-20	No	Not Applicable	Not applicable
Lopinavir	1-10	No	Not Applicable	Not applicable
Water	1-10	No	Not Applicable	Not applicable
Glycerol	1-10	No	Not Applicable	Not applicable
Kollidon	1-10	No	Not Applicable	Not applicable
Magnasweet flavor	1-10	No	Not Applicable	Not applicable
Ritonavir	1-9	No	Not Applicable	Not applicable
Vanilla flavor	1-10	No	Not Applicable	Not applicable
Cotton candy flavor	1-10	No	Not Applicable	Not applicable
Castor Oil	1-10	No	Not Applicable	Not applicable

Immediate Health: Yes

Delayed Health: No

Fire: Yes

Sudden Pressure: No

Reactivity: No

RCRA Status: Not determined.

Proposition 65 Status: Chemicals known to the State of California to cause cancer or reproductive harm listed below.

Component	Percent	Proposition 65 Listed Materials
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Ethyl Alcohol 64-17-5 (30-50)	30-50	carcinogen, initial date 4/29/11 (in alcoholic beverages) developmental toxicity, initial date 10/1/87 (in alcoholic beverages)
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WHMIS Hazard Class: Not determined.

NFPA Rating:

Health: 1

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

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

H225 - Highly flammable liquid and vapor

H302 - Harmful if swallowed

H319 - Causes serious eye irritation

H351 - Suspected of causing cancer

H361 - Suspected of damaging fertility or the unborn child

H373 - May cause damage to organs (a,b,c) through prolonged or repeated exposure

Document Authored By: Occupational and Environmental Toxicology

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Supersedes the SDS dated: Apr-12-2013

Disclaimer:

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