

Product Name: Simdax
Issued: Jun-23-2015

abbvie
SAFETY DATA SHEET

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

1.1 Product Identifier

Product Name: Simdax

Synonyms: Simdax Infusion Concentrate; Levosimendan injectable; Simdax; Levosimendan for Injection; Simdax for Injection; Simdax Solucion Inyectable; Simdax Viales; Simdax 2.5 mg/mL; Daxim

Trade name: Simdax

List Number: M974

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: Manufactured for:
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

Flammable liquids

Category 2

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

Indication of danger: F - Highly flammable
Risk Phrases: R11 - Highly flammable

2.2 Label elements

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Signal Word: Danger

Hazard Statements: H225 - Highly flammable liquid and vapor

Precautionary Statements

- P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
- P233 - Keep container tightly closed
- P241 - Use explosion-proof electrical/ventilating/lighting/equipment
- P242 - Use only non-sparking tools
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P403 + P235 - Store in a well-ventilated place. Keep cool

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	90-99	Present	F; R11	Flam. Liq. 2 (H225)	No data available
Kollidon 9003-39-8	1-5	NA		Not Hazardous*	No data available
Levosimendan 141505-33-1	0.1-1	NA	Repr. Cat. 3. R25, R62, R63	Repr. 2 (H361fd)	No data available
Citric Acid 77-92-9	0.1-1	Present	Xi; R36/37/38	STOT SE 3 (H335) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)	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.

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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: Direct contact with the eyes could result in the following: eye irritation. Clinical data suggests the following: headaches, dizziness, palpitation.

Medical Conditions Aggravated by Exposure: None known from occupational exposure. Data suggest any pre-existing ailments in the following organs: kidney, female reproductive system, cardiovascular system. Pregnancy.

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 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: Flammable Liquid. 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.

Incompatibilities: Strong oxidizing agents.

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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.

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions.

7.3. Specific end use(s)

Recommended use: Pharmaceuticals

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
Kollidon 9003-39-8	Not Applicable	None
Levosimendan 141505-33-1	Not Applicable	None
Citric Acid 77-92-9	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	1000 ppm Peak 1920 mg/m ³ Peak	1000 ppm (STEL)	
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) 1000 ppm (TWA) 1910 mg/m ³ (TWA)	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)

8.2. Exposure controls

Engineering Controls: No special provisions are required under normal product use conditions.

Respiratory Protection: Respiratory protection is not needed during normal product use.

Eyes: Eye protection not required during typical product use conditions.

Gloves: Gloves not required during normal product use conditions.

Other PPE Data: Not needed during normal product use.

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Environmental Exposure Controls: Not determined

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance:	Clear Yellow to orange Solution
Odor:	Alcohol odor.
Odor Threshold:	Not determined
pH:	Not determined.
Boiling Pt. @ 760 mm Hg (°C):	Not determined.
Melting/Freezing Point (°C):	Not determined
Flash Point (°C):	13
Flash Point Method:	Closed cup
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):	Soluble in: ethanol.
Partition coefficient: n-octanol/water	Not determined.
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.

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10.5 Incompatible materials

Strong oxidizing agents, Strong acids, Strong bases

10.6 Hazardous decomposition products

Carbon oxides, Nitrogen oxides (NOx)

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Unlikely The clinical route of administration is by intravenous injection
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
Kollidon 9003-39-8	LD50 = LD50 >	100000 1040 40000	mg/kg	Rats Rabbits Mice
Levosimendan 141505-33-1	LD50 = LD50 =	103 152-156	mg/kg mg/kg	Rats Mice
Citric Acid 77-92-9	LD50 >=	3000	mg/kg	Animals

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

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

Chemical Name	Test	Value	Units	Species
Ethyl Alcohol 64-17-5	LC 50 =	20000	ppm	Rats

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

Chemical Name	Test Type	Value	Units	Species	Comments
Levosimendan 141505-33-1	LD50 (iv) = LD50 (iv)=	32-50 57	mg/kg mg/kg	Mice Rats	

Corrosivity: Not determined.

Dermal Irritation: Not determined.

Eye Irritation: Not determined.

Sensitization: Not determined.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: Not determined.

Reproductive Effects: Active Ingredient : In animals adverse reproductive effects include: fetal abnormalities. reduced fertility in females.

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Carcinogenicity: Not determined.

Mutagenicity: Data for component (s) given below.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Levosimendan 141505-33-1	Negative	Negative	Positive	Positive

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

Not determined.

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

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

ADR

Status: Not regulated

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
Kollidon 9003-39-8	-	X	X	Not listed.	X
Levosimendan 141505-33-1	-	-	-	Not listed.	-
Citric Acid 77-92-9	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
Kollidon 9003-39-8	Present	-	X	X	Present	
Levosimendan 141505-33-1	-	-	-	-	-	
Citric Acid 77-92-9	Present	-	X	X	Present	HSR003138

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:

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Chemical Name	Percent	NTP:	IARC:	ACGIH:
Ethyl Alcohol	90-99	Not Listed	Not Listed	Not Listed
Kollidon	1-5	Not Listed	Not Listed	Not Listed
Levosimendan	0.1-1	Not Listed	Not Listed	Not Listed
Citric Acid	0.1-1	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	90-99	No	Not Applicable	Not applicable
Kollidon	1-5	No	Not Applicable	Not applicable
Levosimendan	0.1-1	No	Not Applicable	Not applicable
Citric Acid	0.1-1	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
Ethyl Alcohol 64-17-5 (90-99)	90-99	developmental toxicity, initial date 10/1/87 (in alcoholic beverages)

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

Risk Phrases:

R11 - Highly flammable

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

H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child

H301 - Toxic if swallowed

H225 - Highly flammable liquid and vapor

H335 - May cause respiratory irritation

H315 - Causes skin irritation

H319 - Causes serious eye irritation

Document Authored By: Occupational and Environmental Toxicology

Issued: Jun-23-2015

Supersedes the SDS dated: Aug-26-2014

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