

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: **LUCASSIN FOR INJECTION**
 SYNOYMS: Terlipressin acetate, Haemopressin, Glypressin, Glycylpressin, Variquel
 U.N. NUMBER: None
 U.N. DANGEROUS GOODS CLASS: Non-Regulated Material
 MANUFACTURER'S NAME: **IKARIA**
 ADDRESS: Perryville III Corporate Park, 53 frontage Road, Third Floor, P.O. Box 9001, Hampton, New Jersey 08827-9001 USA
 BUSINESS AND EMERGENCY PHONE: 1-877-566-9466 (Product Information and reportable adverse reactions)
 1-800-424-9300 *CHEMTREC US and Canada (Chemical release)*
 +1 (703) 527-3887 *CHEMTREC International and Maritime*
 WEB SITE: www.ikaria.com
 DATE OF PREPARATION: November 26, 2012
 DATE OF LAST REVISION: New

SECTION 2 - HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: This product is a white lyophilized powder with no odor. Non-hazardous during contact with skin or when swallowed. Powder may cause slight eye or respiratory irritation.

US DOT SYMBOLS
Non-Regulated Material

CANADA (WHMIS) SYMBOLS
Not controlled

EUROPEAN and (GHS) Hazard Symbols
None
Signal Word: **Caution!**

EU LABELING AND CLASSIFICATION:

Classification of the substance or mixture according to Regulation (EC) No1272/2008 Annex 1
EC# 238-680-8 This substance is not classified in the Annex I of Directive 67/548/EEC

GHS Hazard Classification(s):

None

Hazard Statement(s):

None

Precautionary Statement(s):

P262: Do not get in eyes
 P264: Wash hands thoroughly after handling

EU HAZARD CLASSIFICATION PER DIRECTIVE 1999/45/EC:

Hazard Symbol(s):

None

EU HAZARD CLASSIFICATION PER DIRECTIVE 1999/45/EC:

None

Risk Phrases:

None

Safety Phrases:

S25: Avoid contact with eyes

HEALTH HAZARDS OR RISKS FROM EXPOSURE:

ACUTE: Possible respiratory system and eye irritation.

INHALATION: Inhalation of dusts, generated by the material, during the course of normal handling, may cause irritation.

EYE: Direct contact with the eye may cause transient discomfort characterized by tearing or conjunctival redness.

SKIN: Skin contact with this product is not expected to have any adverse health effects.

INGESTION: Ingestion of this product is not expected to have any adverse health effects.

CHRONIC: None known

TARGET ORGANS:

ACUTE: Eyes, Respiratory System

CHRONIC: None known

SECTION 3 - COMPOSITION and INFORMATION ON INGREDIENTS

HAZARDOUS INGREDIENTS:	CAS #	EINECS #	ICSC #	WT %	HAZARD CLASSIFICATION; RISK PHRASES
Terlipressin Acetate	14636-12-5	238-680-8	Not Listed	100%	HAZARD CLASSIFICATION: None RISK PHRASES: None
Balance of other ingredients are non-hazardous or less than 1% in concentration (or 0.1% for carcinogens, reproductive toxins, or respiratory sensitizers).					

SECTION 4 - FIRST-AID MEASURES

EYE CONTACT: If product enters the eyes, open eyes while under gentle running water for at least 15 minutes. Seek medical attention if irritation occurs or persists.

SKIN CONTACT: Wash skin thoroughly after handling. Seek medical attention if irritation develops and persists.

INHALATION: If breathing becomes difficult, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if breathing difficulty continues.

INGESTION: If product is inadvertently swallowed, call physician or poison control center for most current information. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or who cannot swallow. Seek medical advice. Take a copy of the label and/or MSDS with the victim to the health professional.

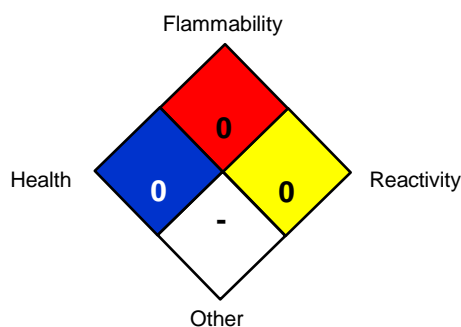
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: None known

RECOMMENDATIONS TO PHYSICIANS: Treat symptoms and reduce over-exposure.

SECTION 5 - FIRE-FIGHTING MEASURES

FLASH POINT: Not Applicable
AUTOIGNITION TEMPERATURE: Not Applicable
FLAMMABLE LIMITS (in air by volume, %): Lower (LEL): NA Upper (UEL): NA
FIRE EXTINGUISHING MATERIALS: Carbon dioxide, foam, dry chemical, halon, or water spray. Use extinguishing media appropriate for surrounding fire.
UNUSUAL FIRE AND EXPLOSION HAZARDS: When heated to decomposition this material emits toxic fumes of nitrogen oxides and carbon.
Explosion Sensitivity to Mechanical Impact: Not Sensitive.
Explosion Sensitivity to Static Discharge: Not Sensitive
SPECIAL FIRE-FIGHTING PROCEDURES: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Isolate materials not yet involved in the fire and protect personnel. Move containers from fire area if this can be done without risk; otherwise, cool with carefully applied water spray. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

NFPA RATING SYSTEM



HMS RATING SYSTEM

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM			
HEALTH HAZARD (BLUE)			0
FLAMMABILITY HAZARD (RED)			0
PHYSICAL HAZARD (YELLOW)			0
PROTECTIVE EQUIPMENT			
EYES	RESPIRATORY	HANDS	BODY
	See Sect 8		See Sect 8
For Routine Industrial Use and Handling Applications			

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe * = Chronic hazard

SECTION 6 - ACCIDENTAL RELEASE MEASURES

SPILLS: Carefully collect spilled material and place in a suitable, clean, dry bag or container for waste disposal. Dispose of in accordance with applicable Federal, State, and local procedures (see Section 13, Disposal Considerations).

SECTION 7 - HANDLING and STORAGE

WORK PRACTICES AND HYGIENE PRACTICES: Avoid contact with eyes, skin and clothing. Do not breathe dust. Wash thoroughly after handling this product. Do not eat, drink, smoke, or apply cosmetics while handling this product. Work in a hood or dry box.

STORAGE AND HANDLING PRACTICES: Keep in a tightly closed container, away from heat and moisture per the label instructions.

SECTION 8 - EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/GUIDELINES:

Chemical Name	CAS#	ACGIH TWA	OSHA TWA	OEL
Terlipressin Acetate	14636-12-5	Not Listed	Not Listed	Not Listed

Note: For Dust use 10 mg/m³

Currently, International exposure limits are not established for the components of this product. Please check with competent authority in each country for the most recent limits in place.

VENTILATION AND ENGINEERING CONTROLS: Use with adequate ventilation to ensure exposure levels are maintained below the limits provided above. Use local exhaust ventilation to control airborne dust.

The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132) or equivalent standard of Canada, or standards of EU member states (including EN 149 for respiratory PPE, and EN 166 for face/eye protection), and those of Japan. Please reference applicable regulations and standards for relevant details.

RESPIRATORY PROTECTION: Maintain airborne contaminant concentrations below guidelines listed above, if applicable.

If necessary, use only respiratory protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134), equivalent U.S. State standards, Canadian CSA Standard Z94.4-93, the European Standard EN149, or EU member states.

EYE PROTECTION: Safety glasses or chemical goggles as appropriate to prevent eye contact. If necessary, refer to U.S. OSHA 29 CFR 1910.133 or appropriate Canadian Standards.

SKIN PROTECTION: Use gloves as appropriate to prevent skin contact. If necessary, refer to U.S. OSHA 29 CFR 1910.138 or appropriate Standards of Canada.

SECTION 9 - PHYSICAL and CHEMICAL PROPERTIES

PHYSICAL STATE:	Solid
APPEARANCE & ODOR:	White lyophilized powder with no odor
ODOR THRESHOLD (PPM):	None
VAPOR PRESSURE (mmHg):	Not Applicable
VAPOR DENSITY (AIR=1):	Not Applicable
EVAPORATION RATE (nBuAc = 1):	Not Applicable
BOILING POINT (C°):	Not Applicable
FREEZING POINT (C°):	Not Applicable
pH:	4.5 – 7.0
SPECIFIC GRAVITY 20°C: (WATER =1)	Not Available
SOLUBILITY IN WATER (%)	Soluble

SECTION 10 - STABILITY and REACTIVITY

STABILITY: Product is stable

DECOMPOSITION PRODUCTS: When heated to decomposition this product produces toxic fumes of nitrogen oxide, carbon oxides and sulfur oxides.

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: Avoid contamination with oxidizing agents and reducing agents.

HAZARDOUS POLYMERIZATION: Will not occur.

SECTION 11 - TOXICOLOGICAL INFORMATION**TOXICITY DATA:**

No LD50 Data Available

SUSPECTED CANCER AGENT: None of the ingredients are found on the following lists: FEDERAL OSHA Z LIST, NTP, CAL/OSHA, IARC and therefore is not considered to be, nor suspected to be a cancer-causing agent by these agencies.

IRRITANCY OF PRODUCT: Contact with intact tablets is not considered to be a skin irritant.

SENSITIZATION OF PRODUCT: This product is not considered a sensitizer.

TERATOGENIC EFFECTS: No data available

REPRODUCTIVE TOXICITY INFORMATION: No data available

MUTAGENICITY: No data available

SECTION 12 - ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

ENVIRONMENTAL STABILITY: No environmental data for this product.

EFFECT OF MATERIAL ON PLANTS, ANIMALS AQUATIC LIFE: Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

SECTION 13 - DISPOSAL CONSIDERATIONS

PREPARING WASTES FOR DISPOSAL: Waste disposal must be in accordance with appropriate Federal, State, and local regulations, those of Canada, Australia, EU Member States and Japan.

SECTION 14 - TRANSPORTATION INFORMATION**US DOT: IATA: IMO: ADR:**

THIS PRODUCT IS NOT HAZARDOUS AS DEFINED BY 49 CFR 172.101 BY THE U.S. DEPARTMENT OF TRANSPORTATION.

PROPER SHIPPING NAME: Non-Regulated Materials

HAZARD CLASS NUMBER and DESCRIPTION: None

UN IDENTIFICATION NUMBER: None

PACKING GROUP: None

DOT LABEL(S) REQUIRED: None

NORTH AMERICAN EMERGENCY RESPONSE GUIDEBOOK NUMBER (2004): None

MARINE POLLUTANT: None of the ingredients are classified by the DOT as a Marine Pollutant (as defined by 49 CFR 172.101, Appendix B)

U.S. DEPARTMENT OF TRANSPORTATION (DOT) SHIPPING REGULATIONS:

This product is not classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA):

This product is not classified as Dangerous Goods, by rules of IATA:

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION:

This product is not classified as Dangerous Goods by the International Maritime Organization.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD

(ADR): This product is not classified by the United Nations Economic Commission for Europe to be dangerous goods

SECTION 15 - REGULATORY INFORMATION**UNITED STATES REGULATIONS**

SARA REPORTING REQUIREMENTS: This product is not subject to the reporting requirements of Sections 302, 304 and 313 of Title III of the Superfund Amendments and Reauthorization Act., as follows: None

TSCA: All components in this product are listed on the US Toxic Substances Control Act (TSCA) inventory of chemicals.

SARA 311/312:

Acute Health: No

Chronic Health: No

Fire: No

Reactivity: No

U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for this product. The default Federal MSDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) may apply, per 40 CFR 370.20.

U.S. CERCLA REPORTABLE QUANTITY (RQ): None

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): None of the ingredients are on the California Proposition 65 lists.

CANADIAN REGULATIONS:

CANADIAN DSL/NDL INVENTORY STATUS: All of the components of this product are on the DSL Inventory

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS: No component of this product is on the CEPA First Priorities Substance Lists.

CANADIAN WHMIS CLASSIFICATION and SYMBOLS: This product is categorized as Not Controlled, as per the Controlled Product Regulations

EUROPEAN ECONOMIC COMMUNITY INFORMATION:

EU LABELING AND CLASSIFICATION:

Classification of the mixture according to Regulation (EC) No1272/2008. See section 2 for details.

AUSTRALIAN INFORMATION FOR PRODUCT:

AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES (AICS) STATUS: All components of this product are listed on the AICS.

STANDARD FOR THE UNIFORM SCHEDULING OF DRUGS AND POISONS: Not applicable.

JAPANESE INFORMATION FOR PRODUCT:

JAPANESE MINISTER OF INTERNATIONAL TRADE AND INDUSTRY (MITI) STATUS: The components of this product are not listed as Class I Specified Chemical Substances, Class II Specified Chemical Substances, or Designated Chemical Substances by the Japanese MITI.

INTERNATIONAL CHEMICAL INVENTORIES:

Listing of the components on individual country Chemical Inventories is as follows:

Asia-Pac:	Listed
Australian Inventory of Chemical Substances (AICS):	Listed
Korean Existing Chemicals List (ECL):	Listed
Japanese Existing National Inventory of Chemical Substances (ENCS):	Listed
Philippines Inventory of Chemicals and Chemical Substances (PICCS):	Listed
Swiss Giftliste List of Toxic Substances:	Listed
U.S. TSCA:	Listed

SECTION 16 - OTHER INFORMATION

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MSDS Authoring PLUS

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