

### **SECTION 1: PRODUCT IDENTIFICATION**

PRODUCT NAME	ADEMETIONINE DISULFATE TOSYLATE (SAMe)	
PRODUCT CODE	2904	
SUPPLIER	MEDISCA Inc.         Tel.: 1.800.932.1039   Fax.: 1.855.850.5855         661 Route 3, Unit C, Plattsburgh, NY, 12901         6641 N. Belt Line Road, Suite 130, Irving, TX, 75063         MEDISCA Pharmaceutique Inc.         Tel.: 1.800.665.6334   Fax.: 514.338.1693         4509 Rue Dobrin, St. Laurent, QC, H4R 2L8         21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2         MEDISCA Australia PTY LTD         Tel.: 1.300.786.392   Fax.: 61.2.9700.9047         Unit 7, Heritage Business Park         5-9 Ricketty Street, Mascot, NSW 2020	
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670	
RECOMMENDED USES	Manufacturing and Compounding	
RESTRICTIONS ON USE	Not applicable	

## SECTION 2: HAZARDS IDENTIFICATION

#### GHS CLASSIFICATION

PICTOGRAM

SIGNAL WORD HAZARD STATEMENT(S)

ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS PRECAUTIONARY STATEMENT(S) Acute Toxicity - Oral (Category 5) Eye Damage (Category 1)



Danger May be harmful if swallowed Causes severe skin burns and eye damage. Not Applicable.

Prevention

Do not breathe dust or mist. Wash thoroughly after handling. Wear protective gloves, protective clothing, eye protection and face protection.



	Response	<ul> <li>IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Get medical help.</li> <li>IF ON SKIN (OR HAIR): Take off immediately all contaminated clothing. Immediately rin skin with water for several minutes. Wash contaminated clothing before reuse.</li> <li>IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get emergency medical help immediately; Immediately call a poison center or medical professional;</li> <li>IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, i present and easy to do. Continue rinsing.</li> </ul>					et al
	Storage Disposal Health Hazard	Store lo	ocked up.				
		Dispos	e of contents and	or container in acco	rdance with local re	gulations.	
HMIS CLASSIFICATION			3	Flamm	ability	1	
	Reactivity		0	Persor	nal Protection	Е	

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	S-Adenosyl-L-methionine disulfate tosylate
BOTANICAL NAME	Not applicable
SYNONYM	Ademetionine disulfate p-toluensulfonate; S-adenosyl-L-methionine-p-toluenesulfonate disulfate
CHEMICAL FORMULA	C22H34N6O16S4
CHEMICAL FAMILY	Not applicable
CAS NUMBER	97540-22-2
ALTERNATE CAS NUMBER	29908-08-0
MOLECULAR WEIGHT	766.80
COMPOSITION	CHEMICAL NAME CAS NUMBER EC NUMBER % BY WEIGHT
	ADEMETIONINE DISULFATE TOSYLATE 97540-22-2 810-270-9 100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

### **SECTION 4: FIRST-AID MEASURES**

IN CASE OF EYE CONTACT	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
IF SWALLOWED	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
IF INHALED	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician
MEDICAL ATTENTION AND SPECIAL TREATMENT	Get emergency medical help.
SYMPTOMS CAUSED BY EXPOSURE	Not expected to present a significant hazard under anticipated conditions of normal use.

### **SECTION 5: FIREFIGHTING MEASURES**



SPECIFIC HAZARDS ARISING FROM THE CHEMICAL	Corrosive to the eyes and respiratory tract.
FLAMMABLE PROPERTIES	May be combustible at high temperature
HAZARDOUS COMBUSTION PRODUCTS	Under fire conditions, hazardous fumes will be present.
SUITABLE & UNSUITABLE EXTINGUISHING MEDIA	Small fire: dry chemical, CO <sub>2</sub> or water spray. Large fire: dry chemical, CO <sub>2</sub> , alcohol resistant foam or water spray. Do not get water inside containers.
PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS	Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.					
METHODS & MATERIAL FOR CONTAINMENT	On land, sweep or shovel into suitable containers. Minimize generation of dust.					
CLEANUP PROCEDURE	Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.					
REFERENCE TO OTHER SECTIONS	See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.					

### **SECTION 7: HANDLING AND STORAGE**

PRECAUTIONS FOR SAFE HANDLING	Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.
CONDITIONS FOR SAFE STORAGE	Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.
STORAGE CONDITIONS	Store in original container, tightly sealed, protected from direct sunlight and moisture.
	Store at a temperature of 2-8°C. Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 25 °C are acceptable.

## SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

#### Chemical Name: ADEMETIONINE DISULFATE TOSYLATE CAS #: 97540-22-2

		Country	Limit value-8 hours		Limit value-Short Term		Limit value-Short Term		IDLH	REL	Advisory	Notes
			ppm	mg/m³	ppm	mg/m³						
4	OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A		



ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

#### N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

CONTROL BANDING

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m<sup>3</sup>

PERSONAL PROTECTIVE EQUIPMENTEyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's<br/>eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. Skin: Wear appropriate<br/>gloves to prevent skin exposure. Clothing: Wear appropriate protective clothing to minimize contact with skin.<br/>Respirators: Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard<br/>EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are<br/>exceeded or if irritation or other symptoms are experienced. Thermal Hazards: For products representing a<br/>thermal hazard, appropriate Personal Protective Equipment should be used.SPECIFIC ENGINEERING CONTROLSAdequate mechanical ventilation. Fumehood, eye wash station, and safety shower.BIOLOGICAL MONITORINGNot available

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Not available

PHYSICAL STATE	Solid							
DESCRIPTION	White to off-white hygroscopic powder.							
SOLUBILITY	Freely soluble in water, pr	actically insoluble in hexane and a	acetone.					
ODOR	Odorless							
FLAMMABILITY	May be combustible at hig	h temperature						
AUTO-IGNITION TEMPERATURE	Not available	BOILING POINT	Not available	DECOMPOSITION TEMPERATURE	Not available			
EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available	FLASH POINT	(115 - 120)°C, (239-248)°F			
log P (OCTANOL-WATER)	-2.270	LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	Not available			
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	рН	0.9 - 1.5 (5%)			
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	0.250	UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available			



VAPOR DENSITY (AIR = 1) Not available

VAPOR PRESSURE

Not available

VISCOSITY

Not available

The physical data presented above are typical values and should not be construed as a specification.

## SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established	
CHEMICAL STABILITY	Stable under recommended storage conditions	
INCOMPATIBLE MATERIALS	Bases. Reducing agents. Strong oxidizers.	
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur	
HAZARDOUS POLYMERIZATION	Will not occur	
POSSIBLITY OF HAZARDOUS REACTION	Not established	
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures	

## SECTION 11: TOXICOLOGICAL INFORMATION

Hygroscopic-Avoid exposure to moisture

ACUTE TOXICITY	Dermal: Rabbit L	Oral: Rat: LD50: (mg/kg): 3320 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available					
SKIN CORROSION/IRRITATION	May be corrosive	e to skin (pH: 0.9 - 1.5)					
SERIOUS EYE DAMAGE/EYE IRRITATION	Causes severe e	Causes severe eye damage (pH: 0.9 - 1.5)					
RESPIRATORY SENSITIZATION	Due to lack of da	Due to lack of data the classification is not possible.					
SKIN SENSITIZATION	Due to lack of da	ta the classification is not possible.					
GERM CELL MUTAGENICITY	Due to lack of da	Due to lack of data the classification is not possible.					
CARCINOGENICITY	OSHA	ADEMETIONINE DISULFATE TOSYLATE is not listed.					
	NTP	ADEMETIONINE DISULFATE TOSYLATE is not listed.					
	IARC	ADEMETIONINE DISULFATE TOSYLATE is not evaluated.					
	California Proposition 65	This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.					
ADDITIONAL CARCINOGENICITY INFORMATION	Due to lack of da	ata the classification is not possible.					
REPRODUCTIVE TOXICITY	Tests on rats and	ble data, the classification criteria are not met. d rabbits did not show adverse effects on fertility, reproductive performance or fetal demetionine has been used therapeutically in pregnant women.					
SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE	Due to lack of data the classification is not possible.						
SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE	Due to lack of da	ata the classification is not possible.					



ASPIRATION HAZARDS	Based on availab	le data, the classification criteria are not met.				
SIGNS AND SYMPTOMS OF EXPOSURE	Skin, eyes, inges EARLY ONSET S Not available DELAYED HEAL Not available Symptoms relate	DELAYED HEALTH EFFECT FROM EXPOSURE:				
	neadache. Frequ	Headache. Frequent urination. Gastrointestinal disturbances. Mood changes.				
POTENTIAL HEALTH EFFECTS	Inhalation	May be harmful if inhaled. Corrisive to the respiratory tract.				
	Ingestion	May be harmful if swallowed.				
	Skin	May be harmful if absorbed through skin. May be corrosive to skin.				
	Eyes	Causes severe eye damage.				

### SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY
PERSISTENCE AND DEGRADABILITY
BIOACCUMULATIVE POTENTIAL
MOBILITY IN SOIL
OTHER ADVERSE EFFECTS

EC50: 48 Hr: Crustacea: (mg/L): Not available LC50: 96 Hr: Fish: (mg/L): Not available EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available Not available Moderate; Log Pow: -2.270. Freely soluble in water Not available

This product is not intended to be released into the environment

### SECTION 13: DISPOSAL CONSIDERATIONS

#### **DISPOSAL METHODS**

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

### **SECTION 14: TRANSPORT INFORMATION**

UN PROPER SHIPPING NAME	Not dangerous good
UN NUMBER	Not applicable
CLASS	Not applicable
PACKING GROUP	Not applicable
AUSTRALIA HAZCHEM	Not applicable
EU TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE	Not Listed



ENVIRONMENTAL HAZARDS SPECIAL SHIPPING INFORMATION Not available Not applicable

## SECTION 15: REGULATORY INFORMATION

#### UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CF Appendix A	R Part 355 Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
ADEMETIONINE DISULFATE TOSYLATE 97540-22-2	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

#### AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemcials
ADEMETIONINE DISULFATE TOSYLATE 97540-22-2	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed

#### EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
ADEMETIONINE DISULFATE TOSYLATE 97540-22-2	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT

**SECTION 16: OTHER INFORMATION** 

#### REFERENCES

Available upon request

Not applicable



ABBREVIATIONS AND ACRONYMS	ACGIH - American Conference of Governmental Industrial Hygienists; AIHA WEEL – American Industrial Hygiene Association Workplace Environment Exposure Levels; CAESAR – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; CAS – Chemical Abstract Service; CERCLA – Comprehensive Environmental Response, Compensation, and Liability Act; EC50 – Effective Concentration, 50%; EPA – Environmental Protection Agency; GHS – Global Harmonized System; HMIS – Hazardous Materials Information System; HSE – Health and Safety Executive; HSIS – Hazardous Substances Information System; IARC – International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IRFMN – Ready Biodegradability Model; ISS – Instituto Superiore Sanità; LC50 – Lethal Concentration, 50%; LD50 – Lethal Dose, 50%; MSHA - Mine Safety and Health Administration; NIOSH – National Institute for Occupational Safety and Health; NTP – National Toxicology Program; OSHA PEL – Occupational Safety & Health Administration Permissible Exposure Limits; QSAR – Quantitative Structure-activity relationship; REL - Recommended Exposure Limit; SARA – Superfund Amendments and Reauthorization Act; STEL – Short Term Exposure Limit; TLV – Threshold Limit Value; TWA – Time Weighted Average; WHMIS – Workplace Hazardous Materials Information System
LAST REVISION	02/2023
SUPERSEDES	03/2022
	For a list of changes to the SDS since the last version, please communicate with MEDISCA at <u>www.medisca.com</u>
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