Safety Data Sheet

Section 1. Identification		
Domestic Product Name:	**Atridox®**	
Export Product Name:	**Atridox®**	
Manufacturer:	TOLMAR, Inc. 701 Centre Avenue Fort Collins, CO 80526	Phone: 970.212.4500 970.212.4511
Chemical Use: Atridox® is a two syringe, time-release system used to help treat periodontal disease		

Section 2. Hazard(s) Identification		
Appearance:	Syringe A: White to light gold liquid Syringe B: Yellow powder	Ratings:
Classification:	Eye Irritation: 2A Skin Irritation: 2 Flammability: 3 (Syringe A)– 0 (Syringe B) Reactivity: 0 Environment (Air-Water-Soil): No information available Special Hazards: No information available	Minimal 0 Slight 4 Moderate 3 Severe 2 Extreme 1
Signal Word:	Warning	
Hazard Information:	Hazard Statements: H302- Harmful if swallowed H315- Causes skin irritation H319- Causes serious eye irritation H335- May cause respiratory irritation Pictograms: 	
Precautionary Information:	Precautionary statements: P264- Wash hands thoroughly after handling P270- Do not eat, drink or smoke when using this product P280- Wear protective gloves/protective clothing/eye protection/face protection P302+P352- IF ON SKIN: wash with plenty of soap and water P301+P312- IF SWALLOWED: call a POISON CENTER or doctor/physician IF you feel unwell P305+P351+P338- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P337+P313- IF eye irritation persists: Get medical advice/attention P332+P313- IF SKIN irritation occurs: Get medical advice/attention P362- Take off contaminated clothing and wash before reuse P330- Rinse mouth	
Other Hazards:	No applicable information available	

Section 3. Composition and Information for Product Ingredients

Chemical Name	**CAS#**	**Synonyms**	**% W/W**
2-Pyrrolidinone 1-Methyl (Syringe A)	872-50-4	n-Methylpyrrolidone, NMP	>1%
Polylactic acid (Syringe A)	34346-01-5	Polyactide	>1%
Doxycycline Hyclate (Syringe B)	2439-14-5	Doxycycline, hydrochloride, hemiethanolate, hemihydrate	100%
Other constituents <1% w/w each in the formulation	Remainder of formulation is not considered hazardous. Further information can be made available to medical personnel in the event of an emergency		

Section 4. First Aid Measures

Exposure Scenario	First Aid Measures
Inhalation	**2-Pyrrolidinone, 1-Methyl (Syringe A):** General precautionary. Remove from source of exposure. If not breathing, give artificial respiration, preferably mouth-to-mouth. If breathing is difficult, give oxygen. If signs of toxicity occur, seek medical attention. No specific treatment is necessary since material is not likely to be hazardous by inhalation. **Doxycycline Hyclate (Syringe B):** Remove to fresh air. May cause irritation to the respiratory tract. If not breathing, give artificial respiration, preferably mouth-to-mouth. If breathing is difficult, give oxygen. Call a physician.
Ingestion	**2-Pyrrolidinone, 1-Methyl (Syringe A):** General Precautionary. Do not induce vomiting. Slowly dilute with 1 –2 glasses of water or milk. Never give anything by mouth to an unconscious person. Remove from source of exposure. Seek medical attention. **Doxycycline Hyclate (Syringe B):** two glasses of water and sticking finger down throat. Never give anything by mouth to an unconscious person. Doxycycline is readily absorbed from the gastrointestinal tract. Following ingestion and/or prior to gastric evacuation, immediately administer 4 – 8 oz of milk or water. IN most cases gastrointestinal decontamination will not be required, but if necessary, administer charcoal slurry. This is most effective within one hour of ingestion. Antacids may help to manage gastric irritation. Call a physician.
Skin Contact	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Remove from source of exposure. Remove contaminated clothing. Flush with copious amounts of water and wash with soap. If irritation persists or signs of toxicity occur, seek medical attention. Wash clothing before reuse. **Doxycycline Hyclate (Syringe B**): Remove from source of exposure. Remove contaminated clothing. Flush with copious amounts of water and wash with soap immediately. If irritation persists or signs of toxicity occur, seek medical attention. Wash clothing before reuse.
Eye Contact	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. No know antidote. Provide symptomatic/supportive care, monitoring hormone/sexual function if necessary. **Doxycycline Hyclate (Syringe B):** Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. No know antidote. Provide symptomatic/supportive care.
General Precautions	**Polylactic Acid (Syringe A):** Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Hot and/or melted polymer can severely burn skin. Handle with care. **Doxycycline Hyclate (Syringe B):** Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. In case of exposure to large areas of skin or prolonged exposure, monitor carefully hypersensitivity symptoms. Overdoses should be treated symptomatically and supportively. Dialysis is not beneficial. ***Persons developing serious hypersensitivity reactions to doxycycline must receive immediate medical attention!!***
Note to Physician	No applicable information available

Section 5. Fire Fighting Measures

Characteristic	Details
Flash Point	**2-Pyrrolidinone, 1-Methyl (Syringe A):** 199.00°F
Extinguishing Media	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Water, alcohol foam, dry chemical, carbon dioxide **Polylactic Acid (Syringe A):** Water, alcohol foam, dry chemical, carbon dioxide **Doxycycline Hyclate (Syringe B):** Water, dry chemical, carbon dioxide or foam
Unusual Fire/Explosion Hazards	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Combustible liquid. Dangerous fire hazard when exposed to heat or flame. Vapors are heavier than air and may travel a considerable distance to a source of ignition and flash back. Vapor-air mixtures are explosive. **Polylactic Acid (Syringe A):** Avoid dispersion of dust in air to reduce dust explosion hazard. **Doxycycline Hyclate (Syringe B):** This material is assumed to be combustible. Ground mechanical equipment that will be in contact with dry material to dissipate the build-up of static electricity.
Special Protective Equipment	Fire fighters should wear full protective clothing, including self-contained breathing apparatus.

Section 6. Accidental Release Measures

Measure	Details
Personal Precautionary Measures	Use appropriate protective equipment. Avoid breathing any dust.
Cleaning/Absorption Measures	Remove ignition sources. Contain liquid spills with sand or other inert material. Flush area with water. Avoid dispersion of dust. Observe regulations. Contain dust spills with high efficiency vacuum cleaner. Place in an appropriate and labeled container for disposal.

Section 7. Handling and Storage

Action	Details
Handling	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Avoid contact with eyes. Wash thoroughly with soap and water after handling. **Polylactic Acid (Syringe A):** Avoid contact with eyes. Wash thoroughly with soap and water after handling. **Doxycycline Hyclate (Syringe B):** Avoid dust inhalation. Wash thoroughly after handling.
Storage	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Keep containers tightly closed when not in use. Store in a cool, dry place, out of direct sunlight. **Polylactic Acid (Syringe A):** Avoid contact with atmosphere. Keep closed until ready for use. **Doxycycline Hyclate (Syringe B):** Keep containers tightly closed when not in use. Avoid exposure to light during storage. Store per label instructions. Store in a cold place.

Section 8. Exposure Controls and Personal Protection

Action	Details
Engineering Controls	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Do not remove contents from syringe, however if spill occurs and contents must be handled outside the syringe do so in a well-ventilated area. **Polylactic Acid (Syringe A**): Do not remove contents from syringe, however if spill occurs and contents must be handled outside the syringe do so in a well-ventilated area. **Doxycycline Hyclate (Syringe B):** Handle in a well-ventilated area.
Respiratory Protection	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Do not remove contents from syringe, however if spill occurs and contents must be handled outside the syringe do so in a well-ventilated area. **Polylactic Acid (Syringe A):** Do not remove contents from syringe, however if spill occurs and contents must be handled outside the syringe use a respirator. **Doxycycline Hyclate (Syringe B):** None Required during normal use. If aerosols or dust are generated, a disposable dust/mist respirator may be used. Personnel wearing respirators should be fit tested and approved for respirator used according to OSHA standards.
Protective Clothing	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Hand Protection- Do not remove contents from syringe, however if spill occurs and contents must be handled outside the syringe wear impervious gloves of natural latex or neoprene (Natural latex gloves AR-340 & Style # Y-18 from Glover Latex, Inc. – Anaheim, CA; Neoprene gloves "Scorpio #8-352 from Edmont Wilson – Coshocton, OH). **Polylactic Acid (Syringe A):** Hand Protection Do not remove contents from syringe, however if spill occurs and contents must be handled outside the syringe use rubber gloves. **Doxycycline Hyclate (Syringe B):** Protective Gloves (rubber, latex or nitrile), Protective Gowning. Protect exposed skin.
Eye Protection	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Do not remove contents from syringe, however if spill occurs and contents must be handled outside the syringe use chemical goggles; also wear face shield if splashing hazard exists. **Polylactic Acid (Syringe A):** No applicable information available **Doxycycline Hyclate (Syringe B):** Safety Glasses – Avoid contact with eyes.
OSHA PEL	No applicable information available
ACGIH TLV	No applicable information available

Section 9. Physical and Chemical Properties of Product

Characteristic	Details
Appearance	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Clear liquid **Polylactic Acid (Syringe A):** White to light gold, solid pellets or granules **Doxycycline Hyclate (Syringe B):** Light yellow, solid crystalline powder
pH	**2-Pyrrolidinone, 1-Methyl (Syringe A):** 7.20 (~10% solution) **Polylactic Acid (Syringe A):** No applicable information available **Doxycycline Hyclate (Syringe B):** 6.0 – 7.5
Specific gravity	**2-Pyrrolidinone, 1-Methyl (Syringe A):** 1.025 – 1.035 @ 25 °C **Polylactic Acid (Syringe A):** 1.34 **Doxycycline Hyclate (Syringe B):** Not applicable
Boiling point/ Boiling Range	**2-Pyrrolidinone, 1-Methyl (Syringe A):** 396 °F **Polylactic Acid (Syringe A):** No applicable information available **Doxycycline Hyclate (Syringe B):** No applicable information available
Melting point/Freezing Point	**2-Pyrrolidinone, 1-Methyl (Syringe A):** MP: -12 °F **Polylactic Acid (Syringe A):** Amorphous **Doxycycline Hyclate (Syringe B):** MP: 201 °C – chars without melting
Flash Point	**2-Pyrrolidinone, 1-Methyl (Syringe A):** 199°F **Polylactic Acid (Syringe A):** No applicable information available **Doxycycline Hyclate (Syringe B):** No applicable information available
Flammability	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Combustible **Polylactic Acid (Syringe A):** No applicable information available **Doxycycline Hyclate (Syringe B):** No applicable information available
Flammability & Explosive Limits	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Explosive limits: Upper- 9.5 vol %, Lower- 1.3 vol % **Polylactic Acid (Syringe A):** No applicable information available **Doxycycline Hyclate (Syringe B):** No applicable information available
Vapor Pressure	**2-Pyrrolidinone, 1-Methyl (Syringe A):** 0.29 mm Hg @ 20 °C **Polylactic Acid (Syringe A):** No applicable information available **Doxycycline Hyclate (Syringe B):** < 1 mm Hg @ 20 °C
Vapor Density	**2-Pyrrolidinone, 1-Methyl (Syringe A):** 3.4 **Polylactic Acid (Syringe A):** No applicable information available **Doxycycline Hyclate (Syringe B):** No applicable information available
Relative Density	No applicable information available
Solubility	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Miscible in water **Polylactic Acid (Syringe A):** Reacts slowly with water to become soluble **Doxycycline Hyclate (Syringe B):** Soluble in water
Odor Threshold	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Mild amine-like **Polylactic Acid (Syringe A):** Mild odor **Doxycycline Hyclate (Syringe B):** Essentially odorless
Evaporation Rate (nBuAc = 1)	**2-Pyrrolidinone, 1-Methyl (Syringe A):** 0.06

Section 9 cont. Physical and Chemical Properties of Product

Characteristic	Details
Partition coefficient	No applicable information available
Auto-ignition temperature	No applicable information available
Decomposition temperature	No applicable information available
Viscosity	No applicable information available

Section 10. Stability and Reactivity of Product

Characteristic	Details
Reactivity/ Chemical Stability	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Stable under normal conditions of handling, use and transport **Polylactic Acid (Syringe A):** Stable **Doxycycline Hyclate (Syringe B):** Stable under normal conditions of handling, use and transport
Hazardous Polymerization	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Will not occur **Polylactic Acid (Syringe A):** No applicable information available **Doxycycline Hyclate (Syringe B):** Will not occur
Conditions to Avoid	**2-Pyrrolidinone, 1-Methyl (Syringe A):** None anticipated **Polylactic Acid (Syringe A):** No applicable information available **Doxycycline Hyclate (Syringe B):** Light and heat
Incompatible Materials	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Strong oxidizing agents; strong reducing agents **Polylactic Acid (Syringe A):** None **Doxycycline Hyclate (Syringe B):** Strong oxidizing agents; water-reactive materials
Hazardous Decomposition	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Carbon monoxide, oxides of nitrogen **Polylactic Acid (Syringe A):** Decomposition will occur in the presence of water, but no hazardous decomposition except during combustion when carbon monoxide and or carbon dioxide may form. **Doxycycline Hyclate (Syringe B):** When heated material emits toxic fumes of nitrogen oxides, carbon monoxide, carbon dioxide, sulfur oxides and hydrochloric acid.

Section 11. Health Hazard Information

Toxicity Category	Details
Acute Oral Toxicity	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Rat LD50 – 4,200 mg/kg **Doxycycline Hyclate (Syringe B):** Rat LD50 – > 2 g/kg; Mouse LD50 – 1870 mg/kg; Dog LD50 - >500 mg/kg
Target Organs	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Respiratory system, Eyes, Skin, Liver, Kidney, spleen, Blood **Doxycycline Hyclate (Syringe B):** Liver, teeth, nerves, bone
Skin Irritation	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Prolonged contact may induce defatting of skin that may result in redness and/or cracking. Mild irritation in the rabbit; however, human experience has demonstrated severe dermatitis, e.g. blisters, cracking, edema and redness upon prolonged or repeated contact. **Doxycycline Hyclate (Syringe B):** May cause skin irritation, possible allergic reactions
Eye Irritation	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Moderate Eye Irritant **Doxycycline Hyclate (Syringe B):** May cause skin irritation, possible allergic reactions
Inhalation	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Misted or at high conc., may cause pallor, nausea, anesthetic or narcotic effects. **Polylactic Acid (Syringe A):** No harmful effects expected. Consult a physician **Doxycycline Hyclate (Syringe B):** Irritation
Ingestion	**2-Pyrrolidinone, 1-Methyl (Syringe A):** No applicable information available **Polylactic Acid (Syringe A):** No harmful effects expected. Consult a physician **Doxycycline Hyclate (Syringe B):** Stomach pain, diarrhea, nausea, vomiting
General Toxicity	**Polylactic Acid (Syringe A):** No known toxicity associated with this product. May cause mild eye or skin irritation if reacted with water.

Section 11 cont. Health Hazard Information

Toxicity Category	Details
Injection	No applicable information available
Carcinogenicity	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Not found as carcinogenic
Mutagenicity	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Nonmutagenic - NMP was tested in the Ames assay. CHO/HGPRT forward mutation assay, mouse lymphoma assay, rat primary hepatocyte, unscheduled DNA synthesis assay, *in vivo* dominant lethal test and mouse micronucleus test, *in vivo* Chinese hamster inhalation test. In each case, NMP was fond to be nonmutagenic. **Doxycycline Hyclate (Syringe B):** No applicable information available
Reproductive Toxicity	**2-Pyrrolidinone, 1-Methyl (Syringe A):** NMP: Rat; dermal; developmental toxicity; 75, 237 and 750 mg/kg. Maternal and developmental NOAEL (No Observed Adverse Effect Level): 237 mg/kg – rat; inhalation developmental toxicity 0.1 (25 ppm) and 0.36 (89 ppm) mg/L; Maternal and developmental NOAEL: 0.36 (89 PPM) mg/L. Rabbit; oral; developmental toxicity; 55, 175 and 540 mg/kg/day; maternal NOAEL: 55 mg/kg/day; developmental NOAEL: 175 mg/kg/day. Rat; oral; multi-generation; 50, 160 and 500 mg/kg/day; parental, reproductive and developmental NOAEL: 160 mg/kg/day. **Doxycycline Hyclate (Syringe B):** The therapeutic use of tetracycline is not recommended during the last half of pregnancy since they may cause permanent discoloration of the fetus's teeth, incomplete development or lack of enamel, inhibition of skeletal growth in the fetus.
Teratogenicity	No applicable information available

Section 12. Ecological Information

Characteristic	Details
Toxicity	**2-Pyrrolidinone, 1-Methyl (Syringe A):** The LC50/96-hour values for fish are over 100 mg/l. **Polylactic Acid (Syringe A):** No applicable information available **Doxycycline Hyclate (Syringe B):** Avoid release into the environment. Runoff from fire control or dilution water may cause pollution
Degradability	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Biodegradable **Polylactic Acid (Syringe A):** Biodegradable **Doxycycline Hyclate (Syringe B):** No applicable information available
Persistence	No applicable information available
Bioaccumulation	**2-Pyrrolidinone, 1-Methyl (Syringe A):** This material is not expected to significantly bioaccumulate **Polylactic Acid (Syringe A):** No applicable information available **Doxycycline Hyclate (Syringe B):** No applicable information available
Mobility in Soil	**2-Pyrrolidinone, 1-Methyl (Syringe A):** When released into the soil, this material may evaporate to a moderate extent **Polylactic Acid (Syringe A):** No applicable information available **Doxycycline Hyclate (Syringe B):** No applicable information available

Section 13. Disposal of Product

Measure	Details
Disposal Methods	**2-Pyrrolidinone, 1-Methyl (Syringe A):** Federal, State and local disposal laws and regulations will determine the proper waste disposal/recycling/reclamation procedure. Disposal requirements are dependent on the hazard classification and will vary by location and the type of disposal selected. **Polylactic Acid (Syringe A):** Bury in a landfill in compliance with all Federal, State and local regulations. Material is nonhazardous and biodegradable. **Doxycycline Hyclate (Syringe B**): Dispose by incineration at an approved/permitted incinerator. Review local, state and federal regulations for your regulatory area.
Disposal Container	No applicable information available
Waste Handling	No applicable information available

Section 14. Transport Information

Land Transportation

DOT (*non-bulk*)	DOT Shipping Name	Not regulated
	UN/NA Number	None
	Hazard Class	None
DOT (*bulk*)	DOT Shipping Name	Combustible liquid, N.O.S. (Contains n-Methyl-2-Pyrrolidone)
	UN/NA Number	1993
	Hazard Class	Combustible liquid
	Packing Group	III
		NOTE: Not regulated by IATA for air transportation; IMO for sea transportation; or by TDG for transport in Canada.
Polylactic Acid	*NOTE: Not regulated by DOT for ground transport; not regulated by IATA for air transportation; IMO for sea transportation; or by TDG for transport in Canada.*	
Doxycycline Hyclate	*NOTE: Not regulated by DOT for ground transport; not regulated by IATA for air transportation; IMO for sea transportation; or by TDG for transport in Canada.*	

Section 15. Regulatory Information

Category	**Details**
TSCA Inventory	**2-Pyrrolidinone, 1-Methyl (Syringe A):** TSCA inventory list
SARA Hazard Categories	**2-Pyrrolidinone, 1-Methyl (Syringe A):** EPCRA SARA Sec 313 - Subject to reporting under in quantities greater than 10,000 lbs
CERCLA	No applicable information available
California Proposition 65	**2-Pyrrolidinone, 1-Methyl (Syringe A):** CA Prop 65 - Reproductive hazard **Polylactic Acid (Syringe A):** CA Prop 65 Code D

Section 16. Other Information

Preparation and/or Revision Date: 7/8/2014