Material Safety Data Sheet

PHARMAQ
ROMET® TC
Revised 15. October 2012

1. Chemical Product and Company Identifications:

Product Name:	ROMET®TC
TSCA Status:	FDA Exemption Not on Inventory
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2. Hazardous Components:

Ingredient Name	CAS Number	Concentration %
Ormetoprim	6981-18-6	1-5
Sulfadimethoxine	122-11-2	12-20

3. Hazards Identification:

EMERGENCY OVERVIEW

Physical State:	Fine Powder
Color:	Tan to light brown
Odor:	Strong, fish like

Possible dust explosion hazard based on information on related materials.

POTENTIAL HEALTH EFFECTS

Relevant Routes of Exposure:	Inhalation, skin absorption, eye contact, ingestion
Target Organs:	Dermal system, immune system, hematopoietic/blood system
Acute Effects General:	May cause allergic reactions. My cause mucous membrane irritation (inflammation)
Eye:	May cause eye irritation
Chronic Effects General:	May cause blood system effects

Carcinogenicity:	Formulation not listed by NTP, IARC, or OSHA
Reproductive Toxicity:	May cause birth defects based on animal data. Since this material may affect the developing fetus, females planning to have a child an pregnant women should exercise caution regarding exposure. It is also advisable for nursing mothers to exercise regarding exposure. Sulfamethoxine: May cause birth defects based on animal data. Ormetoprim: May cause birth defects based on related materials.
Conditions Aggravated:	Hypersensitivity to this material. Asthma. Kidney conditions and/or impaired renal function. Blood system disorders. Folic acid deficiency.

4. First Aid Measures:

Inhalation:	Remove to fresh air. If discomfort occurs or persists, get medical attention.
Skin Contact:	Remove contaminates clothing and shoes. Wash skin with soap and plenty of water. If irritation occurs or persists, get medical attention. Wash clothing and shoes before reuse.
Eye contact:	Immediately flush eyes with plenty of water. If irritation occurs or persists, get medical attention.
Ingestion:	If large quantities of this material are swallowed, get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

5. Fire Fighting Measure

Flash point:	Not applicable
Extingushing Media:	Water, carbon dioxide, dry chemical, foam
Unusual Fire and Explosion Hazards:	Violent decomposition may occur when heated or in a fire based on information on related materials. Toxic emissions may be given off in a fire.
Fire Fighting Instructions:	Wear NIOSH/MSHA approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Use caution in approaching fire. Remove containers of this material if it can be done safely. Use water to keep fire exposed containers cool.

6. Accidental Release Measures:

Spill Clean Up Procedures:	Review “Section 3. Hazards Identification”, and “Section 8. Exposure Controls/Personal Protection” before proceeding with the clean up. Shut off the source of the spill or leak if it is safe to do so. Eliminate possible ignition sources. Scoop or shovel spilled material into a suitable labeled open head drum. Secure the drum cover and move the container to a safe holding area. Clean spill area thoroughly.
Treatment and Disposal:	Decontaminate all protective clothing and equipment. See “Section 13. Disposal Considerations” for disposal information.
Reporting Requirements:	The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material. In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials. State and local regulations vary and may impose additional reporting requirements.

7. Handling and Storage:

Special Sensitivity:	Exposure to the following may effect the integrity of this material: Do not heat above 100^{o}C.
Handling & Storage Precautions:	Do not generate dust or expose to ignition sources. Ground and bond all transfer equipment. Milling/mixing/drying should be done at the lowest possible temperature under vacuum or inert conditions. Use with adequate ventilation. Avoid contact with eyes, skin, and clothing. Avoid breathing dust. When handling, use proper personal protective equipment specified in Section 8. Wash thoroughly after handling. Keep container tightly closed when not in use. Store out of direct sunlight in a well ventilated area at room temperature.

8. Exposure Controls and personal Protection:

ENGINEERING CONTROLS Ventilation:	General room ventilation is adequate unless the process generates airborne dust or fume.
PERSONAL PROTECTION Respirator Type(s):	Half face, toxic dust/mist/fume high-efficiency filter

Conditions for Use:	Respiratory protection is recommended as a precaution to minimize exposure. Respiratory protection is recommended under excessively dusty conditions. OSHA considers effective engineering controls to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls. Whenever respiratory protection is used, a complete respirator program should be developed in accordance with OSHA Subpart I (29CFR1910.134) requirements.
Glove Materials:	Any plastic or rubber glove
Conditions for Use:	Gloves are recommended if there is a potential for skin contact.
Skin Protection:	Use protective clothing (lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Eye protection:	Safety glasses required.
OTHER CONTROL MEASURES Additional Protective Measures:	Work clothing should be removed in a change room on site and laundered professionally. Prevent the accumulation of dust in the work area by thorough periodic cleaning of the area.
EXPOSURE LIMITS	There are no exposure limits specified either for this material or for any of its ingredients.

9. Physical and Chemical Properties:

Physical State:	Fine Powder
Color:	White to light tan
Odor:	Characteristic
Pure/Mixture:	Mixture

10. Stability and Reactivity:

Stability:	Normally stable but may become unstable at elevated temperatures or reacts with water, releasing some energy but not violently.
Conditions to Avoid:	Temperatures > 100^{o}C Humidity Dust accumulation Airborne dust Sources of ignition Incompatibility
Materials to Avoid:	Unknown

Decomposition Products:	Carbon dioxide, carbon monoxide, and oxides of nitrogen, and sulfur
Polymerization:	No
Conditions of Polymerization:	Will not occur

11. Toxicological Information:

Sulfadimethoxine:

Acute Oral, Single Dose, Rat: 4000 mg/kg
Summary: Acute oral LD50 (rat) of 4000 mg/kg/body weight at 5 days classifies this material as slightly toxic orally under the study conditions utilized.

Subacute/Subchronic Oral, Dog
Summary: Studies in dogs have shown thyroid gland enlargement and diffuse follicular hyperplasia.

Subacute/Subchronic Oral, 90 day, Rat
Summary: This material was administered daily to rats as a dietary admixture at levels of 0, 5, 10 and 20 mg/kg/day for thirteen weeks (90 day). No abnormal signs in general health or behavior were observed. No abnormalities were noted in hematologic, clinical chemistry, and urinalysis studies, and gross examination of internal organs. Gross examination and histological study of the thyroid glands revealed enlargement and diffuse follicular cell hyperplasia limited to the high dose group.

Reproductive Oral, Rat
Summary: Twenty male and twenty female rats were fed a dietary admixture of 50 mg/kg/day for 74 weeks. Mating occurred during the eleventh week and a first generation of 52 weanlings was produced. No malformation was observed. The first generation was maintained a
50 mg/kg/day for 74 weeks without any adverse effects.

Teratogenicity Oral, Rat
Summary: Studies with pregnant rats given this material on days 8-16 of pregnancy at 267 and 400 mg/kg/day showed birth defects manifested as mainly cleft palate.

Mutagenicity
Summary: In a study to evaluate the ability of this material to induce unscheduled DNA synthesis, no indication of a significant degree of DNA repair was observed. This indicates no evidence of mutagenic activity under the study conditions utilized.

Ormetoprim:	Acute Oral, Single dose, Rat: 665 mg/kg/body weight, which classifies this material as moderately toxic orally under the study conditions utilized. Irritation Eye, Single Dose, Rabbit Summary: An eye irritation study with New Zealand white rabbits produced a score of 2.3, 0.0 for 1 day, 2 days, and 3 days post-instillation, respectively, which indicates that this material was practically non-irritating to the eyes of rabbits under the study conditions utilized. Mutagenicity Salmonella Typhimurium Summary: This material was found to be non-mutagenic in the Ames Assay, with of without metabolic activations, mouse lymphoma forward mutation assay, and unscheduled DNA synthesis assay using rat hepatocytes.

12. Ecological Information

Ecological Information:	No ecological data available on this material.

13. Disposal Considerations:

Disposal Recommendations:	Dispose of in accordance with local, state and federal regulations.
RCRA Waste #:	Not regulated under RCRA.
Empty Containers:	Empty containers must be triple rinsed prior to disposal, recycling, or reuse.

14. Transport information:

Enforcement Agency:	US Dept. of Transportation
Country/Community:	USA
Proper Ship. Name:	Non-regulated
Enforcement Agency:	International Air Transport Association
Transportation Mode:	Air
Country /Community:	International
Proper Ship. Name:	Non-regulated
Enforcement Agency:	International Maritime Organization
Transportation Mode:	Ocean
Country /Community:	International
Proper Ship. Name:	Non-regulated

15. Regulatory Information:

Law/Regulation:	Hazardous Chemical reporting: Community Right-To-Know 40 CFR370
Common name:	SARA Title Section 312 Hazardous Chemical Inventory
Enforcement Agency:	Environmental Protection Agency (EPA)
Governing Authority:	USA
Criteria Met:	Acute, Fire
Law/Regulation:	Safe Drinking Water and Toxic Enforcement Act of 1986 Proposition 65
Common Name:	Prop 65
Enforcement Agency:	California Environmental Protection Agency
Governing Authority:	California, USA

16. Other Information:

Addition information: NFPA RATING: These ratings are based on NFPA Code 704 and are intended for use by emergency personnel to determine the immediate hazards of a material.

Health 1

Fire 2

Reactivity 1

The information presented on this MSDS is, to the best of our knowledge, accurate and reliable. It is provided in good faith without warranty or acceptance of any liability on the part of PHARMAQ. It is the responsibility of the user to evaluate the relevance and completeness of this information for their application and to determine the safety, suitability and status under applicable regulations relating to this product or byproducts arising out of their process.