SAFETY DATA SHEETS

This SDS packet was issued with item:

078952692

N/A

SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name	:	sulfamethoxazole and trimethoprim tablet
Trade Name	:	sulfamethoxazole and trimethoprim tablet
Relevant Identified Uses of the Substance or Mixture and Uses Advised Against		
Intended Use	:	Pharmaceutical product used as antibiotic agent
Details of the Supplier of the Safety Data Sheet		
Company Name (US)	:	Cronus Pharma LLC Two tower center Boulevard Suite 1101A East Brunswick, New Jersey 08816 (USA 1-844-227-6687, 1-844-2-CRONUS contact@cronuspharma.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Acute Oral Toxicity	:	Category 4
Reproductive Toxicity	:	Category 2

Label Elements

Signal Word	:	Warning
Hazard Statements	:	H302 - Harmful if swallowed H361d - Suspected of damaging the unborn child
Precautionary Statements	:	P201 - Obtain special instructions before use P202 - Do not handle until all safety precautions have been read and understood P264 - Wash hands thoroughly after handling P270 - Do not eat, drink or smoke when using this product

P281 - Use personal protective equipment as required

P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell

P308 + P313 - IF exposed or concerned: Get medical attention/advice

P330 - Rinse mouth

P405 - Store locked up

P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards : An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note : This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Trimethoprim	738-70-5	212-006-2	Acute Tox.3 (H301) Repro. Tox.2 (H361d)	15
Sulfamethoxazole	723-46-6	211-963-3	Repr. 2; H361d	74
Starch, pregelatinized	9005-25-8	232-679-6	Not Listed	*
Magnesium Stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Sodium benzoate	532-32-1	208-534-8	Not Listed	*
Sodium starch glycolate	9063-38-1	Not Listed	Not Listed	*
FD & C Red No. 40	25956-17-6	247-368-0	Not Listed	*
Docusate Sodium	577-11-7	209-406-4	Not Listed	*

Additional Information	:	* Proprietary Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures Eye Contact:	:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin Contact	:	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Inhalation	:	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Most Important Symptoms and Effects, Both Acute and Delayed		
Symptoms and Effects of Exposure	:	For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.
Medical Conditions Aggravated by Exposure	:	None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician	:	None

5. FIRE FIGHTING MEASURES

Extinguishing Media	:	Extinguish fires with CO2, extinguishing powder, foam, or water.
Special Hazards Arising from the Substance or Mixture		
Hazardous Combustion Products	:	Emits fumes of carbon dioxide sulfur oxides nitrogen oxides
Fire / Explosion Hazards	:	Not applicable

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting	:	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
Additional Consideration for Large Spills	:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions	:	Store as directed by product packaging
Specific end use(s)	:	Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Trimethoprim

OEL TWA-8 Hr	:	100µg/m^3

Starch, pregelatinized

ACGIH Threshold Limit Value (TWA)	:	10 mg/m^3
Australia TWA	:	10 mg/m^3
Belgium OEL - TWA	:	10 mg/m^3
Bulgaria OEL - TWA	:	10 mg/m^3

Czech Republic OEL - TWA	:	4.0 mg/m^3
Greece OEL - TWA	:	10 mg/m^3 5 mg/m^3
Ireland OEL - TWAs	:	10 mg/m^3 4 mg/m^3
OSHA - Final PELS - TWAs	:	15 mg/m^3
Portugal OEL - TWA	:	10 mg/m^3
Slovakia OEL - TWA	:	4 mg/m^3
Spain OEL - TWA	:	10 mg/m^3
Switzerland OEL -TWAs	:	3 mg/m^3
Magnesium Stearate		
Lithuania OEL - TWA	:	5 mg/m^3
Sweden OEL - TWAs	:	5 mg/m^3
Sulfamethoxazole		
Occupational Exposure Band (OEB)	:	OEB 1 (control exposure to the range of 1000ug/m^3 to 3000ug/m^3)
Exposure Controls		
Engineering Controls	:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal Protective Equipment	:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Hands	:	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
Eyes	:	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
Skin	:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory protection	:	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State	:	Tablet
Odor	:	No data available
Molecular Formula	:	Mixture
Color	:	Pink
Odor Threshold	:	No data available
Molecular Weight	:	Mixture
Solvent Solubility	:	No data available
Water Solubility	:	No data available
pH	:	No data available
Melting/Freezing Point (°C)	:	No data available
Boiling Point (°C)	:	No data available
Partition Coefficient:	:	(Method, pH, Endpoint, Value)
Magnesium Stearate	:	

No data available

Sodium starch glycolate

No data available

Docusate Sodium

No data available

Sodium benzoate

No data available

Starch, pregelatinized

No data available

FD & C Red No. 40

No data available

Trimethoprim

Measured NA Log P 0.38

Sulfamethoxazole

No data available

Decomposition Temperature (°C)	:	No data available
Evaporation Rate (Gram/s)	:	No data available
Vapor Pressure (kPa)	:	No data available
Vapor Density (g/ml)	:	No data available
Relative Density	:	No data available
Viscosity	:	No data available
Flammablity	:	
Autoignition Temperature (Solid) (°C)	:	No data available
Flammability (Solids)	:	No data available
Flash Point (Liquid) (°C)	:	No data available
Upper Explosive Limits (Liquid) (% by Vol.)	:	No data available
Lower Explosive Limits (Liquid) (% by Vol.)	:	No data available

10. STABILITY AND REACTIVITY

Reactivity	:	No data available

10. STABILITY AND REACTIVITY

Chemical Stability	:	Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties : No data available

Conditions to Avoid : None known

Incompatible Materials : As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products : No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects General Information : The information included in this section describes the potential hazards of the individual ingredients.

Short Term : May be harmful if swallowed. (based on animal data)

Long Term : Animal studies have shown a potential to cause adverse effects on the fetus.

Known Clinical Effects : Adverse effects associated with therapeutic use include nausea, diarrhea, blood cell changes, muscle pain, skin rash, Stevens Johnson Syndrome (epidermal necrosis and exfoliative dermatitis), kidney toxicity (nephrotoxicity). Clinical use has resulted in changes in electrolytes and/or blood chemistry changes. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

Acute Toxicity: (Species, Route, End Point, Dose)

Sodium benzoate

Rat	Oral	LD50	4,070 mg/kg
Mouse	Oral	LD50	1600mg/kg

Trimethoprim

Rat	Oral	LD50	200 mg/kg
Rat	Sub-tenon injection (eye)	LD50	500mg/kg
Mouse	Oral	LD50	2764mg/kg
Mouse	Intravenous	LD50	200mg/kg
Mouse	Intraperitoneal	LD50	1870mg/kg

Sulfamethoxazole

Rat	Oral	LD50	6370
Mouse	Oral	LD50	2650
Rat	Intraperitoneal	LD 50	2690
Mouse	Intraperitoneal	LD 50	2300

Acute Toxicity Comments : A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Magnesium Stearate

13 Week(s)	Rat	Oral	1092 g/kg	LOAEL	Liver

Sodium benzoate

10 Day(s)	Rat	Oral	27370 mg/kg	LOAEL	Liver, Blood
10 Day(s)	Mouse	Oral	45 g/kg	LOAEL	Liver, Kidney, Blood, Ureter, Bladder

11. TOXICOLOGICAL INFORMATION

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Sodium benzoate

Embryo / Fetal Development	Rat	Oral	44 g/kg	LOEL	Developmental toxicity

Trimethoprim

Reproductive & Fertility-Males	Rat	Oral	70 mg/kg/day	NOAEL	Fertility
Reproductive & Fertility - Females	Rat	Oral	14 mg/kg/day	NOAEL	Fertility
Embryo / Fetal Development	Rabbit	Oral	30 mg/kg	LOAEL	Embryotoxicity
Embryo / Fetal Development	Rat	Oral	200 mg/kg	LOAEL	Maternal Toxicity, Teratogenic
Embryo / Fetal Development	Mouse	Oral	70 mg/kg	NOAEL	Not Teratogenic

Sulfamethoxazole

Embryo / Fetal Development	Rat	Oral	512 mg/kg/day	NOEL	Teratogenic
Reproductive & Fertility	Rat	Oral	350 mg/kg/day	NOAEL	No effects at maximum dose

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Trimethoprim

Bacterial Mutagenicity (Ames)	*Salmonella* , *E. coli*	Negative
In Vitro Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative
In Vitro Chromosome Aberration	Human Lymphocytes	Negative

Sulfamethoxazole

Bacterial Mutagenicity (Ames)	*Salmonella*	Negative
In Vivo Chromosome Aberration	Human Lymphocytes	Negative
In Vitro Chromosome Aberration	Human Lymphocytes	Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Sulfamethoxazole

60 Week(s)	Rat	Oral	LOEL	Tumors, Thyroid

Carcinogen Status : None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Sulfamethoxazole
IARC : Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview : Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Toxicity :

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Trimethoprim

Daphnia magna (Water Flea)	OECD	LC50	48 Hours	141 mg/L

Persistence and Degradability : No data available

Bio-accumulative Potential:

Partition Coefficient : **(Method, pH, Endpoint, Value)**

Trimethoprim

Measured	**NA**	**Log P**	**0.38**

Mobility in Soil : No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods : Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.
Not regulated for transport under USDOT, EUADR, IATA, ADG or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Trimethoprim

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	212-006-2

Sulfamethoxazole

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present

15. REGULATORY INFORMATION

Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons: :	Schedule 4
EU EINECS/ELINCS List	211-963-3

Starch, pregelatinized

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present

EU EINECS/ELINCS List	232-679-6
Sodium benzoate	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	208-534-8
Sodium starch glycolate	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
FD & C Red No. 40	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	247-368-0
Magnesium Stearate	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

EU EINECS/ELINCS List	209-150-3
Docusate Sodium	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-406-4

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child

Data Sources	:	Safety data sheets for individual ingredients. Publicly available toxicity information.
Reasons for Revision	:	Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 12 - Ecological Information.
Revision date	:	13 May 2020
Disclaimer		Cronus Pharma LLC. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.