SAFETY DATA SHEETS

This SDS packet was issued with item:

078950982

N/A

Section 1 - Identification of the Substance/Mixture and Supplier

Cronus Pharma LLC
Two tower center Boulevard
Suite 1101A
East Brunswick, New Jersey 08816
(USA)
Tel: 1-844-227-6687

Email: contact@cronuspharma.com

Product Identifier:	**Methylprednisolone Tablets, USP 4 mg**
NADA Number:	**#135-771**
Other names:	Methylprednisolone Tablets, USP 4 mg
Chemical family:	Corticosteroid hormone
Recommended Use:	Pharmaceutical active used as anti-inflammatory.
Restrictions on use:	Not for human use

Section 2 - Hazards Identification

Appearance: Tablets, varying in color depending on strength

Signal Word: DANGER

Statement of Hazard: May damage the unborn child. May cause damage to blood and blood forming organs through prolonged or repeated exposure.

Short Term: May be absorbed through the skin and cause systemic effects.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on blood and blood forming organs. May cause allergic reactions in susceptible individuals following repeated contact with this material.

Known Clinical Effects: Adverse clinical reactions include the development of hypersensitivity and/or irritation leading.to rashes, itching, and burning. Clinical use has resulted in hormonal alterations.

EU Indication of danger: Toxic to reproduction: Category 1. Harmful

EU Hazard Symbols:

EU Risk Phrases: R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed. R61 - May cause harm to the unborn child.

Australian Hazard Classification

(NOHSC): Hazardous Substance. Non-Dangerous Goods.

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

Section 3 - Composition/Information on Ingredients

Ingredients	Cas No.
Methylprednisolone, USP	83-43-2
D&C yellow # 10 Alum lake 14-18%, IH	94891-32-4
Sodium Starch Glycolate (Primojel) Type A, USP	9063-38-1
Anhydrous Lactose, USP (Duralac®-H)	63-42-3
Avicel® Microcrystalline Cellulose (Avicel pH 102), USP	9004-34-6
Stearic acid (Kolliwax S Fine), USP	57-11-4
Vanilla FLV, IH	-

Composition comments: In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

Section 4 - First Aid Measures

Eye Contact: Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention**.**

Skin Contact: Wash skin with soap and water. If irritation occurs or persists, get 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**.**

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.

Section 5 - Fire Fighting Measures

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray**.**

Hazardous Combustion Products: May include oxides of carbon.

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

Fire / Explosion Hazards: Not applicable.

Section 6 - Accidental Release Measures

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

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.

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

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area.

Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

Section 7 - Handling and Storage

General 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 thoroughly after handling.

Storage Conditions: Store as directed by product packaging.

Section 8 - Exposure Controls and Personal Protection

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

Methylprednisolone	
Pfizer OEL TWA-8 Hr	4 µg/m3 , Skin
Calcium stearate	
ACGIH Threshold Limit Value (TWA)	10 mg/m3 TWA
Australia TWA	10 mg/m3
Belgium OEL – TWA	Listed
Ireland OEL – TWAS	Listed
Lithuania OEL – TWA	Listed
Portugal OEL – TWA	Listed
Spain OEL – TWA	Listed
Sweden OEL – TWAs	Listed

Section 9 - Physical and Chemical Properties:

Physical State:	Tablets	**Color:**	Various
Odor:	Vanilla	Molecular Weight:	Mixture

Section 10 - Stability and Reactivity

Chemical Stability: Stable under normal conditions of use.

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

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

Section 11 - Toxicological Information

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

Sucrose
Rat Oral LD50 29.7 g/kg

Lactose
Rat Oral LD50 > 10 g/kg

Sorbic acid
Rat Oral LD50 7360 mg/kg
Mouse Oral LD50 3200 mg/kg

Methylprednisolone
Rat Oral LD 50 > 2000 mg/kg
Mouse Oral LD 50 450 mg/kg
Rat Intraperitoneal LD 50 1000 mg/kg
Mouse Intraperitoneal LD 50 1409 mg/kg
Rat Subcutaneous LD 50 >3000 mg/kg

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.

Irritation / Sensitization: (Study Type, Species, Severity)

Mineral oil
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Methylprednisolone
Skin Irritation Rabbit No effect
Eye Irritation Rabbit No effect
Skin Sensitization - GPMT Guinea Pig No effect

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

Methylprednisolone
42 Day(s) Dog Oral 167 µg/kg/day LOAEL Adrenal gland
6 Week(s) Rat Subcutaneous 500 µg/kg/day LOAEL None identified
14 Week(s) Rat Subcutaneous 0.4 µg/kg/day NOAEL Blood forming organs, Adrenal gland
52 Week(s) Rat Subcutaneous 4 µg/kg/day NOAEL Blood forming organs Adrenal gland

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

Methylprednisolone
Reproductive & Fertility Rat Subcutaneous 0.004 mg/kg/day NOAEL Paternal toxicity
Reproductive & Fertility Rat Subcutaneous 0.02 mg/kg/day LOAEL Fetotoxicity
Embryo / Fetal Development Rat Subcutaneous 1.0 mg/kg/day LOAEL Fetotoxicity, Teratogenic
Embryo / Fetal Development Mouse Intramuscular 330 mg/kg/day LOAEL Teratogenic
Embryo / Fetal Development Rabbit Intramuscular 0.1 mg/kg/day LOAEL Teratogenic

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

Methylprednisolone
Bacterial Mutagenicity (Ames) *Salmonella* Negative
Unscheduled DNA Synthesis Rat Hepatocyte Negative
Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells Negative
Direct DNA Interaction Negative

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

Mineral oil
IARC: Group 3

Section 12 - Ecological Information

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

Section 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 wastewater 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.

Section 14 - Transport Information

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations

Section 15 - Regulatory Information

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

Section 16 - Other Information

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.1A; H360 - May damage fertility or the unborn child

Specific target organ toxicity, repeated exposure-Cat.1; H373 - May cause damage to organs through prolonged or repeated exposure

Toxic to reproduction: Category 1

Xn - Harmful

R61 - May cause harm to the unborn child.

R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Data Sources: The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from published literature.

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00	NA	NA