Safety Data Sheet

SECTION 1: Identification

Contact information

General

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Product identifier Methylprednisolone Sodium Succinate for Injection, USP 125 mg, 500 mg, 1 g

Chemical family Mixture – contains a steroid derivative

Recommended uses and restrictions Anti-inflammatory and immunosuppressant agent. Also used for its effects on blood and lymphatic systems in the palliative treatment of various diseases.

Note This SDS is written to address potential worker health and safety issues associated with the handling of the mixture.

SECTION 2: Hazard(s) identification

Classification of the substance or mixture Drugs in the finished state and intended for the final user are not subject to labeling in the US, EU or Canada. Consult prescribing/packaging information. The classification and labeling listed below is for bulk drug product.

Skin corrosion/irritation Category 2
Causes skin irritation
Serious eye damage/eye irritation Category 2
Causes serious eye irritation
Reproductive toxicity Category 2
Suspected of damaging fertility or the unborn child
Specific target organ toxicity (repeated exposure) Category 1
Causes damage to organs (immune system) through prolonged or repeated exposure

Label elements

GHS Hazard pictograms



GHS Signal word Danger

GHS Hazard statements

H315 - Causes skin irritation

H319 - Causes serious eye irritation

H361 - Suspected of damaging fertility or the unborn child

H372 - Causes damage to organs (immune system) through prolonged or repeated exposure

GHS Precautionary statements P201 - Obtain special instructions before use. P202 - Do not handle until all safety precautions have been read and understood. P260 - Do not breathe dust, mist, spray. P264 - Wash hands thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P280 - Wear eye protection, protective clothing, protective gloves. P302+P352 - If on skin: Wash with plenty of water. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308+P313 - If exposed or concerned: Get medical advice/attention. P314 - Get medical advice/attention if you feel unwell. P332+P313 - If skin irritation occurs: Get medical advice/attention. P337+P313 - If eye irritation persists: Get medical advice/attention. P362+P364 - Take off contaminated clothing and wash it before reuse. P405 - Store locked up. P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Other hazards

Methylprednisolone is a synthetic glucocorticoid used for its anti-inflammatory and immunosuppressive properties. Methylprednisolone is converted into active prednisolone in the body, which activates glucocorticoid receptor mediated gene expression. Commonly observed adverse effects include allergic or hypersensitivity reactions, leukocytosis, cardiovascular effects, skin reactions, endocrine changes, fluid retention, electrolyte disturbances, gastrointestinal effects, hepatitis, musculoskeletal, behavioral and mood changes, and ophthalmic effects. Due to their suppression of the inflammatory response and immune function, corticosteroids may increase susceptibility to fungal, bacterial and viral infections and their severity. The immunosuppressive effects of corticosteroids may also result in activation of latent infection or worsening of existing infection.
Although a clear association between corticosteroid use and human teratogenicity has not been established, maternal use of corticosteroids during the first trimester of pregnancy slightly increased the incidence of cleft palate in several cohort and case controlled studies.

Note

This mixture is classified as hazardous under GHS as implemented by Regulation EC No 1272/2008 (EU CLP), WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA).

SECTION 3: Composition/Information on ingredients

Ingredient	CAS number	EINECS/ELINCS#	Amount	GHS classification
Methylprednisolone sodium succinate	2375-03-3	219-156-8	80 – 90 %	Repr. 2, H361d STOT RE 1, H372
Disodium hydrogen phosphate	7558-79-4	231-448-7	5 – 10 %	Skin Irrit. 2, H315 Eye Irrit. 2, H319
Sodium phosphate monobasic monohydrate	10049-21-5	600-102-0	< 1 %	Skin Irrit. 2, H315 Eye Irrit. 2, H319

***Chemical name, CAS number and/or exact concentration have been withheld as a trade secret**

Note Full text of classification categories and H statements: see section 16

SECTION 4: First-aid measures

Description of first aid measures

Immediate medical attention and special treatment, if necessary None

Inhalation Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.

Skin contact Wash skin with plenty of water. Take off contaminated clothing. If skin irritation occurs: Get medical advice/attention. Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.

Eye contact Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.

Ingestion If swallowed, call a physician immediately. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.

Most Important Symptoms/Effects Commonly observed adverse effects include allergic or hypersensitivity reactions, leukocytosis, cardiovascular effects, skin reactions, endocrine changes, fluid retention, electrolyte disturbances, GI effects, hepatitis, musculoskeletal, behavioral and mood changes, and ophthalmic effects.

Expected Symptoms/Effects, Acute and Delayed None known

SECTION 5: Fire-fighting measures

Suitable (and unsuitable) extinguishing media

Suitable extinguishing media Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical No information identified. May emit carbon monoxide, carbon dioxide, oxides of and other compounds.

Fire hazard No information identified.

Explosion hazard No information identified. High concentrations of finely divided organic particles can explode if ignited.

Special protective equipment and precautions for fire-fighters

Firefighting instructions In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Emergency procedures Do not breathe dust. Avoid contact with skin and eyes.

Protective equipment If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated.

Emergency procedures Do not breathe dust.

Environmental precautions Do not empty into drains. Avoid release to the environment.

Methods and material for containment and cleaning up

Methods for cleaning up DO NOT RAISE DUST. Surround spill or powder with absorbents and place a damp cloth or towel over the area to minimize entry of powder into the air. Add excess liquid to allow the material to enter into solution. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container for disposal in accordance with applicable waste disposal regulations (see section 13). Decontaminate the area twice with an appropriate solvent (see section 9).

Other information Dispose of materials or solid residues at an authorized site.

Reference to other sections See Sections 8 and 13 for more information.

SECTION 7: Handling and storage

Precautions for safe handling Follow recommendations for handling potent pharmaceutical agents (i.e, use of engineering controls and/or other personal protective equipment if needed). Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling. Do not breathe dust.

Conditions for safe storage, including any incompatibilities

Storage conditions Store locked up.

Storage temperature Room temperature

Specific end use(s) Pharmaceuticals.

SECTION 8: Exposure controls/personal protection

Control parameters/Occupational Exposure Limits

Name	Issuer	Value
Methylprednisolone sodium succinate	No data available	No data available
Disodium hydrogen phosphate	No data available	No data available
Sodium phosphate monobasic monohydrate	No data available	No data available

Appropriate engineering controls None required for normal handling of packaged product. If handling bulk mixture/solution or if vials are broken: Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. No open handling. Use specifically designed and engineered local exhaust ventilation (LEV) and/or enclosure at dust-generating points and for dust-generating operations unless process is contained. Isolation and closed containment technologies are strongly recommended (enclosed process - a barrier between the equipment and worker) with use of glove bags/continuous liners, isolator systems, direct connections and closed systems. Use clean-in-place systems.

Respiratory protection None required for normal handling of packaged product. If handling bulk mixture/solution or if vials are broken: Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. A powered air-purifying respirator (PAPR) with HEPA filters and head cover is required when performing dust-generating operations. An airline respirator or self-contained breathing apparatus (SCBA) and disposable outerwear is required for spill cleanup.

Hand protection None required for normal handling of packaged product. If handling bulk mixture/solution or if vials are broken: Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Eye protection None required for normal handling of packaged product. If handling bulk mixture/solution or if vials are broken: Wear safety glasses with side shields, chemical splash goggles, or full-face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin and body protection	None required for normal handling of packaged product. If handling bulk mixture/solution or if vials are broken: Wear disposable coveralls appropriate to the task, booties, two pairs of gloves and safety glasses with side shields. Protective garments (coveralls, disposable coveralls, lab coats) are not to be worn in common areas (e.g., cafeterias) or out-of-doors. Employees must be trained in proper gowning and degowning practices. An anteroom or transition area must be used for gowning and degowning.
Other protective measures	Wash hands in the event of contact with this substance, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors).
Environmental exposure controls	Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.

SECTION 9: Physical and chemical properties

Physical state	Solid
Appearance	Vials containing granular or powdered solid.
Formula	Mixture - not applicable
Molecular mass	Mixture - not applicable
Color	No data available
Odor	No data available
Odor threshold	No data available
pH	Not applicable
Melting point	No data available
Freezing point	No data available
Boiling point	Not applicable
Flash point	Not applicable
Relative evaporation rate (butyl acetate=1)	No data available
Flammability (solid, gas)	Not applicable
Vapor pressure	Not applicable
Relative vapor density at 20 °C	No data available
Relative density	No data available
Solubility	Material highly soluble in water.
Log Pow	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity, kinematic	Not applicable
Viscosity, dynamic	Not applicable
Explosion limits	No data available
Explosive properties	No data available
Oxidizing properties	No data available

SECTION 10: Stability and reactivity

Reactivity	The product is non-reactive under normal conditions of use, storage and transport.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	No dangerous reactions known under normal conditions of use.
Conditions to avoid	(See section 7: Handling and Storage).
Incompatible materials	No data available
Hazardous decomposition products	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

Likely routes of exposure May be absorbed by inhalation, skin contact and ingestion.

Toxicological information

Acute toxicity

Component	Type	Dose
Methylprednisolone sodium succinate	LD50 Oral rat	> 5 g/kg
Disodium hydrogen phosphate	LD50 Oral rat	17000 mg/kg
	LD50 Dermal rabbit	> 7940 mg/kg
Sodium phosphate monobasic monohydrate	No data available	No data available

Additional information	No data available
Serious eye damage/irritation	No data available
Skin corrosion/irritation	No data available
Sensitization	No data available
STOT-single exposure	No data available
STOT-repeated exposure	Based on conventional studies of safety pharmacology and repeated-dose toxicity, no unexpected hazards were identified. The toxicities seen in the repeated-dose studies were those expected to occur with continued exposure to exogenous adrenocortical steroids.
Reproductive toxicity	No data available.
Developmental toxicity	Corticosteroids have been shown to be teratogenic in many species when given in doses equivalent to the human dose. In animal reproduction studies, glucocorticoids such as methylprednisolone have been shown to induce malformations (cleft palate, skeletal malformations) and intra-uterine growth retardation.
Genotoxicity	There was no evidence of a potential for genetic and chromosome mutations in limited studies performed in bacteria and mammalian cells.
Carcinogenicity	No data available. None of the components of the mixture present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.
Aspiration hazard	No data available
Experience with humans	See "Section 2 - Other Hazards".

SECTION 12: Ecological information

Toxicity

Component	Type	Concentration
Methylprednisolone sodium succinate	No data available	No data available
Disodium hydrogen phosphate	LC50 other aquatic organisms 1	1154 mg/l Daphnia magna (water flea); 25 hours
	LC50 - Other aquatic organisms [2]	1089 mg/l Daphnia magna (water flea); 50 hours
Sodium phosphate monobasic monohydrate	No data available	No data available

Persistence and degradability	Not expected to persist.
Bioaccumulative potential	No data available
Mobility in soil	No data available
Results of PBT assessment	No data available
Other adverse effects	No data available
Note	No data available

SECTION 13: Disposal considerations

Waste treatment methods	Used product should be disposed of according to local, state, and federal regulations. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines.

SECTION 14: Transport information

Transport	Based on the available data, this mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.
UN number	None assigned.
UN proper shipping name	None assigned.
Transport hazard class(es) (DOT)	None assigned.
Packing group	None assigned.
Marine pollutant	This mixture is not regulated as an environmental hazard or a marine pollutant.
Special transport precautions	Avoid release to the environment.
Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture	This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.
Chemical safety assessment	No chemical safety assessment has been carried out.
TSCA	Drugs are exempt from TSCA.
SARA Section 313 - Emission Reporting	This substance or mixture is not known to contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.
California Proposition 65	California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm.
Additional information	No additional information available

SECTION 16: Other information

Full text of H phrases and GHS classification	Eye Irrit. 2 - Serious eye damage/eye irritation Category 2. Repr. 2 - Reproductive toxicity Category 2. Repr. 2 - Reproductive toxicity Category 2. Skin Irrit. 2 - Skin corrosion/irritation Category 2. STOT RE 1 - Specific target organ toxicity (repeated exposure) Category 1. H315 - Causes skin irritation. H319 - Causes serious eye irritation. H361 - Suspected of damaging fertility or the unborn child. H361d - Suspected of damaging the unborn child. H372 - Causes damage to organs through prolonged or repeated exposure.
Data sources	Information from published literature and internal company data.
Abbreviations and acronyms	ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PBT - Persistent, Bioaccumulative, and Toxic; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STOT - Specific Target Organ Toxicity; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System
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