Amneal Pharmaceuticals Pvt. Ltd.

Material Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION

Product Information

Product name	Triamcinolone Acetonide Injection (10 or 40 mg/ml)
Version	0.0, 03/15/2016
Jurisdiction	This Material Safety Data Sheet was prepared for the jurisdiction USA.
Active substance	Triamcinolone Acetonide
Synonyms	Sterile Triamcinolone Acetonide Suspension USP; Kenalog-10 Injection; Kenalog-40 Injection
Product Uses	This material is a finished drug product for patient use. This material is used to provide relief of inflammatory and pruritic skin conditions.

Company/Undertaking Identification

Address	Amneal Pharmaceuticals Pvt. Ltd. New Jersey United States of America
Emergency Phone Number	1-800- - ------ For all international transportation emergencies call Collect calls accepted.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Components	Concentration	CAS-No.
Hazardous components		
Triamcinolone Acetonide	1 - 4 %	76-25-5
Other ingredients		
Water	90 - 100 %	7732-18-5
Sodium Carboxymethylcellulose	<1 %	9004-32-4
Tween 80	<1 %	9005-65-6
Benzyl alcohol	<1 %	100-51-6
Hydrochloric acid	<1 %	7647-01-0
Sodium Chloride	<1 %	7647-14-5
Sodium Hydroxide	<1 %	1310-73-2

3. HAZARDS IDENTIFICATION

Emergency Overview

Appearance	liquid : white to off-white, suspension
Signal Word	Warning!
Hazard Statements	Teratogen May be harmful to fetus. Reproductive toxicant Target Organs: adrenal glands, bone, muscle, gastrointestinal tract, immune system, eyes, nervous system, skin, female reproductive organs, (embryo/fetus).

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3. HAZARDS IDENTIFICATION	
Precautionary Measures	Avoid ingestion, inhalation, skin and eye contact. Wash hands after handling to minimize exposure. Wear suitable protective clothing and gloves. Pregnant or nursing women should avoid exposure. Prevent release to the environment.
Potential Health Effects	
Eyes	Possible mild eye irritant
Skin	Rapidly absorbed through skin., Repeated exposure may cause skin dryness or cracking., May be harmful if absorbed through skin.
Ingestion	May cause damage to organs through prolonged or repeated exposure if swallowed.
Inhalation	May cause damage to organs through prolonged or repeated exposure if inhaled.
Target Organs	adrenal glands, bone, muscle, gastrointestinal tract, immune system, eyes, nervous system, skin, female reproductive organs, (embryo/fetus)
Signs and Symptoms	Chronic: muscle weakness, muscle pain, bone fractures, infection, oedema, headache, difficulty sleeping, vertigo, restlessness, euphoria, mental disturbance, depression, anxiety, mood changes, seizure disorders, nosebleeds, cough, fever, nausea, vomiting, anorexia, gastrointestinal disturbance, sore throat, dry mouth, taste disturbance, speech difficulty, congestion, redness and swelling of eyes, vision changes, facial swelling, skin thinning, acne, redness and swelling of skin, hives, bruising, superficial burning sensation, tingling.
Medical conditions aggravated include:	diabetes, Liver disorders, infection, immunodeficiency, hypertension, myasthenia gravis, osteoporosis, peptic ulcer, psychotic disorders, colitis, kidney disorders
Environmental Effects	Refer to Section 12

4. FIRST AID MEASURES	
Eye contact	Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. Obtain medical attention.
Skin contact	Take off contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. Obtain medical attention. Wash contaminated clothing before re-use.
Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. Obtain medical attention.
Ingestion	Do NOT induce vomiting. Consult a physician if necessary. Never give anything by mouth to an unconscious person.

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4. FIRST AID MEASURES	
Notes to physician	This material is a finished drug product for patient use. This material is used to provide relief of inflammatory and pruritic skin conditions. This product may cause: muscle weakness, muscle pain, bone fractures, infection, oedema, headache, difficulty sleeping, vertigo, restlessness, euphoria, mental disturbance, depression, anxiety, mood changes, seizure disorders, nosebleeds, cough, fever, nausea, vomiting, anorexia, gastrointestinal disturbance, sore throat, dry mouth, taste disturbance, speech difficulty, congestion, redness and swelling of eyes, vision changes, facial swelling, skin thinning, acne, redness and swelling of skin, hives, bruising, superficial burning sensation, tingling, increase in blood pressure, Cushing's syndrome, electrolyte disturbance, hyperglycemia, adrenocortical insufficiency, withdrawal symptoms, osteoporosis, bone effects, menstrual irregularities, sperm abnormalities, cataracts, glaucoma, nose changes, otitis, peptic ulcer, psychotic disorders, pancreatitis, changes in white blood cell parameters. Organs effected may include: adrenal glands, bone, muscle, gastrointestinal tract, immune system, eyes, nervous system, skin, female reproductive organs, (embryo/fetus). Medical conditions aggravated include: diabetes, Liver disorders, infection, immunodeficiency, hypertension, myasthenia gravis, osteoporosis, peptic ulcer, psychotic disorders, colitis, kidney disorders. This product has been reported to interact with the following medications: diuretic, cyclosporine, immunosuppressants, NSAID (non-steroidal antiinflammatory drugs), drug metabolized by cytochrome P-450, drugs that cause hyperglycemia, oral hypoglycemic drugs, neuromuscular blocking agents, fluoroquinoline antibiotics, certain vaccines, drugs that inhibit cytochrome P-450. Refer to Section 11. Pregnant or nursing women should avoid exposure.
Medical Surveillance	A pre-placement physical examination and history for employees with potential exposure to this compound is recommended. Baseline testing would include: Pre-placement:, blood glucose test, a complete blood count with differential. Based on opportunity for exposure and duration of exposure a periodic follow-up examination may be considered. Employees, who are pregnant, are breast-feeding, or who are concerned with other reproductive issues should be encouraged to consult with the occupational health physician monitoring worker's health.

5. FIRE-FIGHTING MEASURES	
Flammable Properties	Not available
Extinguishing Media	Suitable extinguishing media: Dry chemical, Water spray, Foam Unsuitable extinguishing media: Do NOT use water jet.
Protection of Firefighters	Specific hazards: Teratogen skin absorption hazard Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus. Hazardous Combustion Products: carbon oxides, hydrogen halides
Other information:	Decontaminate protective clothing and equipment before reuse. Heating can release hazardous gases. HCl gas can form flammable or explosive mixtures with alcohols or metals.

6. ACCIDENTAL RELEASE MEASURES	
Personal precautions	Refer to protective measures listed in sections 7 and 8. Use personal protective equipment. Examples include tightly fitting safety goggles, disposable lab coat of low permeability with cuffs, double gloves and shoe covers. Wear respiratory protection. Depending on the nature of the spill (quantity and extent of spill) additional protective clothing and equipment such as a self-contained breathing apparatus may be needed.

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6. ACCIDENTAL RELEASE MEASURES	
Environmental precautions	Prevent release to drains and waterways. Prevent release to the environment.
Containment Methods	Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).
Cleanup Methods	Contain and collect spillage and place in container for disposal according to local regulations (see Section 13). Clean spill area with a deactivating solution (if available) followed by detergent and water after spill pick-up. Handle waste materials, including gloves, protective clothing, contaminated spill cleanup material, etc., as appropriate for chemically and pharmacologically similar materials.

7. HANDLING AND STORAGE	
Handling Precautions	Highly potent material. Avoid exposure - obtain special instructions before use. Avoid inhalation of vapour or mist. Keep away from heat and sources of ignition. Prevent release to drains and waterways.
Storage Conditions	Store at room temperature. (20 - 25°C) Protect against light. Avoid freezing.
Container Requirements	Store in sturdy containers appropriate to maintain the integrity of this material for its intended use.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limit(s)	Company Guideline	ACGIH	OSHA	NIOSH
Triamcinolone Acetonide	1 µg/m3 (Skin), Developmental Toxicity	--	--	--
Benzyl alcohol	--	--	--	--
Sodium Hydroxide	--	2 mg/m3 Ceiling	2 mg/m3 TWA	2 mg/m3 Ceiling 10 mg/m3 IDLH
Hydrochloric acid	--	2 ppm Ceiling	5 ppm Ceiling 7 mg/m3 Ceiling	5 ppm Ceiling 7 mg/m3 Ceiling 50 ppm IDLH

Exposure Control Band	<u>Triamcinolone Acetonide</u> ***4*** -- The established company exposure guideline falls within Exposure Control Band 4 (range 1 -20 µg/m3).
Bristol-Myers Squibb Exposure Guidelines Summary	<u>Triamcinolone Acetonide</u> Materials require particular care and handling. Adherence to this guideline should protect employees from experiencing the therapeutic and/or adverse effects of this drug.
Recommended Industrial Hygiene Monitoring Methods	Contact the Bristol-Myers Squibb AIHA accredited Industrial Hygiene Laboratory at 732-227-7368. See Section 4 "Notes to Physician" for information on medical surveillance.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION	
Engineering Controls and Ventilation	When handling small quantities in a clinical setting, good room ventilation is desirable. Specific engineering controls should not be needed. When handling larger quantities, such as in a manufacturing setting, ensure worker exposure is below the recommended exposure limit. If significant aerosol (mist) is generated, use process enclosures, containment technology, or other engineering controls to keep airborne levels below recommended exposure limit.
Respiratory protection	Respiratory protection is not required for normal use of this material. If the occupational exposure limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL. Note: May cause damage to organs through prolonged or repeated exposure if inhaled.
Eye protection	Chemical splash resistant goggles should be worn when potential for splash exists.
Hand protection	Impervious nitrile, rubber and latex gloves are recommended. Please note that employees who are allergic to natural rubber latex should use nitrile gloves.
Skin and body protection	It is recommended that a laboratory coat be worn when handling product.
Hygiene	Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES	
Appearance	
Physical State	liquid
Color	white to off-white
Form	suspension
Descriptive properties	
Molecular Weight	Not available
Molecular formula	Not applicable
Bulk density	Not available
Evaporation rate	Not available
Hydrolysis/Photolysis	Not available
Hygroscopicity	Not available
Log Octanol/Water Partition Coeff [log Kow]	Not available
Surface Tension	Not available
Odor	Not remarkable.
Odor Threshold	Not available
pH	5 - 7
pKa	Not available
Particle Size	Not available
Solubility, Water	soluble
Specific Gravity/ Relative density	1.015
Viscosity	similar to water
Thermal/Stability properties	
Autoignition temperature	Not available
Boiling Point	100 °C
Thermal decomposition	Not available
Explosive Limits, LEL	Not available
Explosive limits, LEL	Not available

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9. PHYSICAL AND CHEMICAL PROPERTIES	
Explosiveness	Not available
Flammability	Not available
Flash point	Not available
Melting Point	0 °C
Oxidizing Potential	Not available
Vapor Properties	
Vapor Density	(Air =1): If adequate temperatures caused material to volatize, its vapor density would be much greater than 1. (Heavier than air)
Vapor Pressure	Not available
Saturated Vapor Concentration	Not available

10. STABILITY AND REACTIVITY	
Stability	
Chemical Stability	Stable under normal conditions.
Conditions to avoid	Not available
Incompatible products	Not available
Hazardous decomposition products	Hazardous decomposition products formed under fire conditions.: carbon oxides, hydrogen halides
Hazardous reactions	Not available
Sensitivity to static discharge/Dust exp.	
Summary Statements	not applicable

11. TOXICOLOGICAL INFORMATION	
Routes of Entry	Ingestion, Inhalation, Eye contact, Skin contact
Eye irritation	Triamcinolone Acetonide Possible mild eye irritant
Skin irritation	Triamcinolone Acetonide Repeated exposure may cause skin dryness or cracking. skin thinning
Respiratory Irritation	Triamcinolone Acetonide May cause irritation of respiratory tract.
Sensitisation	Triamcinolone Acetonide Not a dermal sensitizer Allergic contact dermatitis is quite rare but has been reported.
Acute Toxicity Study	**Acute Oral** Triamcinolone Acetonide Oral LD50(mouse): 5,000 mg/kg **Acute toxicity (other routes of administration)** Triamcinolone Acetonide LD50 (rat, subcutaneous): 13.1 mg/kg LD50 (mouse, subcutaneous): 132 mg/kg LD50 (mouse, Intraperitoneal): 105 mg/kg

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11. TOXICOLOGICAL INFORMATION

Repeated dose toxicity	Triamcinolone Acetonide **Assessment Repeat Dose Toxicity** Several studies were conducted. Results from these studies in multiple species were generally similar with respect to target organs and effects. See Section 11 Target Organs and Symptoms for a description of effects.
Genetic Toxicity	Triamcinolone Acetonide **in vitro** Ames reverse-mutation assay -- negative Forward gene mutation assay -- negative **Mutagenicity Assessment** Several studies were conducted. The weight of evidence demonstrates that this material is not genotoxic.
Carcinogenicity	Triamcinolone Acetonide 104 Weeks Oral rat study : [tumor organs: liver] positive 104 Weeks Oral rat study : NOAEL = 0.001 mg/kg No treatment-related tumors were observed. 104 Weeks Oral mouse study : NOAEL = 0.003 mg/kg No treatment-related tumors were observed. **Carcinogenicity Assessment** Several studies were conducted. The results were negative and positive. Not classifiable as to its carcinogenicity to humans.

Carcinogenicity	**ACGIH**	**OSHA**	**NTP**	**IARC**
Triamcinolone Acetonide	--	--	--	--

Reproductive Toxicity	Triamcinolone Acetonide **Assessment Reproductive Toxicity** Several studies were conducted. May impair fertility. Maternal effects include: menstrual irregularities . Paternal effects include: sperm abnormalities See "Human Experience". See also "Developmental Toxicity" for information on reproductive effects.
Developmental Toxicity	Triamcinolone Acetonide **Developmental Toxicity Assessment** Several developmental studies were conducted. Birth defects were observed in animal studies. Compound may be toxic during early embryonic development. Teratogen This compound and/or its metabolites may be excreted into the milk. May cause harm to breastfed babies.
Human experience	**Experiences with Human Exposure** Triamcinolone Acetonide General effects therapeutic use - Symptoms: muscle weakness, muscle pain, bone fractures, infection, oedema, headache, difficulty sleeping, vertigo, restlessness, euphoria, mental disturbance, depression, anxiety, mood changes, seizure disorders, nosebleeds, cough, fever, nausea, vomiting, anorexia, gastrointestinal disturbance, sore throat, dry mouth, taste disturbance, speech difficulty,

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11. TOXICOLOGICAL INFORMATION

congestion, redness and swelling of eyes, vision changes, facial swelling, skin thinning, acne, redness and swelling of skin, hives, bruising, superficial burning sensation, tingling.

Other effects include: increase in blood pressure, Cushing's syndrome, electrolyte disturbance, hyperglycemia, adrenocortical insufficiency, withdrawal symptoms, osteoporosis, bone effects, menstrual irregularities, cataracts, glaucoma, nose changes, otitis, peptic ulcer, psychotic disorders, pancreatitis, changes in white blood cell parameters.

Epidemiology

Triamcinolone Acetonide

Epidemiological study - Several studies have associated the development of oral clefts with exposure during pregnancy. Fetal effects include: decreased body weight .

Target Organs	Triamcinolone Acetonide adrenal glands, bone, muscle, gastrointestinal tract, immune system, eyes, nervous system, skin, female reproductive organs
Symptoms	Triamcinolone Acetonide See "Human Experience".
Other Toxicity Information	Not available
Other Information:	This MSDS may contain toxicological and/or pharmacological information derived from either the specified product or from compounds in the same pharmacological class.

12. ECOLOGICAL INFORMATION

Ecotoxicological Information (Aquatic)

Acute Toxicity to Aquatic Invertebrates

Triamcinolone Acetonide

EC50 (Daphnia magna, 48 H) : > 100 mg/l

Ecotoxicological Information (Terrestrial) Not available

Chemical fate information

Biodegradation

Triamcinolone Acetonide

Ultimate aerobic biodegradation (28 D) : 3 % ; Not Readily Biodegradable - unlikely to undergo rapid biodegradation in the environment

Summary Statements

Aquatic toxicity

Experimental data indicate low potential for acute harm to aquatic invertebrates

Chemical Fate

Not readily biodegradable.

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13. DISPOSAL CONSIDERATIONS	
Advice On Disposal And Packaging	Disposal should be in accordance with applicable regional, national, and local laws and regulations. Local regulations may be more stringent than regional or national requirements. This information presented only applies to the material as supplied.
Other information	Disposal by incineration is recommended.

14. TRANSPORT INFORMATION
This material is not a dangerous good for the purpose of transportation.

15. REGULATORY INFORMATION	
United States of America	
OSHA Hazard Classification	Teratogen, Target Organs.
313 Toxic Release Inventory. Listed Chemicals/Compounds	No components listed on the SARA 313 inventory.
TSCA Inventory	Not listed. Food, drug and cosmetic products are exempt from TSCA.
International	
Canada	
WHMIS	This product is not regulated under the Hazardous Products Act and Controlled Products Regulations. This product, however, may have significant health hazard and could meet the criteria for: D2A Very Toxic Material Causing Other Toxic Effects
DSL/NDSL	yes
Mexico	
Mexico Classification	Health classification - Serious Hazard - 3 - Substances that can cause serious or permanent harm under emergency conditions
Europe	
EINECS/ELINCS Number	Triamcinolone Acetonide: 200-948-7 Water: 231-791-2 Benzyl alcohol: 202-859-9 Sodium Chloride: 231-598-3 Sodium Hydroxide: 215-185-5 Hydrochloric acid: 231-595-7
R-phrase(s)	Medicinal products are exempt from classification and labeling requirements under EU Preparations Directive 1999/45/EC.

16. OTHER INFORMATION	
MSDS preparation information	
Prepared by	Corporate Quality, Environmental Health & Safety 1-732-227-7380
Prepared on	02/15/2016
	This Safety Data Sheet has been revised. This MSDS has been reformatted in a new electronic system. This data sheet contains changes from the previous version in section(s): All.

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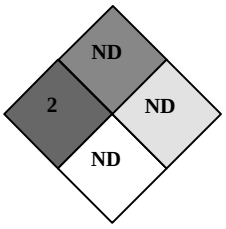
Other information

HMIS

Health	2*
Flammability	Not Determined (ND)
Reactivity	Not Determined (ND)
Personal protective equipment	See Section 8.

NFPA

Health	2
Fire	ND
Reactivity	ND
Special	ND



The information contained in this MSDS is believed to be accurate and represents the best information reasonably available at the time of preparation. However, we make no warranty, express or implied, with respect to such information. and we assume no liability from its use.

End of Safety Data Sheet