



Bristol-Myers Squibb Company

MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

BRISTOL-MYERS SQUIBB
 WORLDWIDE MEDICINES GROUP
 P.O. BOX 191
 NEW BRUNSWICK, NJ 08903
 (732) 519-3683

December 8, 2000

Product Identification Kenalog Injection (10 or 40 mg/ml).

Chemical Names (for active ingredient): Pregna-1,4-diene-3, 20-dione, 9-fluoro-11-beta, 16-alpha,17,21-tetrahydrocyclic 16,17-acetal with acetone

Synonym: Sterile Triamcinolone Acetonide Suspension USP, Kenalog-10 Injection or Kenalog-40 Injection.

How Supplied: Kenalog Injection is provided in glass vials at 10 or 40 mg/ml.

Product Use: Relief of inflammatory and pruritic skin conditions.
 Chemical Family: Glucocorticoids.

Molecular Formula: Active ingredient (Triamcinolone Acetonide).
 C₂₄H₃₁O₆F

CAS NUMBER: Triamcinolone acetonide 76-25-5.

EMERGENCY CONTACTS

Transportation: CHEMTREC (800)424-9300. For all international transportation emergencies call Chemtrec at (703)527-3887, collect call accepted.

EMERGENCY OVERVIEW: Kenalog Injection contains the potent glucocorticoid, triamcinolone acetonide. This drug may be absorbed through the skin. See Health Effects section for additional information.

2. COMPOSITION/ INFORMATION ON INGREDIENTS

| COMPONENTS | HAZARDOUS (Y/N) | CONCENTRATION (wt %) | CAS NUMBER | EXPOSURE GUIDELINE |
|-------------------------|-----------------|----------------------|------------|--------------------------------------|
| Triamcinolone Acetonide | Y | 1-4 | 76-25-5 | 0.001 mg/m ³ BMS-EG(1) |
| Water for Injection USP | N | >1 | 7732-18-5 | None |
| Benzyl alcohol | Y | >1 | 100-51-6 | None |

Present at < 1% or used for pH adjustment:
 Carboxymethylcellulose sodium, 7MF USP; hydrochloric acid; sodium chloride; sodium hydroxide; Tween 80 (Polysorbate 80 NF).

1 BMS-EG = Bristol-Myers Squibb Company Exposure Guideline (8-hour time-weighted average).

DBM

I- 255473 C-00003049420
 I- 459558 C-00003049420
 I- 459991 C-00003049420

DMF

I- 460436 C-00003029320
 I- 462514 C-00003029328
 I- 462515 C-00003029325

HC #06



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3. HEALTH HAZARDS IDENTIFICATION

EFFECTS OF OVEREXPOSURE

Routes of Entry:

1. **Inhalation:** Under normal conditions exposure to this material by inhalation is not expected to occur. However, in a situation where the liquid would be aerosolized there may be potential for inhalation. Triamcinolone acetonide may be absorbed after inhalation.
2. **Skin contact:** Exposure may occur via skin contact if gloves and protective clothing are not worn. Triamcinolone acetonide, which is a glucocorticoid, may be well absorbed after skin contact.
3. **Ingestion:** Ingestion of large quantities of this material in an occupational setting would not be expected to occur. Ingestion of trace amounts of the material might occur if material contacts hands and hands are not washed prior to eating, drinking, or smoking. Triamcinolone acetonide may be absorbed after ingestion.

Acute

Ingestion: The active drug, triamcinolone has low toxicity after acute ingestion. Inadvertent ingestion of trace amounts of this liquid would not be expected to result in harmful effects. Repeated ingestion of high doses might result in symptoms such as headache, dizziness, fatigue, faintness and endocrine symptoms.

Inhalation: Acute inhalation of small doses of aerosolized material would not be expected to result in symptoms.

Skin Contact

a. **Toxic:** Material contains a highly potent drug which is known to be absorbed through the skin. If there is sufficient and repeated skin contact with this material, some of the systemic effects described under acute ingestion and under chronic effects may be possible, particularly if material contacts large areas of the body, when the exposure period is prolonged and when contact area is covered by an occlusive dressing or material.

b. **Irritation:** Dermatological effects, including burning, itching, irritation, drying, cracking, or tightening of the skin; thinning of the skin; acneiform eruption; erythema; folliculitis; hypertrichosis; allergic contact dermatitis and other skin disorders are reported infrequently when topical corticosteroids are used therapeutically. These reactions may occur more frequently if contact area is covered by an occlusive material.

c. **Sensitization:** Rarely occurs.

Eye Contact: The potential for induction of eye irritation has not been evaluated.

Chronic:

Exposure Guideline Summary: Triamcinolone acetonide (SQ 9,727) is a highly potent anti-inflammatory drug classified as a glucocorticoid. An exposure guideline of 0.001 mg/m³ (8-hour TWA) in air has been established for workplace exposure to triamcinolone acetonide. Provided that ingestion and skin contact are avoided, adherence to the exposure guideline will ensure that a worker is not exposed to more than 2% of the



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HEALTH HAZARDS IDENTIFICATION (CONTINUED)

lowest recommended dose of Kenalog aerosol and should protect employees who handle triamcinolone acetonide from experiencing pharmacological effects of this drug. Due to the high potency of this drug and its potential for absorption through the skin persons who handle this drug should avoid skin and eye contact, as well as inhalation of the drug.

Carcinogen Lists IARC: No NTP: No OSHA: No

Target Organs: Skin, lens of eye, bones, nervous system, adrenal glands and immune system.

Medical Conditions Aggravated by Exposure: Therapeutic doses of glucocorticoids may aggravate systemic fungal infections, tuberculosis, peptic ulcers, diabetes mellitus, and certain psychiatric conditions. It is recommended that drugs of this type not be used in large amounts or for prolonged periods of time during pregnancy.

Medical Surveillance Recommendation: Glucocorticoids may aggravate diabetes, peptic ulcer disease and active tuberculosis. Prior to working with triamcinolone acetonide personnel should be questioned to determine whether they have a history or symptoms of diabetes, peptic ulcer or tuberculosis. If exposures exceed the exposure guideline personnel should be monitored for glucose tolerance and symptoms of peptic ulcer and/or tuberculosis disease.

FOR MORE INFORMATION REFER TO SECTION 11: TOXICOLOGICAL INFORMATION

4. FIRST AID MEASURES

Ingestion: Get medical attention.

Inhalation: Remove exposed person to fresh air. If person is not breathing give artificial respiration. If breathing is difficult administer oxygen. Get medical attention.

Skin Contact: Remove contaminated clothing. Flush with plenty of water for 15 minutes.

Eye Contact: Hold eyelids apart and flush with plenty of water for 15 minutes. Get medical attention immediately.

Note to physicians: None.

5. FIRE FIGHTING MEASURES

Flash point: Not determined.
Autoignition Temperature: Not determined.
Flammability limits
LEL: Not applicable.
UEL: Not applicable.

Combustibility of Dusts: Not applicable.

Extinguishing Media: In case of fire use water, carbon dioxide, foam, or dry chemical.

Firefighting Instructions: Firefighters should wear self-contained breathing apparatus (SCBA), flame and chemical resistant clothing, boots



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FIRE FIGHTING MEASURES (CONTINUED)

and gloves. Evacuate personnel to upwind direction, remove unneeded material and cool container(s) with water from maximum distance.

Hazardous Combustion Products: CO, CO₂, HF (small amount), HCl.

Unusual Hazards: See combustion products.

6. ACCIDENTAL RELEASE MEASURES

Spill/Clean-up: Wearing suitable protective clothing, absorb liquid onto appropriate absorbent material and place into a container for disposal. Impermeable gloves (latex or nitrile) and eye protection should be worn as a minimum precaution. Additional protective clothing/equipment may be needed depending on the extent of the spill. The spill area should be ventilated and decontaminated after material has been picked up.

7. HANDLING AND STORAGE

Handling Precautions: Avoid skin and eye contact.

Container Requirements: Glass vials as described in Section 1.

Storage Conditions: Store product at room temperature (avoid temperature extremes) and protect from light.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Ventilation Requirements: Keep airborne concentration below exposure guidelines by enclosure of processes or local exhaust ventilation, as required.

Respiratory Protection: When engineering controls are not sufficient to control exposure, wear NIOSH approved respiratory protection to control employee exposure; self-contained breathing apparatus should be available for emergency use.

Eye Protection: Wear safety goggles (ANSI Z87.1).

Protective Gloves: Wear impervious (latex or nitrile) gloves if the potential exists for dermal contact.

Special Clothing: Wear protective coveralls, whenever the potential for splashing or spraying of liquid exists.

Hygiene: Wash hands after handling compound and before eating, smoking, using lavatory, and at the end of the day.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance/Physical State/Color: White to off-white aqueous suspension.

Boiling point: Approximately 100 degrees C.

Evaporation rate: Not available.

Flash point: Not available.

Freezing point: Not available.

Melting point: Approximately 0 degrees C.



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PHYSICAL AND CHEMICAL PROPERTIES (CONTINUED)

Octanol/water partition coefficient: Not available.
Odor (threshold): Not remarkable.
pH: 5.0 to 7.5.
Solubility in water: Soluble.
Specific gravity: Approximately 1.02.
Vapor density (Air = 1): If adequate temperatures caused the Kenalog liquid to volatilize, the toxic constituents (TACA and benzyl alcohol) are heavier than air.
Vapor Pressure: Not available.
Viscosity: Approximately equal to water. Aqueous solution.

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions.
Incompatibilities: No known hazardous incompatibilities.
Conditions of Reactivity: None known.
Hazardous Decomposition Products: CO, CO₂, HF (small amount), HCl.
Hazardous Polymerization: Will not occur.
Explosion data relative to mechanical impact: Not applicable.
Explosion data relative to static discharge: Not applicable.

11. TOXICOLOGICAL INFORMATION -- for active ingredient.

RTECS NUMBER (U.S.):
TU3920000 (Triamcinolone acetonide)

ACUTE

LD 50:

Acute oral LD50 (mouse) = 5 g/kg;
Acute ip LD50 (mouse) = 105 mg/kg;
Acute sc LD50 (mouse) = 132 mg/kg;
Acute sc LD50 (rat) = 13.1 mg/kg.

LC 50: Not applicable.

CHRONIC

Carcinogenicity: Triamcinolone acetonide has not been tested for carcinogenicity.

Mutagenicity: This compound is not known to be mutagenic. In some cell systems and experimental animals, the compound may decrease DNA synthesis.

Teratogenicity: Glucocorticoids, including triamcinolone acetonide, are generally teratogenic in experimental animals. When triamcinolone acetonide was administered to rats by inhalation during days 6-15 of pregnancy an increased incidence of litters with malformations was noted at doses as low as 0.02 mg/kg/day.

There is no clear evidence of a teratogenic effect of glucocorticoids during human pregnancy at normal therapeutic doses. In



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TOXICOLOGICAL INFORMATION (CONTINUED)

those instances where cleft palate was reported the underlying medical disorder and other drugs used may have contributed to the development of the adverse outcome. This class of drugs administered at therapeutic doses may result in growth retardation during childhood.

Reproductive Effects: It is not known whether topical glucocorticoids affect fertility. Safe use of topical steroids during pregnancy has not been established.

Toxicological synergistic products: Glucocorticoids interact with anticholinesterase agents such as ambenonium, neostigmine, and pyridostigmine and can produce severe weakness in patients. Glucocorticoids may enhance potassium loss in individuals using potassium-depleting diuretics.

12. ECOLOGICAL INFORMATION

Ecotoxicological Information: No information.

Chemical Fate Information: No information.

13. DISPOSAL CONSIDERATIONS

Disposal: Dispose of in accordance with National, State, Local and applicable country regulations.

14. TRANSPORT INFORMATION

DOMESTIC

Hazard Class (UN NUMBER): Not a D.O.T. regulated material.

Proper shipping name: Not applicable.

Label requirements: Not applicable.

Placard requirements: Not applicable.

Limited Quantity Exemption: Not applicable.

INTERNATIONAL

Hazard Class (UN NUMBER or PIN NUMBER): Not a regulated material.

Proper shipping name: Not applicable.

Label requirements: Not applicable.

Placard requirements: Not applicable.

Limited Quantity Exemption: Not applicable.

15. REGULATORY/STATUTORY INFORMATION -- not meant to be all inclusive.

U.S. Federal: None noted.

International: None noted.

EC Labeling: None noted.

16. OTHER INFORMATION

December 8, 2000: This MSDS was revised to change telephone numbers.



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OTHER INFORMATION (CONTINUED)

Therapeutic agents are intended for use under direction of a physician and/or under the conditions of use described on the label. As a general precaution, personnel who handle drug substances should avoid contact (ingestion, inhalation, skin and eye contact) with these substances.

This material safety data sheet is intended for use by personnel who handle this material as part of their job responsibilities. It does not address the therapeutic use of this material. Information concerning the therapeutic use of this drug substance should be obtained from formulated product package inserts and other appropriate references.

The information contained in this MSDS is believed to be accurate and represents the best information 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.