Safety Data Sheet

SDS #882

Bristol-Myers Squibb Company

1. IDENTIFICATION		
Product Information		
Product name	KENALOG®-10, 40,80 mg/ml (triamcinolone acetonide) Injectable Suspension	
Version	2.2, 27.06.2017	
Jurisdiction	This Safety Data Sheet was prepared in accordance with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) for the United States of America (USA) (CFR 1910.1200), European Union (EU) (EC 1272/2008) and United Nations (UN). The following countries utilize the UN GHS classification process: Mexico, Brazil, China, New Zealand, Canada, Japan, and Korea.	
Active substance	Pregna-1,4-diene-3,20-dione, 9-fluoro-11,21-dihydroxy-16,17-[(1-methylethylidene)bis(oxy)]-, (11.beta.,16.alpha.)-	
Synonyms	Sterile Triamcinolone Acetonide Suspension USP; Kenalog-10 Injection; Kenalog-40 Injection; Albicort; Kenacort; Kenalog-80 Injection	
Intended 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	USA **Bristol-Myers Squibb Company** P.O. Box 191 New Brunswick, New Jersey 08903 United States of America 1-800-332-2056	Ireland **Bristol-Myers Squibb Company** Swords Laboratories, Watery Lane Swords, Ireland MG-GBS-MSDS-Request@bms.com 353-1813-9456
Emergency Phone No.	USA (also Canada, Puerto Rico and the Virgin Island): 1-800-424-9300 Other Countries: See "Section 16" for country-specific emergency phone numbers from CHEMTREC.	Ireland: 353-1813-9456

2. HAZARDS IDENTIFICATION	
Classification and Labelling Common to All Jurisdictions	
Classification	Toxic To Reproduction - Reproductive Toxicity - Category 1A Toxic To Reproduction - Developmental Toxicity - Category 1A Effects On Or Via Lactation
Symbol	
Signal Word	Danger
Hazard Statements	May damage fertility (male reproductive toxicity, female reproductive toxicity) . May damage the unborn child (developmental toxicity) . May cause harm to breast-fed children.
Precautionary	Obtain special instructions before use.

2. HAZARDS IDENTIFICATION

Statements	Do not handle until all safety precautions have been read and understood. Avoid contact during pregnancy/while nursing. Use personal protective equipment as required.

Classification and Labelling for Specific Jurisdictions

USA

Classification	Specific Target Organ Systemic Toxicity (Repeated Exposure) - Category 1
Hazard Statements	Causes damage to organs (adrenal glands, bone, muscle, gastrointestinal tract, immune system, eyes, nervous system, skin, female reproductive organs, male reproductive organs) through prolonged or repeated exposure.
Precautionary Statements	Do not breathe gas/fumes/vapour/spray/mist Wash thoroughly after handling. Do not eat, drink or smoke when using this product.

EU

Classification	Specific Target Organ Systemic Toxicity (Repeated Exposure) - Category 2
Hazard Statements	May cause damage to organs (adrenal glands, bone, muscle, gastrointestinal tract, immune system, eyes, nervous system, skin, female reproductive organs, male reproductive organs) through prolonged or repeated exposure.
Precautionary Statements	Do not breathe gas/fumes/vapour/spray/mist

UN

Classification	Specific Target Organ Systemic Toxicity (Repeated Exposure) - Category 1
Hazard Statements	Causes damage to organs (adrenal glands, bone, muscle, gastrointestinal tract, immune system, eyes, nervous system, skin, female reproductive organs, male reproductive organs) through prolonged or repeated exposure.
Precautionary Statements	Do not breathe gas/fumes/vapour/spray/mist Wash thoroughly after handling. Do not eat, drink or smoke when using this product.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	Concentration	CAS No.	EU only		Other Registration No.
			EC No./REACH Registration No.	H-code(s)	
Hazardous components					
Triamcinolone	1 - 8 %	76-25-5	200-948-7	H360F	--

Acetonide				H360D H362 H372	
Other ingredients Non-Hazardous Ingredients	> 90 %	Not available	--	--	--
Other information: Sodium hydroxide and/or hydrochloric acid are used for pH adjustment. See section 16 for H-code text.					

4. FIRST AID MEASURES	
Eye contact	Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. If exposed or concerned: Get medical attention/advice.
Skin contact	Take off contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. Discard contaminated clothing or wash before re-use. If exposed or concerned: Get medical attention/advice.
Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. If exposed or concerned: Get medical attention/advice.
Ingestion	Do NOT induce vomiting. Never give anything by mouth to an unconscious person. If exposed or concerned: Get medical attention/advice.
Notes to Physician	Medical conditions aggravated include: diabetes, liver disorders, infection, immunodeficiency, hypertension, myasthenia gravis, osteoporosis, peptic ulcer, psychotic disorders, colitis, kidney disorders, idiopathic thrombocytopenic purpura. This product has been reported to interact with the following medications: aminoglutethimide, amphotericin B, drugs that decrease serum potassium concentration, antibiotics, anticholinesterases, anticoagulants, antidiabetics, antitubercular drugs, cholestyramine, diuretic, cyclosporine, immunosuppressants, NSAID (non-steroidal antiinflammatory drugs), drugs 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, estrogen, ketoconazole. Refer to Section 11.
Medical Surveillance	The need for a pre-placement, follow-up physical examination and history for employees with potential exposure to this compound is to be evaluated by a physician that is thoroughly knowledgeable about both the toxicity of this compound and the extent of work place exposure. Baseline testing would include: blood glucose test, a complete blood count with differential, a blood test for liver function, a blood test for kidney function. 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.

5. FIRE-FIGHTING MEASURES

Protection of Firefighters	Specific hazards: Refer to HAZARDS IDENTIFICATION section for a description of hazards for this material. Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus. Hazardous Combustion Products: carbon oxides (COx), hydrogen halides Further Information: HCl gas can form flammable or explosive mixtures with alcohols or metals. In the event of fire and/or explosion do not breathe fumes.
Other information	Decontaminate protective clothing and equipment before reuse.

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, lab coat and impervious gloves. 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.
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 area with detergent and water after spill pick-up, if appropriate. 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	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.
Container Requirements	Store in sturdy containers appropriate to maintain the integrity of this material for its intended use. Store in spill containment pallet or other device to confine spills.
Storage Conditions	Store at room temperature. Protect against light. Keep away from heat, sparks and flames. Store locked up.
Specific use(s)	Refer to Section 1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limit(s)	Company Guideline	ACGIH	Germany OEL	UK MEL
Triamcinolone Acetonide	1 µg/m3 8 hour-TWA (Skin)	--	--	--
Benzyl Alcohol		--	--	--

Benzyl Alcohol	Occupational Exposure Limits have been established by: - Czech Republic - Poland - Latvia

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Recommended Industrial Hygiene Monitoring Methods	Contact the Bristol-Myers Squibb AIHA accredited Industrial Hygiene Laboratory at (USA) 732-227-6338. General - The health hazard risk of handling this material is dependent on many factors, including physical form, % API in material being handled, duration and frequency of process task, and effectiveness of controls. If it is necessary to handle this compound outside of engineering controls, an exposure risk assessment should be conducted and procedures documented by a qualified EHS professional.

EXPOSURE CONTROLS / PERSONAL PROTECTION FOR MATERIAL AS SUPPLIED

This formulation contains an active pharmaceutical ingredient (API) with the guideline limit noted above. To keep the API below the recommended guideline, the material as supplied should be controlled during handling to limit total airborne aerosol exposure to: 2.5 µg/m³.

Engineering Controls and Ventilation	FOR MANUFACTURING PROCESSES (BULK): Use process enclosures, containment technology, or other engineering controls to keep airborne levels below recommended exposure limit. When handling quantities up to 150 milligrams, a standard laboratory with general laboratory dilution ventilation (e.g. 6-12 air changes per hour) is appropriate. When handling quantities from 150 milligrams to 1 kilogram, work in a standard laboratory using a fume hood; biological safety cabinet(Class II, all types); and, approved vented enclosure. Quantities exceeding 1 kilogram should be handled in a designated laboratory using laminar flow/powder containment booth. When handling solutions with low energy operations (pipette transfers, pouring, low velocity stirring, fraction collection, etc.) use protective shielding to limit the spread of splash or splatter. For manufacturing and pilot plant operations, use direct coupling and closed transfer systems for all bulk transfers. Use dust tight valves as appropriate. HEPA filtration of local exhaust ventilation (LEV) is required. FOR CLINICAL SETTING USE (DRUG PRODUCT): When handling small quantities in a clinical setting, good room ventilation is desirable. Specific engineering controls should not be needed.
Respiratory protection	Use and selection of respiratory protection is based upon engineering controls in use and potential for aerosol generation. When engineering controls are not sufficient control exposure, wear an approved respirator with NIOSH Class 100 or high efficiency particulate (HEPA) filters or cartridges (EN 140/EN 136) when exposures are up to 10 times the exposure control guideline. Wear a loose-fitting (Tyvek or helmet type) HEPA powered-air purifying respirator (PAPR) (EN 12941) when exposures are 10-25 times the exposure control guideline. Wear a full facepiece negative pressure respirator with Class 100 or HEPA filters (EN 136) when exposures are 25-50 times the exposure control guideline. Wear a tight-fitting, full facepiece HEPA PAPR (EN 12942) when exposures are 50-100 times the exposure control guideline. Wear a hood-shroud HEPA PAPR (EN 12941) or full facepiece supplied air respirator (EN 139) operated in a pressure demand or other positive pressure mode when exposures are 100-1000 times the exposure control guideline.
Eye protection	Safety glasses with side-shields are recommended (EN 166). Face shields or chemical safety goggles (EN 166) may be required if splash potential exists or if corrosive materials are present. Note: Choice of eye protection may be influenced by the type of respirator which is selected.
Hand protection	Impervious nitrile, rubber and latex gloves are recommended (EN 420, EN 374). If material is handled in solution, the solvent should also be considered when selecting protective clothing material. Please note that employees who are allergic to natural rubber latex should use nitrile gloves.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Skin and body protection	Wear a laboratory coat (EN 340) when handling quantities up to 1 kilogram. For quantities over 1 kilogram, wear laboratory coat(EN 340)or coverall of low permeability (EN 1149-1). For manufacturing operations, wear coverall of low permeability (EN 465/1149-1). For manufacturing operations, wear coverall of low permeability.
Hygiene	Wash hands and face before breaks and immediately after handling the product.
Environmental exposure controls	Prevent release to drains and waterways.

9. PHYSICAL AND CHEMICAL PROPERTIES

General Information

Appearance

Physical State	liquid
Color	white to off-white
Form	suspension

Odour

Odour	Not remarkable.
Odor Threshold	Not available

pH	5 - 7

Other information

Bulk density	Not available
Evaporation rate	Not available
Molecular formula	Not applicable
Hydrolysis/Photolysis	Not available
Hygroscopicity	Not available
Molecular Weight	Not applicable
Log Octanol/Water Partition Coefficient [log Kow]	Not available
Surface Tension	Not available
pKa	Not available
Particle Size	Not available
Solubility, Water	soluble
Specific Gravity/ Relative density	1.015
Viscosity, dynamic	similar to water
Viscosity, kinematic	Not available
% Volatile	Not available

Thermal/Stability properties

Autoignition temperature	Not available
Boiling Point	100 °C
Thermal decomposition	Not available
Explosive Limits, LEL	Not available
Explosive limits, UEL	Not available
Explosiveness	Not available
Flammability	Not available
Flash point	Not available
Melting Point	0 °C

9. PHYSICAL AND CHEMICAL PROPERTIES	
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
Materials to avoid	Not available
Hazardous decomposition products	Hazardous decomposition products formed under fire conditions.: carbon oxides (COx), 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 Mildly and/or transiently irritating to eyes
Skin Irritation	Triamcinolone Acetonide Repeated exposure may cause skin dryness or cracking. skin thinning
Respiratory Irritation	Triamcinolone Acetonide May cause irritation of respiratory tract.
Sensitization	Triamcinolone Acetonide Not a dermal sensitizer Allergic contact dermatitis is quite rare but has been reported.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity Study	**Acute Oral** Triamcinolone Acetonide 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
Repeated Dose Toxicity	Not available
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 2 years oral (daily) rat study : Tumor NOAEL = 0.001 mg/kg No treatment-related tumors were observed. 2 years drinking water (daily) rat study : Tumor LOAEL = 0.0048 mg/kg [tumor organs: liver] 2 years oral (daily) mouse study : Tumor NOAEL = 0.003 mg/kg No treatment-related tumors were observed. **Carcinogenicity Assessment** Not classifiable as to its carcinogenicity to humans.

Carcinogenicity	**ACGIH**	**IARC**	**NTP**
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.

11. TOXICOLOGICAL INFORMATION

Human experience	**Experiences with Human Exposure** Triamcinolone Acetonide General effects therapeutic use low exposure - acute effects include: 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, anaphylaxis, vomiting, anorexia, gastrointestinal disturbance, sore throat, dry mouth, taste disturbance, speech difficulty, congestion, redness and swelling of eyes, vision changes, facial swelling, allergic reactions, 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, impaired spermatogenesis, cataracts, glaucoma, nose changes, otitis, peptic ulcer, psychiatric disorders, pancreatitis, changes in white blood cell parameters, alopecia, asthma, growth retardation, skin effects, injection site reactions, cardiac disorders, death.
Target Organs	Triamcinolone Acetonide adrenal glands, bone, muscle, gastrointestinal tract, immune system, eyes, nervous system, skin, female reproductive organs, male reproductive organs
Symptoms	Triamcinolone Acetonide See "Human Experience".
Pharmacokinetics/ Toxicokinetics	Triamcinolone Acetonide Absorption: Not available Distribution: Not available Metabolism: Not available Elimination: Half-life = 2 - 3 Hour(s) (Human).
Other Toxicity Information	Not available
Other Information:	This SDS may contain toxicological and/or pharmacological information derived from either the specified product or from compounds in the same pharmacological class.

12. ECOLOGICAL INFORMATION

Ecotoxicity effects

Acute Toxicity to Aquatic Invertebrates

Triamcinolone Acetonide

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

Mobility	Not available

Persistence and degradability

12. ECOLOGICAL INFORMATION

Biodegradation

Triamcinolone Acetonide

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

PBT and vPvB assessment	Not available

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 in all modes.

15. REGULATORY INFORMATION

United States of America

313 Toxic Release Inventory	No components listed on the SARA 313 inventory.
TSCA Inventory	Not listed. Food, drug and cosmetic products are exempt from TSCA.

EU Regulation (EC) No 1272/2008)

Regulatory Authorizations and Restrictions:	Not available

16. OTHER INFORMATION

Text of H-code(s) mentioned in Section 3.

H360D	May damage the unborn child
H360F	May damage fertility
H362	May cause harm to breast-fed children.
H372	Causes damage to organs through prolonged or repeated exposure.

Recommended Restrictions for Use:

Not available

SDS preparation information

Prepared by	Global Environment, Health, Safety, and Sustainability 1-732-227-7380
Prepared on	01.06.2017 DD/MM/YYYY
	This Safety Data Sheet has been revised. This data sheet contains changes from the previous version in section(s): 1, 2, 3, 8, 15,

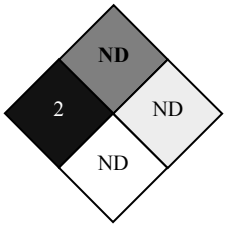
Other information

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



Country- Specific Emergency Phone Numbers

CHEMTREC In-Country Dial Numbers	Local # Provided in Country	Toll Free in Country*	Greeting Language
CHEMTREC South Africa*		0-800-983-611	English
CHEMTREC Argentina (Buenos Aires)	+(54)-1159839431		Latin American Spanish
CHEMTREC Brazil (Rio De Janeiro)	+(55)-2139581449		Portuguese
CHEMTREC Chile (Santiago)	+(56)-25814934		Latin American Spanish
CHEMTREC Colombia *		01800-710-2151	Latin American Spanish
CHEMTREC Mexico*		01-800-681-9531	Latin American Spanish
CHEMTREC Peru (Lima)	+(51)-17071295		Latin American Spanish
CHEMTREC China*	4001-204937		Mandarin
CHEMTREC Hong Kong (Hong Kong)*		800-968-793	Cantonese
CHEMTREC India *		000-800-100-7141	Hindi
CHEMTREC Indonesia*		001-803-017-9114	Indonesian
CHEMTREC Japan (Tokyo)	+(81)-345209637		Japanese
CHEMTREC Malaysia *		1-800-815-308	Malay
CHEMTREC Philippines *		1-800-1-116-1020	Tagalog
CHEMTREC Singapore*		800-101-2201	Mandarin
CHEMTREC Singapore	+(65)-31581349		Mandarin
CHEMTREC South Korea*		00-308-13-2549	Korean
CHEMTREC Taiwan*		00801-14-8954	Mandarin
CHEMTREC Thailand *		001-800-13-203-9987	Thai
CHEMTREC Vietnam (Ho Chi Minh City)	+(84)-838012436		Vietnamese
CHEMTREC Australia (Sydney)	+(61)-290372994		English
CHEMTREC Belgium (Brussels)	+(32)-28083237		French and Flemish
CHEMTREC Czech Republic (Prague)	+(420)-228880039		Czech
CHEMTREC France	+(33)-975181407		French
CHEMTREC Germany *		0800-181-7059	German
CHEMTREC Hungary (Budapest)	+(36)-18088425		Hungarian
CHEMTREC Italy *		800-789-767	Italian
CHEMTREC Italy (Milan)	+(39)-0245557031		Italian
CHEMTREC Netherlands	+(31)-858880596		Dutch
CHEMTREC Poland (Warsaw)	+(48)-223988029		Polish
CHEMTREC Spain*		900-868538	European Spanish
CHEMTREC Sweden (Stockholm)	+(46)-852503403		Swedish
CHEMTREC Switzerland (Zurich)	+(41)-435016715		German
CHEMTREC UK (London)	+(44)-870-8200418		English
CHEMTREC Bahrain (Bahrain)	+(973)-16199372		Arabic
CHEMTREC Israel (Tel Aviv)	+(972)-37630639		Hebrew
*Phone numbers for countries marked with an asterisk must be dialed within the country			

The information contained in this SDS 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.