Safety Data Sheet

SECTION 1: Identification

Contact Information
General

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24/7 Emergency Telephone Number

CHEMTREC (CCN: 1012275)
+1 (800) 424-9300 (USA and Canada)
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Product identifier	Triamcinolone Acetonide Injectable Suspension, 40 mg/mL
Synonyms	None identified
Trade name	KENALOG 40® Injection
Chemical family	Mixture
Recommended uses and restrictions	Formulated pharmaceutical product/mixture packaged in final form for patient use; used for the treatment of many inflammatory and allergic conditions.
Note	This SDS is written to address potential worker health and safety issues associated with the handling of the formulated product/mixture. Workers manufacturing this product/mixture should consult the SDS of each hazardous ingredient for hazard information and handling recommendations. This SDS will be revisited if more data become available.

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.

Reproductive toxicity Category 2
Suspected of damaging fertility. Suspected of damaging the unborn child.
Specific target organ toxicity (repeated exposure) Category 2
May cause damage to organs (endocrine system) through prolonged or repeated exposure

Label elements

GHS Hazard pictograms

GHS Signal word

Warning

GHS Hazard statements

H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child.

H373 - May cause damage to organs (endocrine system) through prolonged or repeated exposure

GHS Precautionary statements

P201 - Obtain special instructions before use. P260 - Do not breathe dust/fume/gas/mist/vapors/spray. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P308+P313 - If exposed or concerned: Get medical advice/attention. P314 - Get medical advice/attention if you feel unwell. 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

Triamcinolone acetonide is a synthetic glucocorticosteroid which acts similarly to the endogenously produced hormone cortisol. Long-term topical use of triamcinolone has been associated primarily with depigmentation and/or atrophy of the skin. The most common effects seen following inhalation use are headache and sore throat.

Adverse effects caused by prolonged or excessive systemic exposure to corticosteroids as a class can include: increased blood pressure, metabolic imbalance, suppression of the hypothalamic-pituitary adrenal axis (which may result in a syndrome characterized by weight gain, skin changes, excessive hair growth, menstrual irregularities, and decreased libido,), increased infections, and psychological effects (e.g., mood swings, euphoria, or insomnia). Sudden withdrawal may cause adrenal insufficiency, characterized by joint and/or muscular pain, lethargy, and depression. Corticosteroid use by male patients can cause decreased sperm count and sperm motility. Evidence of teratogenicity has been seen in animals; however, no congenital malformations were reported in the offspring of women treated with systemic or topical triamcinolone during pregnancy.

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
Triamcinolone acetonide	76-25-5	200-948-7	≤ 4 %	Acute Tox. 4 (Oral), H302 Repr. 2, H361fd STOT RE 2, H373
Benzyl alcohol	100-51-6	202-859-9	< 1 %	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation), H332

Note

The primary ingredient in this formulation is sterile water for injection. The additional ingredient(s) listed above are considered hazardous. The remaining components are not hazardous and/or present at amounts below reportable limits. Amounts are listed as ranges; the exact percentage of composition is withheld as a trade secret. See Section 16 for full text of GHS classifications.

SECTION 4: First-aid measures

Description of first aid measures

Immediate medical attention and special treatment, if necessary

Yes.

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 exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.

Eye contact

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

Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

Expected Symptoms/Effects, Acute and Delayed

See Sections 2 and 11

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.

Specific hazards arising from the chemical

No information identified. May emit carbon monoxide, carbon dioxide, oxides of nitrogen and other fluorine-containing compounds.

Fire hazard

No information identified. As product is an aqueous solution, it is not expected to be flammable.

Explosion hazard

No information identified. As product is an aqueous solution, it is not expected to be explosive.

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

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 vapors/mist/spray.

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

Methods and material for containment and cleaning up

Methods for cleaning up If vials are broken or crushed, DO NOT CAUSE MATERIAL TO BECOME AIRBORNE. For small spills, soak up material with absorbent, e.g, paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper 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 If vials are crushed or broken, drug substance may be released. 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 vapor/mist/spray.

Conditions for safe storage, including any incompatibilities

Storage conditions Store at controlled room temperature; protect from temperatures below 20 °C (68 °F). Store vials in carton to protect from light. Store vials upright.

Storage temperature 20 – 25 °C (68 °F to 77 °F).

Specific end use(s) Pharmaceuticals.

SECTION 8: Exposure controls/personal protection

Note Dispose of broken vials in a sharps container.

Control parameters/Occupational Exposure Limits

Name	Issuer	Value
Benzyl alcohol	CZ - Exposure limits (NPK-P) (mg/m³)	80 mg/m³
	CZ - Exposure limits (NPK-P) (ppm)	18 ppm
	CZ - Exposure limits (PEL) (mg/m³)	40 mg/m³
	CZ - Exposure limits (PEL) (ppm)	9 ppm
	FI - HTP-arvo (8h) (mg/m³)	45 mg/m³
	FI - HTP-arvo (8h) (ppm)	10 ppm
	LT - IPRV (mg/m³)	5 mg/m³
	LV - OEL TWA	5 mg/m³
	PL - NDS (mg/m³)	240 mg/m³
	DE - Occupational exposure limit value (mg/m³)	22 mg/m³
	DE - Occupational exposure limit value (ppm)	5 ppm
	SI - OEL STEL	44 mg/m³
Triamcinolone acetonide	No data available	No data available

Appropriate engineering controls None required for normal handling of packaged product. If vials are crushed or broken or if handling bulk formulation: Control exposures to below the OEL (for the active ingredient(s) if available). 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 vials are crushed or broken or if handling bulk formulation: 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 vials are crushed or broken or if handling bulk formulation: 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 vials are crushed or broken or if handling bulk formulation: 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	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	Liquid containing solid active ingredient for suspension
Appearance	Suspension, essentially free of foreign particulate matter
	Supplied in three volumes: 1 mL per vial, 5 mL per vial, and 10 mL per vial
Formula	Not applicable (Mixture)
Molecular mass	Not applicable (Mixture)
Color	White to almost white
Odor	No data available
Odor threshold	No data available
pH	5.0 – 7.5
Melting point	No data available
Freezing point	No data available
Boiling point	No data available
Flash point	No data available
Relative evaporation rate (butyl acetate=1)	No data available
Flammability (solid, gas)	No data available
Vapor pressure	No data available
Relative vapor density at 20 °C	No data available
Relative density	No data available
Solubility	Liquid portion is miscible with water; solid active ingredient present is not soluble in water
Log Pow	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity, kinematic	No data available
Viscosity, dynamic	No data available
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	None under recommended storage and handling conditions (see section 7).
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

Note	The pharmacological and toxicological properties of this product/mixture have not been fully

characterized.

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

Toxicological information

Acute toxicity

Component	Type	Dose
Benzyl alcohol	LD50 Oral rat	1230 - 1660 mg/kg
	LD50 Dermal rabbit	2000 mg/kg
	LC50 Inhalation rat	> 500 mg/m³
Triamcinolone acetonide	LD50 Oral rat	1451 mg/kg
	LD50 Oral mouse	2168 mg/kg

Additional information No data available

Serious eye damage/irritation Triamcinolone was slightly irritating to rabbit eyes.

Skin corrosion/irritation Triamcinolone was non-irritating to rabbit skin.

Sensitization No data available

STOT-single exposure No data available

STOT-repeated exposure Subacute toxicity studies in rats, rabbits and dogs were completed with conventional routes of administration and by inhalation of aerosolized triamcinolone. All findings were generally minimal; observed changes were consistent with expected pharmacological activity of glucocorticoids.

Product contains benzyl alcohol, which has been associated with serious adverse effects in pediatric patients. Central nervous system depression, metabolic acidosis, and gasping respiration have been associated with benzyl alcohol dosages >99 mg/kg/day in neonates, resulting in high levels of benzyl alcohol and its metabolites in blood and urine. Although normal therapeutic doses of this product deliver amounts of benzyl alcohol that are substantially lower than those reported in association with this “gasping syndrome,” the minimum amount of benzyl alcohol at which toxicity may occur is not known.

Reproductive toxicity Triamcinolone did not impair fertility in rats given oral doses of up to 15 µg/kg/day. However, maternally toxic doses of 8 or 15 µg/kg/day in dams resulted in difficult/prolonged delivery. No effects on reproductive performance were seen in female rats treated with 0.5-1 µg/kg/day, doses that were only slightly maternally toxic.

Developmental toxicity Cleft palates were induced in embryos of mice treated with triamcinolone at doses as low as 1 µg during late gestation. Teratogenic effects in both rats and rabbits at 20-80 µg/kg/day included cleft palate, internal hydrocephaly, and skeletal defects. Inhalation studies with rats and rabbits produced comparable effects to those seen with other routes. Intramuscular injection of 0.5-2.5 mg/kg and greater caused increased fetal deaths, craniofacial deformities, and central nervous system defects.

Genotoxicity Triamcinolone was negative in the Ames bacterial assay and an *in vitro* chromosomal aberration study with Chinese Hamster Ovary cells. However, it was positive in an *in vivo* mouse micronucleus study.

Carcinogenicity No evidence of treatment-related carcinogenicity was demonstrated after two years of once daily oral administration of triamcinolone at a maximum daily dose of 1 and 3 µg/kg/day in rats and mice, respectively. 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
Benzyl alcohol	No data available	No data available
Triamcinolone acetonide	No data available	No data available

Persistence and degradability No data available

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 The environmental characteristics of this product/mixture have not been fully investigated. Releases to the environment should be avoided.

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, e.g, appropriately permitted chemical waste incinerator. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g, appropriately permitted municipal or on-site wastewater treatment facility.

SECTION 14: Transport information

Transport	Based on the available data, this product/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	Based on the available data, this product/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	Acute Tox. 4 (Dermal) - Acute toxicity (dermal) Category 4. Acute Tox. 4 (Inhalation) - Acute toxicity (inhalation) Category 4. Acute Tox. 4 (Oral) - Acute toxicity (oral) Category 4. Repr. 2 - Reproductive toxicity Category 2. STOT RE 2 - Specific target organ toxicity (repeated exposure) Category 2. H302 - Harmful if swallowed. H312 - Harmful in contact with skin. H332 - Harmful if inhaled. H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child. H373 - May cause damage to organs (endocrine system) 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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Disclaimer

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.