SAFETY DATA SHEETS

This SDS packet was issued with item:

078949190

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078928040 078942939

Safety Data Sheet



1. IDENTIFICATION			
Product Information			
Product name	KENALOG®-10, 40,80 mg/ml (triamcinolone acetonide) Injectable Suspension		
Version	2.3, 25.05.2018		
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 Iden	ntification		
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 Cruiserath Road, Mulhuddart - Dublin 15 Cruiserath, Ireland MG-GBS-MSDS-Request@bms.com + 353.1.8854000	
Emergency Phone No.	USA (also Canada, Puerto Rico and the Virgin Island): 1-800-424-9300		
	Other Countries: See "Section 16" for counCHEMTREC.	ntry-specific emergency phone numbers from	

2. HAZARDS IDENTIFICATION			
Classification and L	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 IDENTIF	ICATION			
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 L	abelling 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					
			EU only		
Components	Concentration	CAS No.	EC No./REACH Registration No.	H-code(s)	Other Registration No.
Hazardous components Triamcinolone	1 - 8%	76-25-5	200-948-7	H360F	

KENALOG®-10, 40,80 mg/ml (triamcinolone acetonide) Injectable Suspension	Bristol-Myers Squibb Company 00000000782	Page 3 of
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Acetonide				H360D H362 H372	
Other ingredients					
Non-Hazardous	> 90 %	Not			
Ingredients		available			
Other information: S	odium hydroxide	and/or hydrochlor	ic acid are use	d for pH adjustment.	See section 16 for H-
code text.	•	•		2 0	

4. FIRST AID MEASURES	3				
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 MEA	ASURES
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	E 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					

Hygiene

Dagammandad	Canada. The health beyond rich of handling this metarial is demandant on many factors				
Recommended Industrial Hygiene Monitoring Methods	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 proces 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 CONTRO	OLS / PERSONAL PROTECTION FOR MATERIAL AS SUPPLIED				
	hins an active pharmaceutical ingredient (API) with the guideline limit noted above. To keep the nended guideline, the material as supplied should be controlled during handling to limit total ture to: $2.5~\mu g/m^3$.				
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.				
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.				

Wash hands and face before breaks and immediately after handling the product.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Environmental Prevent release to drains and waterways. exposure controls

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			
рН	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	Not available			
Coefficient [log Kow]				
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			
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 di	ischarge/Dust exp.			
Summary Statements	not applicable			

11. TOXICOLOGICAL INFORMATION					
Routes of Entry	Ingestion, inhalation, Eye contact, Skin contact				
Eye Irritation	<u>Triamcinolone Acetonide</u> Mildly and/or transiently irritating to eyes				
Skin Irritation	<u>Triamcinolone Acetonide</u> Repeated exposure may cause skin dryness or cracking. skin thinning				
Respiratory Irritation	Triamcinolone Acetonide May cause irritation of respiratory tract.				
Sensitization	<u>Triamcinolone Acetonide</u> Not a dermal sensitizer Allergic contact dermatitis is quite rare but has been reported.				
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				

11. TOXICOLOGICAL INFORMA	TION				
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.				
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,				

11. TOXICOLOGICAL INFORMAT	ION		
	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	<u>Triamcinolone Acetonide</u> 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

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

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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

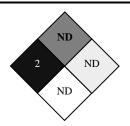
This material is not a dangerous good for the purpose of transportation in all modes.

15. REGULATORY INFORMATION United States of America					
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	n Section 3.			
	H360D	May damage the unborn child		
	H360F	May damage fertility		
	H362	May cause harm to breast-fed	d children.	
	H372	Causes damage to organs through prolonged or repeated exposure.		
Recommended Restrictions for	r Use:			
	Not available			
SDS preparation information				
Prepared by	Global Er	Global Environment, Health, Safety, and Sustainability 1-732-227-7380		
Prepared on	25.05.2018 DD/MM/YYYY			
-	This Safe	ty Data Sheet has been revised.	This data sheet contains changes from the	
	previous	version in section(s): 1.	_	
Other information				
HMIS		Health	2*	
		Flammability	Not Determined (ND)	
		Reactivity	Not Determined (ND)	
	Pers	sonal protective equipment	See Section 8.	

NFPA

Health 2
Fire ND
Reactivity ND
Special ND



Country- Specific Emergency Phone Numbers

Country	Local # or Toll Free in Country*	Greeting Language	Country	Local # or Toll Free in Country*	Greeting Language
AMERICAS .			Latvia (Riga)	+(371)-66165504	Latvian
Argentina (Buenos Aires)	+(54)- 1159839431	Latin American Spanish	Lithuania (Vilnius)	+(370)-52140238	Lithuanian
Brazil (Rio De Janeiro)	+(55)- 2139581449	Portuguese	Luxembourg	+(352)-20202416	French, German, Luxembourgish
Cayman Islands	+(1)-345-749- 8392	English	Netherlands	+(31)-858880596	Dutch
Chile (Santiago)	+(56)-225814934	Latin American Spanish	Norway (Oslo)	-(47)-21930678	Norwegian.
Colombia *	01800-710-2151	Latin American Spanish	Poland (Warsaw)	+(48)-223988029	Polish
Costa Rica*	+(506)-40003869	Latin American Spanish	Portugal	+(351)- 308801773	Portuguese
Mexico*	01-800-681-9531	Latin American Spanish	Romania	(+40)-37- 6300026	Romanian
Panama	+(507)-8322475	Latin American Spanish	Russia*	8-800-100-6346	Russian
Peru (Lima)	-(51)-17071295	Latin American Spanish	Slovakia (Bratislava)	+(421)+ 233057972	Slovak
Trinidad and Tobago*	+(1)-868-224- 5716	English	Slovenia (Ljubljana)	+(386)-18888016	Slovene/Slovenian
EUROPE		Spain (Barcelona)	+(34)-931768545	European Spanish	
			Spain*	900-868538	European Spanish
Austria (Vienna)	+(43)-13649237	German	Sweden (Stockholm)	+(46)-852503403	Swedish
Belgium (Brussels)	+(32)-28003237	French, Fiemish, German	Switzerland (Zurich)	+(41)- 435082011	Swiss German, French and Italian
Bulgaria (Plovdiv)	+(359)-32570104	Bulgarian	Turkey (Istanbul)	+(90)-212- 7055340	Turkish
Croatia (Zagreb)	+(3\$5)-17776920	Croatian	Ukraine	+(380)- 947101374	Ukrainian
Czech Republic (Prague)	+(420)- 228880039	Czech	UK (London)	+(44)-870- 8200418	English
Finland (Helsinki)	+(358)- 942419014	Finnish		EAST ASIA	
France	+(33)-975181407	French	China	86-21-33235036	Mandarin
Germany *	0800-181-7059	German	Hong Kong*	800-968-793	Cantonese
Denmark	+(45)-69918573	Danish	Japan	+(81)-345209637	Japanese
Estonia	+(372-6681294	Estonian	Singapore	+(65)-31581349	English and Mandarii
Germany (Frankfurt)	+(49)- 69643508409	German	South Korea	+(82) 070-7686- 0086	Korean
Greece (Athens)	+(30)- 2111768478	Greek		AUSTRALIA & OC	EANIA
Hungary (Budapest)	-(36)-18088425	Hungarian	Australia (Sydney)	+(61)-290372994	English
ttaly •	\$00-789-767	Italian	New Zealand*	+(64)-98010034	English
Italy (Milan)	+(39)- 245557031	Italian	ındiə *	000-800-100- 7141	Hindi

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.