

KINEVAC MATERIAL SAFETY DATA SHEET

The author of this Material Safety Data Sheet (MSDS) is Bracco Diagnostics Inc. This MSDS is generated and/or distributed by the Bristol-Myers Squibb Company on behalf of Bracco Diagnostics Inc. Please carefully review all of the information disclosed in this MSDS prior to handling or using the product referenced below.

SECTION 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Bracco Diagnostics Inc.
P.O. Box 5225
Princeton, NJ 08543

Product Identification: KINEVAC (5 ug/vial)

1. Chemical Name: L-a-aspartyl-O-sulfo-L-tyrosyl-L-methionylglycyl-L-tryptophyl-L-methionyl-L-a-aspartyl-L-phenylalaninamide.
2. Synonyms: Sincalide for Injection.
3. How Supplied: Package of 10 vials with 5 micrograms per vial.
4. Product Use: Stimulate gallbladder contraction and pancreatic secretion and/or intestinal motility for diagnostic purposes.
5. Chemical Family: Cholecystopancreatic-gastrointestinal hormone peptide.
6. Molecular Formula: C49H62N10O16S3*
7. CAS NUMBER: 25126-32-3*
*Information pertains to sincalide.

EMERGENCY CONTACTS: (Health) 1-800-257-5181.
(U.S. Transportation) Chemtrec 1-800-424-9300.
(International Transportation) Chemtrec 1-703-527-3887.

EMERGENCY OVERVIEW: Single dose vials containing a sterile lyophilized white powder. See Health Effects and Toxicology sections for additional information.

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

COMPONENTS	HAZARDOUS (Y/N)	CONCENTRATION		CAS NUMBER	EXPOSURE GUIDELINE
		%(w/w)	%(w/v)		
Sincalide	Y	<0.01		25126-32-3	None
Mannitol	N	>1		69-65-8	None
Arginine hydrochloride	N	>1		1119-34-2	None
Potassium phosphate dibasic	N	>1		7758-11-4	None
Methionine	N	>1		59-51-8	None
Lysine hydrochloride	N	>1		675-27-2	None

Components present at <1% or used for pH adjustment: pentetic acid, sodium metabisulfite, polysorbate 20, hydrochloric acid and/or sodium hydroxide.
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SECTION 3: HEALTH HAZARDS IDENTIFICATION

Effects of Overexposure

Routes of Entry:

1. Inhalation: Under normal conditions, this material is handled in closed vials and exposure by inhalation is not expected to occur.
2. Skin Contact: Exposure may occur via skin contact if gloves and protective clothing are not worn. No information for absorption through skin.
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 the material contacts hands and hands are not washed prior to eating, drinking or smoking. The extent of systemic absorption after ingestion is not known. Many peptides are inactivated in the gastrointestinal tract.

Note: When prepared in a clinical setting, sterile water for injection is added to the vial containing sincalide. The resulting solution is intended for intravenous injection or infusion under the care of a physician.

Acute

1. Ingestion: Inadvertent ingestion of trace amounts of this material would not be expected to result in symptoms.
2. Inhalation: Inhaling trace amounts of airborne dust would not be expected to produce symptoms. However, some peptides are active following inhalation.
3. Skin Contact:
 - a. Toxic: Contact with small quantities of material for short periods is not expected to result in pharmacologic or toxic effects.
 - b. Irritation: Material contains components that are irritants. It may have potential to cause mild irritation, however, moderate or severe irritation is not expected.
 - c. Sensitization: This material may act as a sensitizer (allergen) for those persons who are allergic to the formulation or components in the formulation.
 - d. Eye Contact: May cause irritation.

Chronic

Repeated and prolonged exposure to skin may cause skin irritation.

Exposure Guideline Summary: An exposure guideline has not been established for this material.

Carcinogen Lists for sincalide: IARC: No. NTP: No. OSHA: No.

Target organs for sincalide: At therapeutic doses, sincalide causes reversible pharmacological effects on the gallbladder, pancreas and intestinal smooth muscle.

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KINEVAC Material Safety Data Sheet (continued)

Medical Condition Aggravated by Exposure: Exposure to therapeutic doses may cause small gallbladder stones to be evacuated, leading to blockage of the bile duct. It may also cause aggravation of pre-existing pancreatitis or of the symptoms of pre-existing bowel inflammation or obstruction. Sincalide should not be administered to pregnant women near term; due to its effects on smooth muscle, it may induce labor.

SECTION 4: FIRST AID MEASURES

1. Ingestion: Get medical attention immediately. Vomiting may be induced if a person is conscious and if ingestion has occurred within the past three hours. Never induce vomiting in a person who is unconscious or experiencing convulsions.
 2. Inhalation: Remove exposed person to fresh air. If person is not breathing, give artificial respiration. If breathing is difficult administer oxygen. Get medical attention immediately.
 3. Skin Contact: Remove contaminated clothing. Wash skin with plenty of water for 5 minutes. Seek medical attention if irritation (redness, itching or swelling) develops or persists.
 4. Eye Contact: Hold eyelids apart and flush with plenty of water for 5 minutes. Get medical attention if signs of irritation develop.
 5. Note to physicians: Carefully review the "Medical Conditions Aggravated by Exposure" statement in Section 3 above.
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SECTION 5: FIRE FIGHTING MEASURES

1. Flash Point: Not available.
 2. Auto-ignition Temperature: Not available.
 3. Flammability Limits:
 - a. LEL: Not available.
 - b. UEL: Not available.
 4. Combustibility of Dusts: Not available.
 5. Extinguishing Media: In case of fire, flood with water.
 6. Fire-fighting Instructions: Firefighters should wear self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves. Evacuate personnel to an upwind direction, remove unneeded material and cool container(s) with water from a maximum distance.
 7. Hazardous Combustion Products: Carbon monoxide, carbon dioxide, hydrogen chloride, nitrogen oxides, sulfur oxides. Unusual Hazards: None known.
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SECTION 6: ACCIDENTAL RELEASE MEASURES

Spill/Clean-up: Lab coat, impermeable gloves (latex, latex/ nitrile or nitrile) and eye protection should be worn as a minimum precaution. Sweep material onto paper and place into a fiber drum for reclamation or disposal. The spill area should be ventilated and decontaminated after material has been picked up.

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SECTION 7: HANDLING AND STORAGE

1. Handling Precautions: Avoid skin and eye contact.
2. Container Requirements: Package of 10 vials.
3. Storage Conditions: Store at 15-30 degrees C (59 to 86 degrees F).

SECTION 8: EXPOSURE CONTROLS & PERSONAL PROTECTION

1. Ventilation Requirements: None beyond good room ventilation.
2. Respiratory Protection: Not anticipated for normal clinical environment. Non-routine exposure conditions may require NIOSH approved respiratory protection. Self-contained breathing apparatus should be available for emergency use.
3. Eye Protection: Wear safety glasses (ANSI Z87.1).
4. Protective Gloves: Wear impervious gloves (latex, latex/nitrile, or nitrile) if the potential exists for dermal contact.
5. Special Clothing: None.
6. Hygiene: Wash hands after handling product and before eating, smoking, using lavatory and at the end of the day.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

1. Appearance/Physical State/Color: White powder.
2. Boiling Point: Not applicable.
3. Evaporation Rate: Not applicable.
4. Flash Point: Not available.
5. Freezing point/Melting Point: Not available.
6. Octanol/Water Partition Coefficient: Not available.
7. Odor: Not available.
8. pH (of solution): 6.0 to 8.0.
9. Solubility in Water: Soluble.
10. Specific Gravity: Not available.
11. Vapor Density: Not available.
12. Vapor Pressure: Minimal, material exists as a solid.
13. Viscosity (cP): Not applicable (solid material).

SECTION 10: STABILITY AND REACTIVITY

1. Stability: Stable under normal conditions.
2. Incompatibilities: None known.
3. Conditions of Reactivity: None known.
4. Hazardous Decomposition Products: Carbon monoxide, carbon dioxide, hydrogen chloride, nitrogen oxides, sulfur oxides.
5. Hazardous Polymerization: Will not occur.
6. Explosion data relative to mechanical impact: No information.
7. Explosion data relative to static discharge: No information.

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KINEVAC Material Safety Data Sheet (continued)

SECTION 11: TOXICOLOGICAL INFORMATION - for active ingredient, sincalide.

RTECS # (U.S.): No RTECS number for sincalide.

1. Acute toxicity data: When administered intravenously to female mice at up to 20 micrograms/kg, all mice survived the 5-day observation period. In subacute toxicity studies, dogs survived intravenous doses of 1000 ng/kg given 6-days/week for 3-weeks, and mice survived intravenous doses of 5000 ng/kg given 6-days/week for 2-weeks.
2. Chronic: No harmful effects are expected from sincalide under normal use conditions.
 - a. Carcinogenicity: No information.
 - b. Mutagenicity: No information.
 - c. Teratogenicity: Stage II teratology studies showed no effects in rabbits and hamsters injected with sincalide in doses up to 750 ng/kg. Studies in rats administered sincalide subcutaneously at doses 12.5 times the maximum recommended human dose showed no evidence of harm to the fetus.
 - d. Reproductive Effects: Sincalide should not be administered to pregnant women near term due to its smooth muscle stimulation effect, which could result in premature labor.
 - e. Toxicological Synergistic Products: No information.

SECTION 12: ECOLOGICAL INFORMATION

1. Ecotoxicological Information: Not available.
2. Chemical Fate Information: Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

Dispose of in accordance with all local, state and federal regulations or with the regulations of the country in which the material is used.

SECTION 14: TRANSPORT INFORMATION

1. Domestic
 - a. Proper Shipping Name: Not classified.
 - b. Hazard Class, UN Number, Packing Group: Not classified.
 - c. Label Requirements: Not applicable.
 - d. Placard Requirements: Not applicable.
2. International
 - a. Proper Shipping Name: Not classified.
 - b. Hazard Class, UN Number, Packing Group: Not classified.
 - c. Label Requirements: Not applicable.
 - d. Placard Requirements: Not applicable.

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SECTION 15: REGULATORY/STATUTORY INFORMATION (limited to health, safety, environmental)

NOTE: Not meant to be all-inclusive.

1. U.S. Federal: None noted.
2. International: None noted.
3. EC Labeling: Not applicable.

SECTION 16: OTHER INFORMATION

February 13, 2002: New MSDS for KINEVAC was developed by Bracco Diagnostics, Inc. and supercedes the previous version.

March 4, 1993: Bristol-Myers Squibb MSDS for KINEVAC.

Diagnostic agents are intended for use under direction of a physician and only under the conditions of use described on the label and in the product's package insert. As a general precaution, personnel who handle these products should avoid contact (ingestion, inhalation, skin and eye contact) with them.

This material safety data sheet is intended for use by personnel who handle this material as part of their job responsibilities and it does not address the diagnostic use of this material. Information concerning the use of this diagnostic agent should be obtained from the product package insert and other appropriate references.

The information contained in this MSDS was obtained by Bracco Diagnostics from sources believed to be accurate and reliable and represents the best information currently on file and known by Bracco. However, Bracco makes no representation, guaranty or warranty, express or implied, with respect to any such information, and specifically disclaims and assumes no liability resulting from the use, misuse or mishandling of either the product or this MSDS.

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