

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 11/07/2011

Version 1

Reviewed on 11/07/2011

1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Sheets Code: 272

Trade name: Kinevac (5 µg / vials)

Chemical Name:

L-a-aspartyl-O-sulfo-L-tyrosyl-L-methionylglycyl-L-tryptophyl-L-methionyl-L-a-aspartyl-L-phenylalaninamide

Synonyms: Sincalide for Injection.

How Supplied: Package of 10 vials with 5 micrograms per vial.

1.2 Relevant identified uses of the substance or mixture and uses advised against

We recommend that you use this product in a manner consistent with the listed use. If your intended use is not consistent with the stated use, please contact your sales or technical service representative.

Application of the substance / the preparation

Stimulate gallbladder contraction and pancreatic secretion and/or intestinal motility for diagnostic purposes.

Chemical Family: Cholecystopancreatic-gastrointestinal hormone peptide

Molecular Formula: C₄₉H₆₂N₁₀O₁₆S₃*

CAS Number:

25126-32-3*

*Information pertains to sincalide.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Bracco Diagnostics Inc.

P.O. Box 5225

Princeton, NJ 08543

Further Information Obtainable from:

B-Lands Consulting

WTC, 5 Place Robert Schuman, BP 1516

38025 Grenoble, FRANCE

Tel: +33 476 295 869

Fax: +33 476 295 870

services@reachteam.eu

www.reachteam.eu

1.4 Emergency telephone number:

EMERGENCY CONTACT:

Health: 1-800-257-5181

U.S. Transport - Chemtrec: 1-800-424-9300

International Transport - 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.

2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

The product is not classified according to the CLP regulation.

Classification according to Directive 67/548/EEC or Directive 1999/45/EC Not applicable.

Information concerning particular hazards for human and environment:

The product does not have to be labelled due to the calculation procedure of international guidelines.

(Contd. on page 2)

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 11/07/2011

Version 1

Reviewed on 11/07/2011

Trade name: Kinevac (5 µg / vials)

(Contd. of page 1)

Classification system:

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 Void

Hazard pictograms Void

Signal word Void

Hazard statements Void

Effects of Overexposure - Routes of Entry:

Inhalation:

Under normal conditions, this material is handled in closed vials and exposure by inhalation is not expected to occur.

Skin Contact:

Exposure may occur via skin contact if gloves and protective clothing are not worn.
No information for absorption through skin.

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.

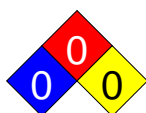
Information pertaining to particular dangers for man and environment:

Negative Effects on the Health: See also Sections 11

Negative Effects on the Environment: See also Section 12

Classification system:

NFPA ratings (scale 0 - 4)



Health = 0
Fire = 0
Reactivity = 0

HMIS-ratings (scale 0 - 4)



HEALTH 0 Health = 0
FIRE 0 Fire = 0
REACTIVITY 0 Reactivity = 0

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

3: Composition/information on ingredients

3.1 Substances

Active Ingredients:

CAS: 25126-32-3	Sinacalide
EINECS: 246-639-0	

(Contd. on page 3)

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 11/07/2011

Version 1

Reviewed on 11/07/2011

Trade name: Kinevac (5 µg / vials)

(Contd. of page 2)

Impurities and stabilising additives:

CAS: 67-43-6 EINECS: 200-652-8	Pentetic Acid
CAS: 9005-64-5 NLP: 500-018-3 RTECS: TR7400000	Polysorbate 20
CAS: 7681-57-4 EINECS: 231-673-0 Index number: 016-063-00-2	sodium metabisulphite ☒ Xn R22; ☒ Xi R41 R31 ☞ Eye Dam. 1, H318; ☠ Acute Tox. 4, H302
EINECS: 231-595-7 Index number: 017-002-01-X RTECS: MW 9620000	hydrochloric acid ☒ C R34; ☒ Xi R37 ☞ Skin Corr. 1B, H314; ☠ STOT SE 3, H335
CAS: 1310-73-2 EINECS: 215-185-5 Index number: 011-002-00-6	sodium hydroxide ☒ C R35 ☞ Skin Corr. 1A, H314

3.2 Mixtures

Description: Mixture: consisting of the following components.

Dangerous Components

CAS N°	Description	%
CAS: 7681-57-4 EINECS: 231-673-0 Index number: 016-063-00-2	sodium metabisulphite ☒ Xn R22; ☒ Xi R41 R31 ☞ Eye Dam. 1, H318; ☠ Acute Tox. 4, H302	<1%
EINECS: 231-595-7 Index number: 017-002-01-X RTECS: MW 9620000	hydrochloric acid ☒ C R34; ☒ Xi R37 ☞ Skin Corr. 1B, H314; ☠ STOT SE 3, H335	<1%
CAS: 1310-73-2 EINECS: 215-185-5 Index number: 011-002-00-6	sodium hydroxide ☒ C R35 ☞ Skin Corr. 1A, H314	<1%

Not Dangerous Components

CAS N°	Description	%
CAS: 67-43-6 EINECS: 200-652-8	Pentetic Acid	<1%
CAS: 9005-64-5 NLP: 500-018-3 RTECS: TR7400000	Polysorbate 20	<1%
CAS: 25126-32-3 EINECS: 246-639-0	Sincalide	<0.01%
CAS: 69-65-8 EINECS: 200-711-8	D-mannitol	>1%
CAS: 1119-34-2 EINECS: 214-275-1 RTECS: CF 1995500	(+)-L-arginine hydrochloride	>1%
CAS: 7758-11-4 EINECS: 231-834-5	dipotassium hydrogenorthophosphate	>1%
CAS: 59-51-8 EINECS: 200-432-1	DL-methionine	>1%
CAS: 675-27-2 EINECS: 211-519-9	Lysine hydrochloride	>1%

(Contd. on page 4)

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 11/07/2011

Version 1

Reviewed on 11/07/2011

Trade name: Kinevac (5 µg / vials)

(Contd. of page 3)

Additional information: For the wording of the listed risk phrases refer to section 16.

4: First aid measures

4.1 Description of first aid measures

General information: No special measures required.**After Inhalation:**

Remove from exposure and move to fresh air immediately.

If not breathing, give artificial respiration.

If breathing is difficult, give oxygen.

Call a doctor immediately.

After 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.

After Eye Contact:

Wash with running water for several minutes holding the eyelids open.

If any symptoms of irritation develop and / or persist, consult your doctor.

After Swallowing:

Get medical attention immediately.

Vomiting may be induced only 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.

4.2 Most important symptoms and effects, both acute and delayed See also Section 2 and 11.**4.3 Indication of any immediate medical attention and special treatment needed:**

No further relevant information available.

Means of Specific and Immediate Treatment to Keep at the Workplace: No special measures required.**Note to physicians:**

Carefully review the "Medical Conditions Aggravated by Exposure" statement in Section 11, here below.

5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents: In case of fire, flood with Water**For safety reasons unsuitable extinguishing agents:** Unknown.**5.2 Special hazards arising from the substance or mixture** See also Section 10.**Hazardous Combustion Products:**Carbon Dioxide (CO₂)In the absence of Oxygen: Carbon Monoxide (CO_x)Nitrogen Oxides (N_xO_y)

Hydrogen Chloride (HCl)

Sulfur Oxides (SO_x)**Additional Information:** Not Available

5.3 Advice for Firefighters

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

Move container from fire area if you can do it without risk.

(Contd. on page 5)

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 11/07/2011

Version 1

Reviewed on 11/07/2011

Trade name: Kinevac (5 µg / vials)

(Contd. of page 4)

Protective Equipment:

Firefighters should wear adequate personal protective equipment with protection of respiratory tract (self-contained breathing apparatus) (SCBA).

Besides they should wear flame and chemicals resistant clothing, boots and gloves (see Section 8).

6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Wear protective equipment appropriate to the circumstances (see Section 8)

Avoid inhalation of dust / fog.

6.2 Environmental precautions: Do not allow product to reach sewage system or any water course.

6.3 Methods and material for containment and cleaning up:

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.

6.4 Reference to other sections

See Section 7 for information on Safe Handling.

See Section 8 for information on Personal Protection Equipment.

See Section 13 for Disposal Information.

See Section 12 for Ecological Information.

7: Handling and storage**7.1 Precautions for Safe Handling**

Adopt adequate aspiration at places where you develop dust.

Avoid skin and eye contact.

Information about protection against explosions and fires: No special measures required.

7.2 Conditions for Safe Storage, including any Incompatibilities**Requirements to be Met by Storerooms and Receptacles:**

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

Container Requirements: Package of 10 vials

Storage Conditions: Store at 15-30 degrees C (59 to 86 degrees F).

Information about Storage in one Common Storage Facility: Not required.

Further information about storage conditions: None.

7.3 Specific end use(s) No further relevant information available.

8: Exposure controls/personal protection

Additional information about design of technical systems: No further data; see item 7.

8.1 Control parameters**Components with limit values that require monitoring at the workplace:**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Additional information: The lists that were valid during the creation were used as basis.

8.2 Exposure controls

Appropriate Technical Controls: Provide adequate aspiration / ventilation in the workplace

Additional information about Design of Technical Facilities: No further data (see Section 7).

(Contd. on page 6)

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 11/07/2011

Version 1

Reviewed on 11/07/2011

Trade name: Kinevac (5 µg / vials)

(Contd. of page 5)

Personal protective equipment

General Protective and Hygienic Measures:

The usual precautionary measures for handling chemicals should be followed.

Wash hands before breaks and at the end of work.

Wear protective equipment (PPE) appropriate to the circumstances.



Do not eat, drink, smoke while working.

Provide appropriate ventilation

Breathing Equipment:

Not anticipated for normal clinical environment.

In non-routine exposure conditions, where risk assessment shows air-purifying respirators are appropriate, use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Self-contained breathing apparatus should be available for emergency use.

Protection of Hands:



Wear impervious gloves if the potential exists for dermal contact.

Material of Gloves:

Latex, Latex / Nitrile or Nitrile Gloves.

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

The glove material has to be impermeable and resistant to the product/ the substance/ the mixture.

Penetration Time of Glove Material:

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye Protection:



Wear safety glasses (ANSI Z87.1)

Body Protection: Normal working clothes.

Limitation and Supervision of Exposure into the Environment: See also Section 7.

Additional Information about Design of Technical Systems: No further data; see Section 7.

9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:

Form:	Solid
Color:	White
Odour threshold:	Not determined.

pH-value: 6.0 - 8.0 (of Solution)

(Contd. on page 7)

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 11/07/2011

Version 1

Reviewed on 11/07/2011

Trade name: Kinevac (5 µg / vials)

(Contd. of page 6)

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
Flash point:	Not applicable.
Flammability (solid, gaseous):	Not determined.
Ignition temperature:	
Decomposition temperature:	Not determined.
Auto igniting:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapor pressure:	Not applicable.
Density:	Not determined.
Relative density	Not determined.
Vapour density	Not applicable.
Evaporation rate	Not applicable.
Solubility in / Miscibility with Water:	Soluble.
Segregation coefficient (n-octanol/water):	Not determined.
Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
9.2 Other information	No further relevant information available.

10: Stability and reactivity

10.1 Reactivity:

There are not particular dangerous reactions with other substances in normal conditions of use

10.2 Chemical stability: Stable under normal conditions.

10.3 Possibility of hazardous reactions: No dangerous reactions known.

10.4 Conditions to avoid: No further relevant information available.

10.5 Incompatible materials: No further relevant information available.

10.6 Hazardous decomposition products: No further relevant information available (See Section 5)

11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity:

LD/LC50 values that are relevant for classification:

69-65-8 D-mannitol

Oral	LD50	13500 mg/kg (rat)
------	------	-------------------

(Contd. on page 8)

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 11/07/2011

Version 1

Reviewed on 11/07/2011

Trade name: Kinevac (5 µg / vials)

(Contd. of page 7)

1119-34-2 (+)-L-arginine hydrochloride		
Oral	LD50	12000 mg/kg (rat)
657-27-2 L-(+)-Lysine Hydrochloride		
Oral	LD50	10000 mg/kg (rat)
hydrochloric acid		
Oral	LD50	900 mg/kg (rabbit)
1310-73-2 sodium hydroxide		
Oral	LD50	2000 mg/kg (rat)

Toxicological Information for Active Ingredients:

When Sincalide was 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.

Primary irritant effect:

By Inhalation:

Inhaling trace amounts of airborne dust would not be expected to produce symptoms. However, some peptides are active following inhalation.

By Ingestion:

Inadvertent ingestion of trace amounts of this material would not be expected to result in symptoms.

on the skin:

Material contains low concentration of components that are mild irritants or possible irritants.

It may have potential to cause mild irritation, however, moderate or severe irritation is not expected.

on the eyes: May cause Irritation.

Sensitization:

This material may act as a sensitizer (allergen) for those persons who are allergic to the formulation or components in the formulation.

Germ Cell Mutagenicity: No further relevant information available

Carcinogenicity: Not Available.

Reproductive Toxicity:

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.

Sincalide should not be administered to pregnant women near term due to its smooth muscle stimulation effect, which could result in premature labor.

Specific Target Organ Toxicity

Single Exposure (STOT - SE): No further relevant information available

Repeated Exposure (STOT - RE): No further relevant information available

Aspiration Hazard: No further relevant information available

Other information (about experimental toxicology): No further relevant information available

Subacute to Chronic Toxicity: No further relevant information available

Additional toxicological information:

Contact with small quantities of material for short periods is not expected to result in pharmacologic or toxic effects.

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

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

(Contd. on page 9)

Material Safety Data Sheet
acc. to ISO/DIS 11014

Printing date 11/07/2011

Version 1

Reviewed on 11/07/2011

Trade name: Kinevac (5 µg / vials)

(Contd. of page 8)

Any Eventual Delayed Effect after Prolonged Exposure:

Repeated and prolonged exposure to skin may cause skin irritation

12: Ecological information

12.1 Toxicity

Aquatic toxicity:

1310-73-2 sodium hydroxide

LC50 180 mg/l (fish)

12.2 Persistence and degradability No further relevant information available.

12.3 Bioaccumulative potential No further relevant information available.

12.4 Mobility in soil: No further relevant information available.

Additional ecological information

General notes:

Generally not hazardous for water
Avoid transfer into the environment.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Other adverse effects No further relevant information available.

Additional Information: Use according to good working practice.

13: Disposal considerations

13.1 Waste treatment methods:

Recommendation:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Reutilise if possible or contact a waste processors for recycling or safe disposal.

Uncleaned packagings:

Recommendation: Dispose in accordance with national, state, local or applicable country regulations.

Recommended cleansing agent: Water, if necessary with cleansing agents.

14: Transport information

14.1 UN-Number

DOT, ADR, ADN, IMDG, IATA

Void

14.2 UN proper shipping name

DOT, ADR, ADN, IMDG, IATA

Void

14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA

Class

Void

14.4 Packing group

DOT, ADR, IMDG, IATA

Void

(Contd. on page 10)

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 11/07/2011

Version 1

Reviewed on 11/07/2011

Trade name: Kinevac (5 µg / vials)

(Contd. of page 9)

14.5 Environmental hazards:

Marine pollutant: No

14.6 Special precautions for user Not applicable.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable.

UN "Model Regulation": -

15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

Sara

Section 355 (extremely hazardous substances):

None of the ingredients is listed.

Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

TSCA (Toxic Substances Control Act):

69-65-8	D-mannitol
1119-34-2	(+)-L-arginine hydrochloride
7758-11-4	dipotassium hydrogenorthophosphate
59-51-8	DL-methionine
657-27-2	L-(+)-Lysine Hydrochloride
7681-57-4	sodium metabisulphite
67-43-6	Pentetic Acid
9005-64-5	Polysorbate 20
1310-73-2	sodium hydroxide

Proposition 65

Chemicals known to cause cancer:

None of the ingredients is listed.

Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

Carcinogenic categories

EPA (Environmental Protection Agency)

None of the ingredients is listed.

IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

NTP (National Toxicology Program)

None of the ingredients is listed.

(Contd. on page 11)

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 11/07/2011

Version 1

Reviewed on 11/07/2011

Trade name: Kinevac (5 µg / vials)

(Contd. of page 10)

TLV (Threshold Limit Value established by ACGIH)

7681-57-4	sodium metabisulphite	A4
-----------	-----------------------	----

NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Significant Dangers:

Relevant phrases

H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H318 Causes serious eye damage.
H335 May cause respiratory irritation.

R22 Harmful if swallowed.
R31 Contact with acids liberates toxic gas.
R34 Causes burns.
R35 Causes severe burns.
R37 Irritating to respiratory system.
R41 Risk of serious damage to eyes.

Training Hints:

All persons handling this product should be informed on the existence of the hazard, on any possible risk they might be subjected to and about all required protective measures to prevent such a damage or to reduce the exposition.

WARNINGS:

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

Department issuing MSDS:

B-Lands Consulting
WTC, 5 Place Robert Schuman, BP 1516
38025 Grenoble, FRANCE
Tel: +33 476 295 869
Fax: +33 476 295 870
services@reachteam.eu
www.reachteam.eu

Contact:

HSE Department - Bracco Group
hse@bracco.com

Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
ICAO: International Civil Aviation Organization
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
ACGIH: American Conference of Governmental Industrial Hygienists
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)

(Contd. on page 12)

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 11/07/2011

Version 1

Reviewed on 11/07/2011

Trade name: Kinevac (5 µg / vials)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

*** Data compared to the previous version altered.**

- data updating on the basis of the latest amendments.
- adaptation of the form according to Regulation 1907/2006/CE.

(Contd. of page 11)