Safety Data Sheet

According to OSHA HazCom Standard [2012]

Printing date 03/04/2019 Version 4 Reviewed on 03/05/2022

1 Identification

Product identifier Sheet 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-Lphenylalaninamide
Synonyms: Sincalide for Injection.

Application of the substance / the mixture:
Stimulate gallbladder contraction and pancreatic secretion and/or intestinal motility for diagnostic purposes. 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.
Package of 10 vials with 5 micrograms per vial.

Details of the supplier of the safety data sheet

Manufacturer/Supplier:
Bracco Diagnostics Inc.
P.O. Box 5225 Princeton, NJ 08543
Phone number: 1-800-257-5181
Email: Hse@bracco.com (responsible for the SDS)

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

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

2 Hazard(s) identification

Classification of the substance or mixture

The product is not classified, according to the Globally Harmonized System (GHS).

Label elements

GHS label elements Not applicable.

Hazard pictograms Not applicable.

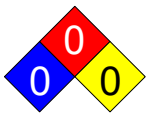
Signal word Not applicable.

Hazard statements Not applicable.

Additional Information:

Classification system:

NFPA ratings (scale 0 - 4)



Health = 0
Fire = 0
Reactivity = 0

HMIS-ratings (scale 0 - 4)

Health = 0
Fire = 0
Reactivity = 0

Other hazards No further relevant information available.

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Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

3 Composition/information on ingredients

Chemical characterization: Mixtures

Description: Mixture: consisting of the following components.

Hazardous Components: Not applicable.

Information on components		
CAS No.	**Name**	**Qty.**
69-65-8	D - Mannitol	10 – 25 %

4 First-aid measures

Description of first aid measures

General information: No special measures required.

After inhalation: Move patient to fresh air. If symptom arise consult a doctor.

After skin contact:
Immediately wash with water and soap and rinse
thoroughly. If skin irritation continues, consult a doctor.

After eye contact:
Rinse opened eye for several minutes under running
water. If irritation persists get medical attention.

After swallowing:
Immediately call a doctor.
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.

Most important symptoms and effects, both acute and delayed

No further relevant information available.

Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Fire-fighting measures

Extinguishing media

Suitable extinguishing agents: Water

Special hazards arising from the substance or mixture

In case of fire, the following can be released:
Carbon dioxide (CO_2)
Carbon monoxide (CO)
Nitrogen oxides (NO_x)
Hydrogen chloride (HCl)
Sulphur dioxide (SO_2)

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.

Protective equipment:
Firefighters should wear adequate personal protective equipment with protection of respiratory tract (selfcontained breathing apparatus) (SCBA).
In addition, firefighters should wear flame and chemicals resistant clothing, boots and gloves.

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6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.
Avoid inhaling dust and fumes.

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

Methods and material for containment and cleaning up:

Retrieve product by mechanical means.
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.

Reference to other sections

No dangerous substances are released.
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

Protective Action Criteria for Chemicals

PAC-1:		
7758-11-4	dipotassium hydrogenorthophosphate	13 mg/m³
7681-57-4	sodium metabisulphite	15 mg/m³
67-43-6	Pentetic Acid	3.5 mg/m³
1310-73-2	sodium hydroxide	0.5 mg/m³
PAC-2:		
7758-11-4	dipotassium hydrogenorthophosphate	140 mg/m³
7681-57-4	sodium metabisulphite	64 mg/m³
67-43-6	Pentetic Acid	39 mg/m³
1310-73-2	sodium hydroxide	5 mg/m³
PAC-3:		
7758-11-4	dipotassium hydrogenorthophosphate	830 mg/m³
7681-57-4	sodium metabisulphite	390 mg/m³
67-43-6	Pentetic Acid	230 mg/m³
1310-73-2	sodium hydroxide	50 mg/m³

7 Handling and storage

Precautions for safe handling

Provide suction extractors if dust is formed.
Avoid contact with the eyes and skin.

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

Conditions for safe storage, including any incompatibilities

Requirements to be met by storerooms and receptacles:
Store in a cool, dry place in well sealed receptacles.

Information about storage in one common storage facility: Not required.

Further information about storage conditions:
Container Requirements: Package of 10 vials
Storage Conditions: Store at 15-30 degrees C (59 to 86 degrees F).

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

8 Exposure controls/personal protection

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.

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Exposure controls

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.
Ensure good ventilation/exhaustion at the workplace.

Do not eat, drink and smoke while working.

Breathing equipment:
Not required.
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:

Protective gloves

The glove material must be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves Natural rubber, NR Nitrile rubber, NBR
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. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

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:

Safety glasses

Body protection: Protective work clothing.

9 Physical and chemical properties

Information on basic physical and chemical properties

General Information

Appearance:	
Form:	Solid
Color:	White
Odor threshold:	Not determined.
pH-value:	6.0 - 8.0 (of Solution)
Melting point/Melting range:	Not determined.
Boiling point/Boiling range:	Not determined.
Flash point:	Not applicable.
Flammability (solid, gaseous):	Not determined.
Ignition temperature:	Not determined.
Decomposition temperature:	Not determined.

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Auto igniting: Product is not selfigniting.

Danger of explosion: Product does not present an explosion hazard.
Not determined.

Explosion limits:
Lower: Not determined.
Upper: Not determined.

Oxidizing properties Not determined.

Vapor pressure: Not applicable.

Density: Not determined.

Relative density Not determined.

Vapor density Not applicable.

Evaporation rate Not applicable.

Solubility in / Miscibility with
Water: Very soluble.

Partition coefficient (n-octanol/water): Not determined.

Viscosity:
Dynamic: Not applicable.
Kinematic: Not applicable.
VOC content: 0.00 %
Solids content: 33.0 %

Other information No further relevant information available.

10 Stability and reactivity

Reactivity
No data available.
No further relevant information available.

Chemical stability

Thermal decomposition / conditions to be avoided:
No decomposition if used according to specifications.

Possibility of hazardous reactions No dangerous reactions known.

Conditions to avoid No further relevant information available.

Incompatible materials
No further relevant information available.

Hazardous decomposition products:
No dangerous decomposition products known.
Sulfur oxides (SOx)

11 Toxicological information

Information on toxicological effects

Acute toxicity:

LD/LC50 values that are relevant for classification:		
69-65-8 D-mannitol		
Oral	LD50	13,500 mg/kg (Rat)
1119-34-2 (+)-L-arginine hydrochloride		
Oral	LD50	12,000 mg/kg (Rat)
657-27-2 L-(+)-Lysine Hydrochloride		
Oral	LD50	10,000 mg/kg (Rat)
hydrochloric acid		
Oral	LD50	900 mg/kg (Rabbit)
1310-73-2 sodium hydroxide		
Oral	LD50	2,000 mg/kg (Rat)

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Primary irritant effect:
on the skin:
No irritant effect.
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 eye: No irritating effect.

Sensitization:
No sensitizing effects known.
This material may act as a sensitizer (allergen) for those persons who are allergic to the formulation or components in the formulation.
Other information (about experimental toxicology):
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.

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.

Additional toxicological information:
The product is not subject to classification according to internally approved calculation methods for preparations.
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.
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.

Carcinogenic categories

IARC (International Agency for Research on Cancer)
None of the ingredients are listed.
NTP (National Toxicology Program)
None of the ingredients are listed.
OSHA-Ca (Occupational Safety & Health Administration)
None of the ingredients are listed.

12 Ecological information

Toxicity

Aquatic toxicity:	
1310-73-2 sodium hydroxide	
LC50	180 mg/L (Fish)

Persistence and degradability No further relevant information available.

Bio accumulative potential No further relevant information available.

Mobility in soil No further relevant information available.

Additional ecological information

General notes:
Avoid transfer into the environment. Not hazardous for water.

Results of PBT and vPvB assessment

PBT: Not applicable.
vPvB: Not applicable.

Other adverse effects No further relevant information available.

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13 Disposal considerations

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 processor for recycling or safe disposal.

Uncleaned packagings:

Recommendation:

Disposal must be made according to official regulations.

Packagings that cannot be cleansed are to be disposed of in the same manner as the product.

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

14 Transport information

UN-Number

DOT, ADR, ADN, IMDG, IATA Not applicable.

UN proper shipping name

DOT, ADR, ADN, IMDG, IATA Not applicable.

Transport hazard class(es)

DOT, ADR, ADN, IMDG, IATA

Class Not applicable.

Packing group

DOT, ADR, IMDG, IATA Not applicable.

Environmental hazards:

Marine pollutant: No

Special precautions for user Not applicable.

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

15 Regulatory information

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

Sara

Section 355 (extremely hazardous substances):
None of the ingredients are listed.
Section 313 (Specific toxic chemical listings):
None of the ingredients is listed.

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 are listed.
Chemicals known to cause reproductive toxicity for males:
None of the ingredients are listed.
Chemicals known to cause developmental toxicity:
None of the ingredients are listed.

Carcinogenic categories

EPA (Environmental Protection Agency)		
None of the ingredients are listed.		
TLV (Threshold Limit Value established by ACGIH)		
7681-57-4	sodium metabisulphite	A4

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NIOSH-Ca (National Institute for Occupational Safety and Health)
None of the ingredients are listed.

GHS label elements Not applicable.
Hazard pictograms Not applicable.
Signal word Not applicable.
Hazard statements Not applicable.

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.
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.

Contact:

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

Date of preparation / last revision 03/05/2022, revision 4
Changes: General revision of the entire Safety Datasheet, changes in section 3.

Abbreviations and acronyms:
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
ICAO: International Civil Aviation Organisation
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
VOC: Volatile Organic Compounds (USA, EU)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent