


Safety Data Sheet:

PKC412-Midostaurin

1. Identification of the Substance and the Manufacturer

1.1. Product identifiers

Product name	PKC412-Midostaurin	Formula	C ₃₅ H ₃₀ N ₄ O ₄
Product Code	PK	RTECS	CV5045180
CAS #	120685-11-2	Molecular weight	570.64 g/mol
ECHA#	848-383-0	Drug-bank	DB06595
		Substance? Mixture?	Substance
Synonyms	<ul style="list-style-type: none"> Benzamide, N-((9S,10R,11R,13R)-2,3,10,11,12,13-hexahydro-10-methoxy-9-methyl-1-oxo-9,13-epoxy-1H,9H-diindolo(1,2,3-gh:3',2',1'-lm)pyrrolo(3,4-j)(1,7)benzodiazonin-11-yl)-N-methyl- (Chem.name) N-Benzoylstauroporine PKC 412 Midostaurin 		
Source	Synthetic	Version Date	12 February, 2023

1.2. Intended uses of the Substance and uses advised against

1.2.1. Intended use:	1.2.2. Uses advised against:
Research and development. Laboratory reagent. Reference material. Manufacturing of substances. To be used by professionals only	Not a drug, Not a food additive Not to be used in humans or animals.

1.3. Contacts

1.3.1. Details of the supplier of the SDS

FERMENTEK ltd 4 Yatziv street, POB 47120 Jerusalem 97800, Israel	Tel: +972 2 5853953 Fax: +972 2 5853943 eMail: Fermentek@Fermentek.com Safety@Fermentek.com Website: Fermentek.com
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This company is the manufacturer of the product and the supplier of the safety data sheet

1.3.2. Emergency Telephone number

For chemical emergency spill, leak, fire, exposure, or accident calls CHEMTREC day or night:
 Within USA and Canada: 1-800-424-9300. Outside USA and Canada: +1 703-527-3887



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2. Hazards' identification

2.1. Classification of the Substance

2.1.1. GHS Classification: According to EU Reg. 1272/2008 and US OSHA 1910.1200)

Notice: another author claims this substance is very toxic to aquatic life with long lasting effects, is harmful if swallowed, is suspected of damaging fertility or the unborn child, may cause damage to organs through prolonged or repeated exposure and may cause respiratory irritation. We found no supporting information for this claim.

Acute Toxicity, Ingestion	Cat.5	H303	May be harmful if swallowed

2.2. GHS Label elements, including precautionary statements.

2.2.1. Pictogram: {  } Signal word: {Warning}

2.2.2. Hazard Statements

H361	Suspected of damaging fertility or the unborn child
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2.2.3. GHS Precautionary Statements

P203	Obtain, read and follow all safety instructions before use.
P261	Avoid breathing dust or mist.
P264	Wash {hands} thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection

2.2.4. GHS Response Phrases:

P301+P317: IF SWALLOWED: Get medical help.
P318: If exposed or concerned, Get medical advice.

3. Composition/information on ingredients

Substance	
Substance Name:	PKC412-Midostaurin
Concentration	<=100%
CAS Registry#:	120685-11-2
EC#:	848-383-0
Molecular Formula:	C ₃₅ H ₃₀ N ₄ O ₄
Molecular Weight:	570.64 g/mol
Classification	Reprotox 2
Mixture?	Substance



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4. First Aid Measures

4.1. Description of First Aid Measures

General advice:	First-aiders need to protect themselves. If medical attention is required, show this safety data sheet to the doctor in attendance.
Eye contact:	Rinse out with plenty of water. Remove contact lenses.
Skin Contact:	In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower.
Ingestion:	If swallowed: give water to drink (two glasses at most). Seek medical advice immediately. In exceptional cases only, if medical care is not available within one hour, induce vomiting (only in persons who are wide awake and fully conscious), administer activated charcoal (20 - 40 g in a 10% slurry) and consult a doctor as quickly as possible.
Inhalation:	If inhaled, move the person into fresh air.

4.2. Most important symptoms and effects, both acute and delayed

General symptoms	None known
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4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	No data available
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5. Fire-fighting measures

5.1. Extinguishing media

Suitable extinguishing media	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Unsuitable extinguishing media	None known

5.2. Other information

Hazardous combustion products	Carbon oxides, Nitrogen oxides (NO _x) Formula C35H30N4O4
Advice for firefighters	Wear self-contained breathing apparatus for fire fighting if necessary. Wear protective suit.

6. Accidental release measures

6.1. Personal precautions, protective equipment, and emergency procedures

Personal precautions	Use personal protective equipment as required. Keep people away from and upwind of spill/leak.
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6.2. Environmental precautions

Environmental precautions	Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.
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6.3. Methods and material for containment and cleaning up

Methods for containment:	Prevent further leakage or spillage if safe to do so. Cover the powder spill with a plastic sheet or tarp to minimize spreading. Dike far ahead of liquid spill for later disposal.
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Methods for cleaning up:

Clean-up should be dealt with only by qualified personnel familiar with the specific substance. Cover liquid spill with sand, earth, or other non-combustible absorbent material (e.g., sand, earth, diatomaceous earth, and vermiculite). Cover the powder spill with a plastic sheet or tarp to minimize spreading. Sweep up and shovel into suitable containers for disposal.

7. Handling and storage

7.1. Precautions for safe handling

Advice on safe handling:

Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Wash contaminated clothing before reuse. Do not breathe dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions:

Keep container tightly closed in a dry and well-ventilated place.
Keep out of the reach of children.
Store at -20 °C.

Suitable packaging

Must only be kept in original packaging.

Incompatible materials:

None known based on information available.

8. Exposure Controls/Personal Protection

8.1. Control parameters

Control parameters

Components with workplace control parameters

8.2. Exposure controls

Appropriate engineering controls

Showers, Eyewash stations, Ventilation systems
Avoid contact with skin, eyes, and clothing.
Wash hands before breaks and immediately after handling the product.
Use fume-hood for routine work.

8.3. Personal protective equipment

[PPE=Personal Protection Equipment]

PPE: Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

PPE: Hand Protection:

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal techniques to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices, and wash and dry hands

PPE: Eye Protection:

Use a face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU)



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PPE: Skin and Body Protection:

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

9. Physical and chemical properties

9.1. Physical/chemical properties

Physical State at room temperature	Solid
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Appearance	Powder, White
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No further safety relevant data are available

10. Stability and reactivity

Reactivity:	No information available.
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Chemical stability:	Stable under normal conditions.
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Conditions to avoid	Heat, flames and sparks. Sunlight.
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Incompatible materials	Strong reducers and oxidizers
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Possibility of Hazardous Reactions	None under normal processing
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Hazardous combustion products	See section 5
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11. Toxicological information

11.1. Information on toxicological effects

To the best of our knowledge, the toxicological effects of this product have not been thoroughly studied yet.

11.1.1. Acute Toxicity

Acute toxicity:	No data available
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Skin corrosion/irritation:	No data available
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Serious eye damage/eye irritation:	No data available
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Respiratory or skin sensitization/corrosion:	No data available
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11.1.2. Chronic toxicity

Chronic toxicity	No data available
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11.1.3. CRM (Carcinogene, Mutagen, Reproductive hazards)

Germ cell mutagenicity:	No data available
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Carcinogenicity:	No data available
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Reproductive toxicity / Teratogenicity:	No data available
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11.2. Additional information

RTECS number	CV5045180
General symptoms	Gastrointestinal - hypermotility, diarrhea Gastrointestinal - nausea or vomiting Blood - normocytic anemia

12. Ecological Information

Eco-Toxicity	No data available
Other adverse effects	No data available

13. Disposal Considerations
13.1. Waste treatment methods

Waste Disposal	Dispose of in accordance with local regulations
Contaminated packaging	Dispose of as unused product

14. Transport information
14.1. UN Number, Proper Shipping Name, Transport Hazard Class, packing group

	US DOT	ADR/RID	IATA	IMDG
UN Number	Not dangerous goods.	Not dangerous goods.	Not dangerous goods.	Not dangerous goods.
UN proper shipping name	Not hazardous for transport	Not hazardous for transport	Not hazardous for transport	Not hazardous for transport
Transport Hazard Class & Packing Group	Not regulated	Not regulated	Not regulated	Not regulated

15. Regulatory information
15.1. Safety, health, and environmental regulations/legislation

Canada/DSL/NDSL	Not listed
USA EPA / TSCA	This product is not listed on the USA EPA TSCA (it is for research)
EU ECHA Status	This product is registered with the EU ECHA, Number 848-383-0 This product is NOT REGISTERED with the EU ECHA as of 02.2023 REACH: Neither Registered nor PreRegistered. ANNEX III (criteria for 1 - 10 tonne registered substances): Not Listed

16. Other information
16.1. Department issuing this SDS

Quality systems and regulatory affairs
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16.2. General Disclaimer

<p>The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication.</p> <p>The information given here is designed only as guidance for safe handling, use, processing, storage, transportation, disposal, and release and is not to be considered a warranty or quality specification.</p>
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The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

16.3. The users'/employers' responsibility:

A risk assessment should be performed by the employer/user prior to the use of this product.

All recommendations included in this document, are advisory in nature.

The type of protective equipment must be selected based on the amount and concentration of all dangerous materials being used in the workplace.

16.4. No-Copyright statement

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Fermentek believes that no one can claim copyright on an SDS.

This sort of document is but a compendium of common knowledge and published facts.

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16.5. Abbreviations and acronyms:

Acute Tox.:	Acute toxicity
CAS:	Chemical Abstracts Service
DOT:	US Department of Transportation
EINECS:	European Inventory of Existing Commercial Chemical Substances
Eye Dam.:	Serious eye damage/eye irritation
HSDB	Hazardous Substances Data Bank
HMIS:	Hazardous Materials Identification System (USA)
IATA:	International Air Transport Association
IMDG:	International Maritime Code for Dangerous Goods
LC50:	Lethal concentration, Median
LD50:	Lethal dose median
LD50:	Lethal dose, Median
NDG	Not dangerous goods (for transport)
NFPA:	National Fire Protection Association USA
NIOSH:	National Institute for Occupational Safety
OSHA:	Occupational Safety & Health
PBT:	Persistent, Bioaccumulative, and Toxic
PEL:	Permissible Exposure Limit
REL:	Recommended Exposure Limit
Repr.:	Reproductive toxicity
RTECS:	Registry of Toxic Effects of Chemical Substances
Skin Irrit:	Skin corrosion/irritation
STOT/SE	Specific target organ toxicity/Single exposure
STOT/RE	Specific target organ toxicity/Repeated exposure
TDL0	Toxic dose, least published

16.6. End of SDS