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According to REACH Regulations (EC) 1907/2006 and (EU) 2020/878

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

1.1 Product identifier

Product code : GP1345
Product name : Ponatinib
CAS number : 943319-70-8
Physical form : solid, substance

REACH : A registration number is not available for this substance as the substance or its uses

are exempted from registration, the annual tonnage does not require a registration or

the registration is envisaged for a later registration deadline.

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

PC21: Laboratory chemicals.

Details of the supplier of the safety data sheet

Company name : Glentham Life Sciences Ltd Telephone : +44 (0) 1225 667 798

Unit 5 Leafield Way Fax : +44 (0) 2033 978 909
Corsham SN13 9SW Email : info@glentham.com
United Kingdom Web : www.glentham.com

1.4 Emergency telephone number

Emergency telephone: NHS Direct 111 (UK, 24 hours), 112 (EU, 24 Hours), +44 (0) 1225 667 798 (09.00 - 17.00 GMT)

number

1.3

2. Hazards identification

2.1 Classification of the substance or mixture

Classification under CLP according to (EC) 1272/2008

H301 Acute Tox. 3 H311 Acute Tox. 3 H331 Acute Tox. 3 H361 Repr. 2 H372 STOT RE 1

2.2 Label elements

Label elements under CLP according to (EC) 1272/2008

Pictograms





Signal words Danger

Hazard statements

H301 Toxic if swallowed
H311 Toxic in contact with skin
H331 Toxic if inhaled

H361 Suspected of damaging fertility or the unborn child

H372 Causes damage to organs through prolonged or repeated exposure

Precautionary statements

P201 Obtain special instructions before use.

P280 Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor/...

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P308+P313 IF exposed or concerned: Get medical advice/attention.

P261 Avoid breathing dust

P261 Avoid breathing dust. P264 Do not breathe fume.

2.3 Other hazards

PBT

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This substance is not identified as a PBT substance.

3.0 Composition/information on ingredients

3.1 Substances

Name	Identifier	%	Classification
Ponatinib	CAS: 943319-70-8 EC: REACH: Not applicable	98.0%	H301, Acute Tox. 3 H311, Acute Tox. 3 H331, Acute Tox. 3 H361, Repr. 2 H372, STOT RF 1

4. First aid measures

4.1 Description of first aid measures

Skin contact	Consult a doctor. Drench the affected skin with running water for 10 minutes or longer if substance is still on skin. Remove all contaminated clothes and footwear immediately unless stuck to skin.
Eye contact	Consult a doctor. Bathe the eye with running water for 15 minutes.
Ingestion	Consult a doctor. Do not induce vomiting. If conscious, give half a litre of water to drink immediately. Wash out mouth with water.
Inhalation	Remove casualty from exposure ensuring one's own safety whilst doing so. Consult a doctor.

4.2 Most important symptoms and effects, both acute and delayed

Skin contact	There may be irritation and redness at the site of contact.		
Eye contact	The eyes may water profusely. There may be irritation and redness.		
Ingestion	Nausea and stomach pain may occur. There may be soreness and redness of the mouth and throat. There may be vomiting.		
Inhalation	Nausea and stomach pain may occur. There may be irritation of the throat with a feeling of tightness in the chest. There may be vomiting.		
Delayed / immediate	Immediate effects can be expected after short-term exposure. Nausea and stomach pain may occur.		

4.3 Indication of any immediate medical attention and special treatment needed

Immediate / special treatment

Do not induce vomiting.

5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media for the surrounding fire should be used. Use water spray to cool containers.

5.2 Special hazards arising from the substance or mixture

Exposure hazards

In combustion emits toxic fumes.

5.3 Advice for fire-fighters

Wear protective clothing to prevent contact with skin and eyes. Wear self-contained breathing apparatus.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions

Do not create dust. If outside do not approach from downwind. If outside keep bystanders upwind and away from danger point. Mark out the contaminated area with signs and prevent access to unauthorised personnel. Refer to section 8 of SDS for personal protection details.

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6.2 Environmental precautions

Do not discharge into drains or rivers.

6.3 Methods and material for containment and cleaning up

Clean-up procedures

Clean-up should be dealt with only by qualified personnel familiar with the specific substance. Transfer to a closable, labelled salvage container for disposal by an appropriate method.

6.4 Reference to other sections

Refer to section 8 of SDS.

7. Handling and storage

7.1 Precautions for safe handling

Handling requirements

Avoid direct contact with the substance. Avoid the formation or spread of dust in the air. Do not handle in a confined space. Ensure there is sufficient ventilation of the area.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Avoid contact with water or humidity. Keep container tightly closed. Store in cool, well ventilated area.

7.3 Specific end use(s)

No data available.

8. Exposure controls/personal protection

8.1 Control parameters

Workplace exposure limits

No workplace exposure limit control parameters set

8.2 Exposure controls

Engineering measures	Ensure there is sufficient ventilation of the area.
Respiratory protection	Respiratory protective device with particle filter. Self- contained breathing apparatus must be available in case of emergency.
Hand protection	Protective gloves.
Eye protection	Ensure eye bath is to hand. Safety glasses.
Skin protection	Protective clothing.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	Solid
Colour	White
Odour	No data available.
Melting point/Freezing point	No data available.
Boiling point/initial boiling point/boiling range	No data available.
Flammability	No data available.
Lower/Upper explosion limit	No data available.
Flash Point	No data available.
Auto-ignition temperature	No data available.
Decomposition temperature	No data available.
рН	No data available.
Kinematic viscosity	No data available.
Solubility	No data available.
Partition coefficient n-octanol/water	No data available.
Vapour pressure	No data available.
Density/relative density	No data available.
Relative vapour pressure	No data available.
Particle characteristics	No data available.

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9.2 Other information

No data available.

10. Stability and reactivity

10.1 Reactivity

Stable under recommended transport or storage conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions

Decomposition may occur on exposure to conditions or materials listed below. Hazardous reactions will not occur under normal transport or storage conditions.

10.4 Conditions to avoid

Heat.

10.5 Incompatible materials

Materials to avoid

Strong acids. Strong oxidising agents.

11. Toxicological information

11.1 Information on toxicological effects

a) Acute toxicity

No data available.

b) Skin corrosion/irritation

No data available.

c) Serious eye damage/irritation

No data available.

d) Respiratory or skin sensitisation

No data available.

e) Germ cell mutagenicity

No data available.

f) Carcinogenicity

No data available.

g) Reproductive toxicity

Reproductive toxicity (Category 2)

h) STOT-single exposure

No data available.

i) STOT-repeated exposure

Specific target organ toxicity, repeated exposure (Category 1)

j) Aspiration hazard

No data available.

11.2 Symptoms / routes of exposure

Skin contact	There may be irritation and redness at the site of contact.	
Eye contact	The eyes may water profusely. There may be irritation and redness.	
Ingestion	Nausea and stomach pain may occur. There may be soreness and redness of the mouth and throat. There may be vomiting.	
Inhalation	Nausea and stomach pain may occur. There may be irritation of the throat with a feeling of tightness in the chest. There may be vomiting.	

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Delayed / immediate effects	Immediate effects can be expected after short-term exposure. Nausea and stomach pain may occur.
Other information	No data available.

Ecological information 12.

12.1 **Toxicity**

No data available.

12.2 Persistence and degradability

Biodegradable.

12.3 Bioaccumulative potential

No bioaccumulation potential.

12.4 Mobility in soil

Readily absorbed into soil.

12.5 Results of PBT and vPvB assessment

This substance is not identified as a PBT substance.

12.6 **Endocrine disrupting properties**

This substance is not identified as having endocrine disrupting properties

12.7 Other adverse effects

No data available.

13. **Disposal considerations**

13.1 Waste treatment methods

Disposal operations

Transfer to a suitable container and arrange for collection by specialised disposal company.

The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

Transport information 14.

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
UN2811	UN2811	UN2811	UN2811	UN2811
14.2. UN proper shipping nar	me			
TOXIC SOLID, ORGANIC, N.O.S.	TOXIC SOLID, ORGANIC, N.O.S.	Toxic solid, organic, n.o.s.	TOXIC SOLID, ORGANIC, N.O.S.	TOXIC SOLID, ORGANIC, N.O.S.
Transport document descrip	tion			
UN2811 TOXIC SOLID, ORGANIC, N.O.S. (PONATINIB), 6.1, III	UN2811 TOXIC SOLID, ORGANIC, N.O.S. (PONATINIB), 6.1, III	UN2811 Toxic solid, organic, n.o.s. (Ponatinib), 6.1, III	UN2811 TOXIC SOLID, ORGANIC, N.O.S. (PONATINIB), 6.1, III	UN2811 TOXIC SOLID, ORGANIC, N.O.S. (PONATINIB) 6.1, III
14.3. Transport hazard class((es)			
6.1	6.1	6.1	6.1	6.1













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14.4. Packing group					
III	Ш	III	III	III	
14.5. Environmental hazaı	rds				
No	No	No	No	No	

15. Regulatory information

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

This Safety Data Sheet is prepared in accordance with Commission Regulation (EC) 1907/2006, amended by Commission Regulation (EU) 2020/787.

Authorisations/Restrictions

Regulation (EC) 1907/2006, REACH, Annex XIV list of substances subject to

No data available.

authorisation:

Regulation (EC) 1907/2006, REACH, Annex XVII restrictions on the manufacture, placing No data available.

on the market and use of certain dangerous substances:

Regulation (EC) 1005/2009 on substances that deplete the ozone layer:

No data available.

Regulation (EC) 850/2004 on persistent organic pollutants, amended by (EU) No

No data available.

2019/1021:

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out for the substance or the mixture by the supplier.

16. Other information

H-Statement Full Texts

H301	Toxic if swallowed
H311	Toxic in contact with skin

H331 Toxic if inhaled

H361 Suspected of damaging fertility or the unborn child

H372 Causes damage to organs through prolonged or repeated exposure

Abbreviations Full Texts

ADN European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

ADR European Agreement concerning the International Carriage of Dangerous Goods by Road

ALARP As low as is reasonably practicable

CAS Chemical Abstracts Service

CLP Classification, Labelling and Packaging Regulations
COSHH Control of Substances Hazardous to Health

EC Number European Community Number EC50 Effective Concentration 50%

EILINCS European List of Notified Chemical Substances

EINECS European Inventory of Existing Commercial Chemical Substances

GHS Globally Harmonised System
HSE Health & Safety Executive UK
IATA International Air Transport Association

IM Intramuscular

IMDG The International Maritime Dangerous Goods Code

IP Intraperitoneal IV Intravascular LD50 Lethal Dose 50%

LOEC Lowest Observable Effective Concentration

LTEL Long Term Exposure Limit

NOEC No Observable Effective Concentration

OECD Organisation for Economic Cooperations and Development

PBT Persistent Bioaccumulative Toxic
PPE Personal Protective Equipment

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REACH Registration, Evaluation, Authorisation and Restriction of Chemicals

RID Regulations Concerning the International Carriage of Dangerous Goods by Rail

SC Subcutaneous SDS Safety Data Sheet

STEL Short Term Exposure Limit VOC Volatile Organic Compounds

vPvB Very Persistent and Very Bioaccumulative

WEL Workplace Exposure Limits

This Safety Data Sheet is prepared in accordance with Commission Regulation (EC) 1907/2006, amended by Commission Regulation (EU) 2020/787.

Disclaimer: Glentham Life Sciences shall not be held liable for any damage resulting from handling or from contact with the above product. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This document does not guarantee the properties or quality of the product.

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