

Safety Data Sheet

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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	: GP2160
Product name	: Sunitinib malate
CAS number	: 341031-54-7
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.

1.3 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

2. Hazards identification

2.1 Classification of the substance or mixture

Classification under CLP according to (EC) 1272/2008

H360	Repr. 1B
H372	STOT RE 1
H400	Aquatic Acute 1
H410	Aquatic Chronic 1

2.2 Label elements

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

Pictograms



Signal words	Danger
Hazard statements	
H360	May damage fertility or the unborn child
H372	Causes damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
Precautionary statements	
P260	Do not breathe dust/fume/gas/mist/vapors/spray.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P264	Do not breathe fume.
Other hazards	
PBT	

This substance is not identified as a PBT substance.

3.0 Composition/information on ingredients

2.3

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3.1 Substances

4.

4.2

Name		Identifier	%	Classification	
Sunitinib malate		CAS: 341031-54-7 EC: REACH: Not applicable	99.0%	H360, Repr. 1B H372, STOT RE 1 H400, Aquatic Acute 1 H410, Aquatic Chronic 1	
First aid measures					
Description of first a	id measures				
Skin contact		I contaminated clothes an	•	for 10 minutes or longer if substance is nmediately unless stuck to skin. Wash	
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.				
lost important symp	otoms and effects, both ac	ute and delayed			
Skin contact	There may be irritation and redness at the site of contact. There may be mild irritation at the site of contact.				
Eye contact	The eyes may water pr	ofusely. There may be irri	ation and re	dness.	
Ingestion	Nausea and stomach pain may occur. There may be irritation of the throat. There may be soreness and redness of the mouth and throat. There may be vomiting.				
Inhalation	Nausea and stomach p in the chest. There may		be irritation	of the throat with a feeling of tightness	
Delayed / immediate effects	Immediate effects can l	be expected after short-te	m 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.

Special hazards arising from the substance or mixture

Exposure hazards

5.2

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.

6.2 Environmental precautions

Do not discharge into drains or rivers.

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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

9.2 Other information

No data available.

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10.	Stability and reactivity	,
10.1	Reactivity	
	Stable under recomme	ended transport or storage conditions.
10.2	Chemical stability	
	Stable under normal co	onditions.
10.3	Possibility of hazardo	us reactions
	Hazardous reactions	
	Decomposition may oc transport or storage co	cur on exposure to conditions or materials listed below. Hazardous reactions will not occur under normal nditions.
10.4	Conditions to avoid	
	Heat.	
10.5	Incompatible materials	5
	Materials to avoid	
	Strong acids. Strong or	xidising agents.
	-	······
11.	Toxicological informat	
11.1	Information on toxicol	ogical effects
a)	Acute toxicity No data available.	
b)	Skin corrosion/irritatio	
-,	No data available.	лі Лі
c)	Serious eye damage/ir	ritation
	No data available.	
d)	Respiratory or skin se	nsitisation
	No data available.	
e)	Germ cell mutagenicit	у
	No data available.	
f)	Carcinogenicity	
	No data available.	
g)	Reproductive toxicity	Cotogony (1P)
h)	Reproductive toxicity (
,	STOT-single exposure No data available.	
i)	STOT-repeated exposi	ure
		oxicity, 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. There may be mild irritation 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 irritation of the throat. 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 effects	Immediate effects can be expected after short-term exposure. Nausea and stomach pain may occur.

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	Other information No data available.
	Ecological information
1	Toxicity
	No data available.
2	Persistence and degradability
	No data available.
	Bioaccumulative potential
	No bioaccumulation potential.
	Mobility in soil
	Readily absorbed into soil.
	Results of PBT and vPvB assessment
	This substance is not identified as a PBT substance.
	Endocrine disrupting properties
	This substance is not identified as having endocrine disrupting properties
	Other adverse effects
	No data available.
	Disposal considerations
	Waste treatment methods
	Disposal operations
	Transfer to a suitable container and arrange for collection by specialised disposal company.
	NB
	The year's attention is drawn to the necesible evictorial of regional or national regulations regarding dianoad

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

14. Transport information

ADR	IMDG	ΙΑΤΑ	ADN	RID
14.1. UN number				
UN3077	UN3077	UN3077	UN3077	UN3077
14.2. UN proper shipping na	me			
ENVIRONMENTALL Y HAZARDOUS SUBSTANCE, SOLID, N.O.S.	ENVIRONMENTALL Y HAZARDOUS SUBSTANCE, SOLID, N.O.S.	Environmentally hazardous substance, solid, n.o.s.	ENVIRONMENTALL Y HAZARDOUS SUBSTANCE, SOLID, N.O.S.	ENVIRONMENTALL Y HAZARDOUS SUBSTANCE, SOLID, N.O.S.
Transport document descrip	tion			
UN3077 ENVIRONM ENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (SUNITINIB MALATE), 9, III	UN3077 ENVIRONM ENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (SUNITINIB MALATE), 9, III	UN3077 Environmentally hazardous substance, solid, n.o.s. (Sunitinib malate), 9, III	UN3077 ENVIRONM ENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (SUNITINIB MALATE), 9, III	UN3077 ENVIRONM ENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (SUNITINIB MALATE), 9, III
14.3. Transport hazard class	(es)			
9	9	9	9	9

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14.4. Packing group					
111	III	111	111	III	
14.5. Environmental hazaro	ls				
×	Le la	<u> </u>	Le la	×2	
Dangerous for the Environment: yes	Dangerous for the Environment: yes	Dangerous for the Environment: yes	Dangerous for the Environment: yes	Dangerous for the Environment: yes	
egulatory information	I				
afety, health and environme	ental regulations/legislation spe	cific for the substance or mixtur	e		

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

Regulation (EC) 1907/2006, REACH, Annex XIV list of substances subject to authorisation:	No data available
Regulation (EC) 1907/2006, REACH, Annex XVII restrictions on the manufacture, placing on the market and use of certain dangerous substances:	No data available
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 2019/1021:	No data available

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

15.

H-Statement Full	Texts
H360	May damage fertility or the unborn child
H372	Causes damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
Abbreviations Fu	II 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 RID	Registration, Evaluation, Authorisation and Restriction of Chemicals 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.