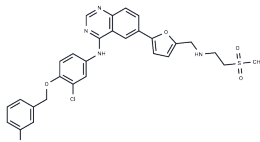


SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Substance
Substance name : Lapatinib [231277-92-2]
CAS-No. : 231277-92-2
Product code : NB-64-00215
Formula : C₂₉H₂₆ClFN₄O₄S
Chemical structure :



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

No additional information available

1.3. Details of the supplier of the safety data sheet

Manufacturer

NeoBiotech SAS
74 Rue des Suisses
92000 Nanterre
France
T +33 9 77 40 09 09, F +33 9 77 40 10 11
tech@neo-biotech.com, <https://www.neo-biotech.com/>

Distributor

CliniSciences
Rue des Suisses 74
92000 Nanterre
France
T +33 9 77 40 09 09, F +33 9 77 40 10 11
info@clinisciences.com, www.clinisciences.com

1.4. Emergency telephone number

Country/Area	Organisation	Emergency number
Italy	Centro Antiveleni di Bergamo. Azienda Ospedaliera Papa Giovanni XXIII. Piazza OMS - Organizzazione Mondiale della Sanità, 1 24127 Bergamo.	800 88 33 00
	Centro Antiveleni di Milano. Ospedale Niguarda Ca' Granda. Piazza Ospedale Maggiore 3 20162 Milan.	02 6610 1029
	Centro Antiveleni di Roma. CAV Policlinico "A. Gemelli". Dipartimento di Tossicologia Clinica Universita Cattolica del Sacro Cuore. Largo Agostino Gemelli, 8 00168 Rome.	06 305 4343
	Centro Antiveleni di Roma. CAV Policlinico "Umberto I". Università di Roma. Viale del Policlinico, 155 00161 Rome.	06 4997 8000
	Centro Antiveleni di Firenze. Az. Osp. "Careggi" U.O. Tossicologia Medica. S.O.D. di Tossicologia Clinica/cologia Clinica. Largo Brambilla, 3 50134 Florence.	055 794 7819
	Centro Antiveleni di Pavia. CAV Centro Nazionale di Informazione Tossicologica. Istituti Clinici Scientifici Maugeri Spa. Via Salvatore Maugeri, 10 27100 Pavia.	03 822 4444

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Country/Area	Organisation	Emergency number
	Centro Antiveleni di Roma. CAV "Osp. Pediatrico Bambino Gesù" Dip. Emergenza e Accettazione DEA. Piazza Sant'Onofrio, 4 00165 Rome.	06 6859 3726
	Centro Antiveleni di Foggia. Az. Osp. Univ. Foggia. V.le Luigi Pinto, 1 71122 Foggia.	800 183 459
	Centro Antiveleni di Napoli. Az. Osp. "A. Cardarelli". Via A. Cardarelli, 9 80131 Naples.	081 54 53 333

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Lapatinib [231277-92-2]	CAS-No.: 231277-92-2	99.81	Not classified

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: If you feel unwell, seek medical advice.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Wash skin with plenty of water.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell.
Self protection of the first-aiders	: Even though no specific hazards are defined, first-aiders should wear eye protection, gloves and disposable half mask. Consider additional protection if repeated or prolonged exposition is likely.

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

Symptoms/effects after inhalation	: None under normal conditions. Dust of the product, if present, may cause respiratory irritation after excessive inhalation exposure.
Symptoms/effects after skin contact	: None under normal conditions. Dust may cause irritation in skin folds or by contact in combination with tight clothing.
Symptoms/effects after eye contact	: None under normal conditions. Dust from this product may cause eye irritation.
Symptoms/effects after ingestion	: None under normal conditions.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Water spray. Dry powder. Foam.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: No fire hazard.
Explosion hazard	: No direct explosion hazard.
Hazardous decomposition products in case of fire	: Toxic fumes may be released.

5.3. Advice for firefighters

Firefighting instructions	: Fight fire from safe distance and protected location. Do not enter fire area without proper protective equipment, including respiratory protection.
Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Notify authorities if product enters sewers or public waters. Absorb spillage to prevent material damage.
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For non-emergency personnel

Protective equipment	: Wear recommended personal protective equipment.
Emergency procedures	: Ventilate spillage area.

For emergency responders

Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
Emergency procedures	: Evacuate unnecessary personnel.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment	: Using a clean shovel, put the material in a dry container and cover without compressing it.
Methods for cleaning up	: Mechanically recover the product.
Other information	: Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed	: Not expected to present a significant hazard under anticipated conditions of normal use.
Precautions for safe handling	: Ensure good ventilation of the work station. Wear personal protective equipment.
Hygiene measures	: Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures	: Keep in a cool, well-ventilated place away from heat.
Storage conditions	: Keep cool. Protect from sunlight.
Packaging materials	: Always store product in container of same material as original container.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Personal protection equipment

Personal protective equipment:

Wear recommended personal protective equipment.

Personal protective equipment symbol(s):



Eye and face protection

Eye protection:

Safety glasses

Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Protective gloves

Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: Not available
Odour	: Not available
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not applicable
Boiling point	: 750.7°C at 760 mmHg
Flammability	: Non flammable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: 407.8 °C
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Organic solvent:DMSO: 262.5 mg/mL (451.76 mM),Sonication is recommended. H2O: < 1 mg/mL (insoluble or slightly soluble), 10% DMSO+40% PEG300+5% Tween 80+45% Saline: 9.3 mg/mL (16.01 mM),Solution. Ethanol: < 1 mg/mL (insoluble or slightly soluble)
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: 0mmHg at 25°C
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: 1.381 g/cm3 (Predicted)
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

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SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

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Viscosity, kinematic	Not applicable

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short-term (acute)	: Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Based on available data, the classification criteria are not met)

12.2. Persistence and degradability

Lapatinib [231277-92-2] (231277-92-2)	
Persistence and degradability	Not rapidly degradable

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional waste regulation	: Disposal must be done according to official regulations.
Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
Sewage disposal recommendations	: Disposal must be done according to official regulations.
Product/Packaging disposal recommendations	: Comply with applicable regulations for solid waste disposal. Disposal must be done according to official regulations.
Additional information	: Do not re-use empty containers.
Ecological waste information	: The waste of the product should be considered as hazardous as the product itself, with the likelihood of impacting the environment in the same way. Consider the handling and disposal of the waste as defined by the product itself.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated for transport				
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

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SECTION 15: Regulatory information

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

EU-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

Ozone Regulation (2024/590)

Not listed on the Ozone Depletion list (Regulation EU 2024/590)

Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

Explosives Precursors Regulation (EU 2019/1148)

Not listed on the Explosives Precursors list (EU)

Drug Precursors Regulation (EC 273/2004)

Not listed on the Drug Precursors list (EU)

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:

ACGIH	American Conference of Governmental Industrial Hygienists
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
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
CAS-No.	Chemical Abstracts Service number
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
COD	Chemical oxygen demand (COD)
CSA	Chemical safety assessment
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration

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Abbreviations and acronyms:	
ED	Endocrine disruptor
EN	European Standard
EWC	European waste catalogue
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
Log Kow	Partition coefficient n-octanol/water (Log Kow)
Log Pow	Partition coefficient n-octanol/water (Log Pow)
MAK	maximum workplace concentration
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
N.O.S.	Not Otherwise Specified
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
OSHA	Occupational Safety & Health Administration
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
PPE	Personal protection equipment
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TF	Technical function
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
TWA	Time Weighted Average
VOC	Volatile Organic Compounds
vPvB	Very Persistent and Very Bioaccumulative
UFI	Unique Formula Identifier

The classification complies with : ATP 12

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.