

Safety Data Sheet

Release 1.0
Revision 03/09/2022
Date of issue 04/25/2022

1 Identification of the substance

1.1 Product identifier

Identification of the substance Regorafenib

Additional identification BAY 73-4506

Catalogue Number FR16116

REACH No. A registration number is not available for this substance as the substance or its uses are exempted from registration or the annual tonnage does not require a registration.

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

Identified uses other biochemicals

Restriction on use not for food or drug use, for laboratory use only

1.3 Details of the supplier of the safety data sheet

Company Carbosynth Ltd
8&9 Old Station Business Park
COMPTON RG20 6NE
Phone +44 1635 578444
Mail customerservice@biosynth-carbosynth.com

1.4 Emergency telephone number

Phone 24hr/7days: +44 118 338 8269

2 Hazards identification

2.1 Classification of the substance or mixture

Physical Hazards

not classified

Health Hazards

not classified

Acute toxicity oral (Category 4), H302

Reproductive toxicity (Category 1B), H360

Lactation effects, H362

Specific target organ toxicity, repeated exposure (Category 1), H372

Environmental Hazards

Acute aquatic toxicity (Category 1), H400

Chronic aquatic toxicity (Category 1), H410

2.2 Label elements

Regulatory List

EC1272/08 Regulation (EC) 1272/2008 (GHS/CLP)

Symbol

GHS07 exclamation mark

Pictogram



GHS08 health hazard

Pictogram



GHS09 environmental hazards

Pictogram**Signal Word**

Danger Danger

Hazard Statement

H302 Harmful if swallowed.
H360 May damage fertility or the unborn child.
H362 May cause harm to breast-fed children.
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 Statement

P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P270 Do not eat, drink or smoke when using this product.
P281 Use personal protective equipment as required.
P301+P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P330 Rinse mouth.
P501 Dispose of contents / container in accordance with local / regional / national / international regulations.

2.3 Other hazards

Caution! To the best of our knowledge the toxicological properties of this material have not been thoroughly investigated.

3 Composition/information on ingredients**Substance related information**

Substance name Regorafenib
Synonyms BAY 73-4506
Cas No. [755037-03-7]
Formula C₂₁H₁₅ClF₄N₄O₃

4 First aid measures**4.1 Description of first aid measures****First Aid: Eye**

Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Consult an ophthalmologist.

First Aid: Skin

Wash immediately with plenty of water and soap for at least 15 minutes. Remove contaminated clothing and shoes. Wash contaminated clothes before reuse. Call a physician.

First Aid: Ingestion

Wash out mouth with water provided person is conscious. Call a physician.

4.2 Most important symptoms and effects, both acute and delayed**Hints for Physician: Symptoms**

See Section 11 for additional information on health hazards

4.3 Indication of any immediate medical attention and special treatment needed**First Aid: Inhalation**

Remove casualty to fresh air and keep warm and at rest. If breathing is irregular or stopped, administer artificial respiration. Call a physician.

Hints for Physician: Treatment

Treat symptomatically.

5 Firefighting measures**5.1 Extinguishing Media****Suitable**

foam, dry extinguishing powder, carbon dioxide (CO₂), water spray jet

5.2 Special hazards arising from the substance or mixture

Wear a self-contained breathing apparatus and chemical protective clothing.

Hazards During Fire-Fighting

toxic fumes

5.3 Fire-Fighting/Further Advice

Do not inhale explosion and combustion gases. Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Move undamaged containers from immediate hazard area if it can be done safely.

6 Accidental release measures**6.1 Personal Precautions, protective equipment and emergency procedures**

Wear breathing apparatus if exposed to vapours/dusts/aerosols. Provide adequate ventilation.

6.2 Environmental Precautions

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains. Ensure all waste water is collected and treated via a waste water treatment plant.

6.3 Methods and material for containment and cleaning up

not available

6.4 Further Accidental Release Measures

Collect in closed and suitable containers for disposal. Clear contaminated areas thoroughly. Ventilate affected area.

7 Handling and storage**7.1 Precautions for safe handling****Handling advice**

Avoid contact with skin, eyes and clothing. Avoid ingestion and inhalation. Avoid prolonged or repeated exposure. Remove contaminated clothing and wash before reuse. Wash thoroughly after handling.

7.2 Conditions for safe storage, including any incompatibilities**Storage temperature**

store at <-15°C

Storage condition

close container well

Storage Requirements

Warm to Room Temperature before use. Keep away from incompatible substances. Keep container tightly closed when not in use.

7.3 Specific end use(s)

8 Exposure controls/personal protection**8.1 Exposure limit values**

Does not contain any substances with occupational exposure limits.

8.2 Exposure controls**Industrial Hygiene**

Mechanical exhaust required. Safety shower and eye shower.

8.3 Personal Protective Equipment**Respiratory Protection**

Wear NIOSH/MSHA or European Standard EN 149 approved respirator.

Hand Protection

Wear compatible chemical-resistant gloves to prevent skin exposure.

Eye Protection

Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA.

Body Protection

Wear compatible chemical-resistant gloves and clothing to prevent skin exposure.

Advice on Safe Handling

Wash contaminated clothing before reuse. Wear appropriate protective clothing to prevent exposure.

9 Physical and chemical properties

9.1 Information on basic Physical and chemical color properties

Color
white

Form
powder

Phase Transition Solid/Liquid
205 °C

9.2 Other information

Molar Mass
482.82 g/mol

10 Stability and reactivity**10.1 Reactivity**

No Data Available

10.2 Chemical stability

No Data Available

10.3 Possibility of hazardous reaction

No Data Available

10.4 Conditions to Avoid (SDS)

incompatible materials

10.5 Incompatible materials

strong oxidizers

10.6 Hazardous decomposition products

nitrogen oxides (NOx), carbon dioxide (CO2), hydrogen chloride (HCl), hydrogen fluoride, carbon monoxide

11 Toxicological information**11.1 Information on toxicological effects****Assessment Toxicity to Reproduction**

May cause reproductive effects based upon animal studies.

Other Relevant Toxicity Information

Only selected Registry of toxic effects of chemical substances (RTECS) data is presented here. For the complete information, consult current entry in RTECS.

12 Ecological Information**12.1 Toxicity**

Acute toxicity versus Fishing	Test Type	Species	Method	Exposure Time	Value in standard unit mg/l
	No data available	No data available	No data available	No data available	No data available
Acute toxicity in aquatic plants	Test Type	Species	Method	Exposure Time	Value in standard unit mg/l
	No data available	No data available	No data available	No data available	No data available
Acute toxicity versus Daphnia and others aquatic invertebrates	Test Type	Species	Method	Exposure Time	Value in standard unit mg/l
	No data available	No data available	No data available	No data available	No data available

12.2 Persistence and degradability

Remarks : no data available

12.3 Bioaccumulative potential

Remarks : no data available

12.4 Mobility in soil

no data available

12.5 Results of PBT and vPvB assessment

no data available

12.6 Other adverse effects

Memo : Very toxic to aquatic life.

13 Disposal considerations**Advice on Disposal and Packaging***Advice on Disposal*

Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and Exhaust air. Dispose of waste according to laws applicable.

Advice on Packaging

not available

14 Transport information

	Road Transport(ADR/GGVS)	Air Transport(IATA)
14.1 UN number	3077	3077
14.2 UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Regorafenib)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Regorafenib)
14.3 Transport hazard class(es)	9	9
14.4 Packing group	III	III
14.5 Environmental hazard class(es)	Hazards identified	Hazards identified
14.6 Special precautions for user	Not applicable	Not applicable
14.7 Transport in bulk according to Annex 11 of MARPOL and the IBC code	Not applicable	Not applicable

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

Component	REACH (1907/2006) - Annex XIV - Substances Subject to Authorization	REACH (1907/2006) - Annex XVII - Restrictions on Certain Dangerous Substances	REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC)
Regorafenib	-----	-----	-----

Regulatory List
EINECS

15.2 Chemical safety assessment

No chemical safety assessment has been carried out.

16 Additional information

BIOSYNTH & CARBOSYNTH provides this MSDS in good faith. No representation is made as to the accuracy or comprehensiveness of the data and BIOSYNTH & CARBOSYNTH shall not be liable for any errors in the data. No representation is made as to the fitness of the data or of the materials for any particular use. No representation or warranty is made as to damages or injury. User assumes all responsibility for compliance with all laws and regulations implicated by use of this material.