

SAFETY DATA SHEET

Creation Date 05-March-2020 Revision Date 24-December-2021 **Revision Number** 3

1. Identification

Product Name Ibrutinib

AC466800000; AC466800010; AC466802500 Cat No.:

CAS-No 936563-96-1

Synonyms No information available

Recommended Use Laboratory chemicals.

Food, drug, pesticide or biocidal product use. Uses advised against

Details of the supplier of the safety data sheet

Company

Manufacturer Importer/Distributor

Acros Organics Fisher Scientific Company Fisher Scientific One Reagent Lane 112 Colonnade Road. One Reagent Lane Fair Lawn, NJ 07410 Fair Lawn, NJ 07410 Ottawa, ON K2E 7L6, Tel: (201) 796-7100

Canada

Tel: 1-800-234-7437

Emergency Telephone Number CHEMTREC®, Inside the USA: 800-424-9300

CHEMTREC®, Outside the USA: 001-703-527-3887

For information **US** call: 001-800-ACROS-01 / **Europe** call: +32 14 57 52 11 Emergency Number US:001-201-796-7100 / Europe: +32 14 57 52 99 CHEMTREC Tel. No.US:001-800-424-9300 / Europe:001-703-527-3887

2. Hazard(s) identification

Classification

WHMIS 2015 Classification Classified as hazardous under the Hazardous Products Regulations (SOR/2015-17)

Reproductive Toxicity Category 1B Specific target organ toxicity - (repeated exposure) Category 2

Label Elements

Signal Word

Danger

Hazard Statements

May damage fertility or the unborn child

May cause damage to organs through prolonged or repeated exposure



Precautionary Statements

Prevention

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

Do not breathe dust/fumes/gas/mist/vapours/spray

Wear protective gloves/protective clothing/eye protection/face protection

Response

IF exposed or concerned: Get medical advice/attention

Storage

Store locked up

Disposal

Dispose of contents/container to an approved waste disposal plant

3. Composition/Information on Ingredients

Component	CAS-No	Weight %		
Ibrutinib	936563-96-1	<=100		

4. First-aid measures

General Advice If symptoms persist, call a physician.

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get

medical attention.

Skin Contact Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists,

call a physician.

Inhalation Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if

symptoms occur.

Ingestion Clean mouth with water and drink afterwards plenty of water. Get medical attention if

symptoms occur.

Most important symptoms/effects

Notes to Physician

None reasonably foreseeable.

Treat symptomatically

Fire-fighting measures

surrounding environment. Dry chemical, CO₂, water spray or alcohol-resistant foam.

Unsuitable Extinguishing Media No information available

Flash Point No information available Method - No information available

Autoignition Temperature No information available

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Explosion Limits

No data available Upper Lower No data available Sensitivity to Mechanical Impact No information available Sensitivity to Static Discharge No information available

Specific Hazards Arising from the Chemical

Keep product and empty container away from heat and sources of ignition.

Hazardous Combustion Products

Carbon oxides. Nitrogen oxides (NOx).

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

NFPA

Health	Flammability	Instability	Physical hazards
2	1	0	N/A

Accidental release measures

Personal Precautions Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust

formation.

Environmental Precautions Should not be released into the environment.

Methods for Containment and Clean Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed

containers for disposal. Up

	7. Handling and storage
Handling	Wear personal protective equipment/face protection. Ensure adequate ventilation. Do not
	get in eyes, on skin, or on clothing. Avoid ingestion and inhalation. Avoid dust formation.

Keep container tightly closed in a dry and well-ventilated place. To maintain product quality, Storage.

Store in freezer. Incompatible Materials. Oxidizing agent.

8. Exposure controls / personal protection

Exposure Guidelines

This product does not contain any hazardous materials with occupational exposure limitsestablished by the region specific regulatory bodies.

Engineering Measures

Ensure that eyewash stations and safety showers are close to the workstation location.

Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source

Personal protective equipment

Eye Protection Goggles

Hand Protection Wear appropriate protective gloves and clothing to prevent skin exposure.

Glove material	Breakthrough time	Glove thickness	Glove comments
Nitrile rubber	See manufacturers	-	Splash protection only
Neoprene	recommendations		
Natural rubber			
PVC			

Inspect gloves before use, observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information) gloves are suitable for the task: Chemical compatability,

Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, gloves with care avoiding skin contamination.

Respiratory Protection

When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained properly Recommended Filter type: Particulates filter conforming to EN 143

When RPE is used a face piece Fit Test should be conducted

Environmental exposure controls

No information available.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Wash hands before breaks and after work.

Physical and chemical properties

Solid Powder **Physical State**

White **Appearance** Odor

No information available No information available **Odor Threshold** No information available Ha Melting Point/Range No data available

Boiling Point/Range No information available **Flash Point** No information available **Evaporation Rate** Not applicable

Flammability (solid,gas) No information available

Flammability or explosive limits

Upper No data available No data available Lower No information available **Vapor Pressure** Not applicable **Vapor Density**

No information available **Specific Gravity** Solubility No information available Partition coefficient; n-octanol/water No data available **Autoignition Temperature** No information available **Decomposition Temperature** No information available

Viscosity Not applicable Molecular Formula C25 H24 N6 O2

440.5 **Molecular Weight**

10. Stability and reactivity

None known, based on information available **Reactive Hazard**

Stability Stable under normal conditions.

Conditions to Avoid Incompatible products.

Incompatible Materials Oxidizing agent

Hazardous Decomposition Products Carbon oxides, Nitrogen oxides (NOx)

Hazardous Polymerization Hazardous polymerization does not occur.

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Hazardous Reactions None under normal processing.

11. Toxicological information

Acute Toxicity

Product Information Component Information

Toxicologically Synergistic No information available

Products

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Irritation No information available

Sensitization No information available

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen.

Component	CAS-No	IARC	NTP	ACGIH	OSHA	Mexico
Ibrutinib	936563-96-1	Not listed				

Mutagenic Effects No information available

Reproductive Effects No information available.

Developmental Effects No information available.

No information available. **Teratogenicity**

STOT - single exposure None known STOT - repeated exposure None known

No information available **Aspiration hazard**

Symptoms / effects,both acute and No information available

delayed

Endocrine Disruptor Information No information available

Other Adverse Effects The toxicological properties have not been fully investigated.

12. Ecological information

Ecotoxicity

Do not empty into drains.

Persistence and Degradability No information available

Bioaccumulation/ Accumulation No information available.

No information available. Mobility

13. Disposal considerations

Waste Disposal Methods Chemical waste generators must determine whether a discarded chemical is classified as a

hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

14. Transport information

Not regulated DOT TDG Not regulated Not regulated **IATA**

IMDG/IMO Not regulated

15. Regulatory information

International Inventories

Component	CAS-No	DSL	NDSL	TSCA	TSCA Inventory notification - Active-Inactive	EINECS	ELINCS	NLP
Ibrutinib	936563-96-1	-	-	-	-	-	-	-

Component	CAS-No	IECSC	KECL	ENCS	ISHL	TCSI	AICS	NZIoC	PICCS
Ibrutinib	936563-96-1	-	-	-	-	-	-	-	-

Legend:

X - Listed '-' - Not Listed

KECL - NIER number or KE number (http://ncis.nier.go.kr/en/main.do)

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

IECSC - Chinese Inventory of Existing Chemical Substances **KECL** - Korean Existing and Evaluated Chemical Substances

ENCS - Japanese Existing and New Chemical Substances

AICS - Australian Inventory of Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

Canada

SDS in compliance with provisions of information as set out in Canadian Standard - Part 4, Schedule 1 and 2 of the Hazardous Products Regulations (HPR) and meets the requirements of the HPR (Paragraph 13(1)(a) of the Hazardous Products Act (HPA)).

Other International Regulations

Authorisation/Restrictions according to EU REACH

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

Component	CAS-No	OECD HPV	Persistent Organic Pollutant	Potential	Hazardous Substances (RoHS)
Ibrutinib	936563-96-1	Not applicable	Not applicable	Not applicable	Not applicable
Component	CAS-No	Seveso III Directive (2012/18/EC) - Qualifying Quantities	Seveso III Directive (2012/18/EC) -	Rotterdam Convention (PIC)	Basel Convention (Hazardous Waste)

	Component	CAS-No	Seveso III Directive (2012/18/EC) -	Seveso III Directive (2012/18/EC) -	Rotterdam Convention (PIC)	Basel Convention (Hazardous Waste)
			Qualifying Quantities	((Hazaraeae Hacto)
-			for Major Accident for Safety Report			
			Notification	Requirements		
	Ibrutinib	936563-96-1	Not applicable	Not applicable	Not applicable	Not applicable

16. Other information

Prepared By Regulatory Affairs

Thermo Fisher Scientific

Email: EMSDS.RA@thermofisher.com

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This document has been updated to comply with the requirements of WHMIS 2015 to align **Revision Summary**

Revision Date 24-December-2021

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with the Globally Harmonised System (GHS) for the Classification and Labelling of Chemicals.

Disclaimer

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. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. 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

End of SDS