

SAFETY DATA SHEET



Version 3.2	Revision Date: 2025/02/28	SDS Number: 100000018617	Date of last issue: 2025/02/24 Date of first issue: 2023/10/26
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SECTION 1. IDENTIFICATION

Substance name : LAZCLUZE FILM COATED TABLET 80 mg
Lazertinib Mesylate Hydrate
JNJ-73841937 80mg FCT G004

Manufacturer or supplier's details

Company name of supplier : Janssen Pharmaceuticals, Inc.

Address : 1125 Trenton-Harbourton Rd
Titusville NJ 08560

USA

Telephone : +16097302000

E-mail address of person responsible for the SDS : SDSJanssen@its.jnj.com

Emergency telephone number : **CHEMTREC US: 1-800-424-9300**
CHEMTREC International: +1 703-741-5970

Recommended use of the chemical and restrictions on use

Recommended use : Finished Pharmaceutical Product
Pharmacotherapeutic group: Cytostatics
This SDS is only intended for occupational use and not for consumer use (see patient packaging insert for consumer use). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished pharmaceutical product. For health and safety information during manufacturing of this product we refer to the appropriate SDS for each component.
This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Skin sensitisation : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity : Category 1
- repeated exposure

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GHS label elements

Hazard pictograms

:



Signal word

:

Danger

Hazard statements

:

H317 May cause an allergic skin reaction.
H361 Suspected of damaging fertility or the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.

Precautionary statements

:

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P363 Wash contaminated clothing before reuse.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture

:

Mixture

Chemical nature

:

Solid

Components

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Chemical name	CAS-No.	Concentration (% w/w)
microcrystalline cellulose	9004-34-6	$\geq 50 - < 70$
Lazertinib Mesylate Hydrate	2411549-88-5	$\geq 20 - < 30$
Octadecanoic acid, magnesium salt	557-04-0	$\geq 0.1 - < 1$
TITANDIOXIDE	13463-67-7	$\geq 0.1 - < 1$
acetic acid	64-19-7	< 0.1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

- If inhaled : Health injuries are not known or expected under normal use.
If breathed in, move person into fresh air.
Consult a physician.
- In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off immediately with plenty of water.
If symptoms persist, call a physician.
Wash contaminated clothing before reuse.
- In case of eye contact : Rinse immediately with plenty of water, also under the eyelids,
for at least 5 minutes.
Remove contact lenses.
If eye irritation persists, consult a specialist.
- If swallowed : If swallowed, rinse mouth with water (only if the person is
conscious).
Call a physician immediately.
- Most important symptoms and effects, both acute and delayed : Rash
infected skin around the nail
Dries out the skin.
Itching
sore throat
constipation
Diarrhoea
Nausea
Vomiting
Tiredness
vein blocked by a blood clot
tingling
numbness
decrease in appetite
changes in certain blood tests
muscle cramps
Fever
May cause an allergic skin reaction.
Suspected of damaging fertility or the unborn child.
Causes damage to organs through prolonged or repeated exposure.
- Notes to physician : Treat symptomatically.

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SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Hazardous combustion products : No information available.
- Further information : No information available.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate. Evacuate personnel to safe areas.
- Environmental precautions : Should not be released into the environment. Do not flush into surface water or sanitary sewer system.
- Methods and materials for containment and cleaning up : Small spills: Moisten a towel, cover the spill, pick up the spill or use HEPA vacuum.
Large spills: Sweep up or vacuum with HEPA filter or via wet cleaning into suitable containers for disposal.
Pick up and arrange without creating dust. Keep in properly labelled containers.
Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : No data available
- Advice on safe handling : Do not break, crush or spill this Finished Pharmaceutical Product.
To avoid thermal decomposition, do not overheat.
Use personal protective equipment as required.
Avoid inhalation, ingestion and contact with skin and eyes.
- Conditions for safe storage : To maintain product quality, do not store in heat or direct sunlight.
Store in original container.
Keep containers tightly closed in a cool, well-ventilated place.
Keep away from heat and sources of ignition.
Store at room temperature.

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Recommended storage temperature : 59 - 86 °F / 15 - 30 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
microcrystalline cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0
Lazertinib Mesylate Hydrate	2411549-88-5	STV	0,100 mg/100cm ²	J&J OEL/PBOEL HHC
		TWA	0.0046 mg/m3	J&J OEL/PBOEL HHC
		PBOEL-HHC	3 B	J&J OEL/PBOEL HHC
Further information: J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 3B., Notation REPRO: has the potential to have adverse effects on reproduction and fetal development, Notation DSEN: has the potential to cause delayed allergic skin reaction (sensitization), such as wheals and rashes				
Octadecanoic acid, magnesium salt	557-04-0	TWA (Inhalable particulate matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH
TITANDIOXIDE	13463-67-7	TWA	2.4 mg/m3	J&J OEL/PBOEL

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				HHC
		TWA	10 mg/m3	ACGIH
acetic acid	64-19-7	TWA	10 ppm	ACGIH
		STEL	15 ppm	ACGIH
		TWA	10 ppm 25 mg/m3	NIOSH REL
		ST	15 ppm 37 mg/m3	NIOSH REL
		TWA	10 ppm 25 mg/m3	OSHA Z-1
		TWA	10 ppm 25 mg/m3	OSHA P0

Engineering measures : All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.
If this product is processed not in accordance with the prescribed use, contact the Industrial Hygiene / Environment Health Safety Expert to assess the situation.
Validated Industrial Hygiene Analytical methods are developed to monitor and quantify inhalable exposure to the Active Pharmaceutical Ingredient. For more information contact Bureau Veritas Laboratories - Lake Zurich (BV_LZLab@bureauveritas.com) or the Laboratory of Occupational and Environmental Hygiene (lamh.be).

Personal protective equipment

Respiratory protection : No information available.

Eye protection : No special precautions required.

Skin and body protection : closed work clothing

Protective measures : The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Consult a Environmental Health and Safety expert if necessary.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Coated, tablet

Colour : yellow

Odour : No data available

pH : No data available

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Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flash point	: No data available
Self-ignition	: No data available
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available
Density	: No data available
Solubility(ies)	
<u>Solubility in other solvents</u>	: No data available
Partition coefficient: n-octanol/water	: No data available
Decomposition temperature	: No data available
Viscosity	
<u>Viscosity, kinematic</u>	: No data available
Particle size	: No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: None reasonably foreseeable.
Chemical stability	: Stable under recommended storage conditions.
Possibility of hazardous reactions	: No dangerous reaction known under conditions of normal use.
Conditions to avoid	: To avoid thermal decomposition, do not overheat. Heat, flames and sparks.
Incompatible materials	: None known.
Hazardous decomposition products	: None known.

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SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity : Acute toxicity estimate: 2,028 mg/kg
Method: Calculation method

Components:

Lazertinib Mesylate Hydrate:

Acute oral toxicity : LD50 (Rat): 600 - 2,000 mg/kg
Method: Acute oral toxicity

acetic acid:

Acute oral toxicity : LD50 (Rat): 3,310 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 44 mg/l
Exposure time: 4 h
Test atmosphere: vapour

Skin corrosion/irritation

Components:

acetic acid:

Result : Causes severe burns.

Serious eye damage/eye irritation

Components:

acetic acid:

Result : Corrosive to eyes

Respiratory or skin sensitisation

Components:

Lazertinib Mesylate Hydrate:

Species : Mouse
Method : Local Lymph Node Assay (LLNA) in mice
Result : May cause sensitisation by skin contact.

Germ cell mutagenicity

Components:

Lazertinib Mesylate Hydrate:

Genotoxicity in vitro : Test Type: Ames test

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Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Rat
Dose: 2000 mg/kg/day
Result: negative

Germ cell mutagenicity - Assessment : In vitro tests did not show mutagenic effects, In vivo tests did not show mutagenic effects

acetic acid:

Germ cell mutagenicity - Assessment : Not mutagenic in Ames Test

Carcinogenicity

IARC No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Components:

Lazertinib Mesylate Hydrate:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Dose: 30 mg/kg
Symptoms: Reduced embryonic survival

Effects on foetal development : Test Type: Fertility/early embryonic development
Species: Rat
Dose: 60 mg/kg body weight
Symptoms: Reduced body weight, Reduced number of viable fetuses

Test Type: Fertility/early embryonic development
Species: Rabbit
Dose: 45 mg/kg body weight
Symptoms: Reduced body weight, Reduced number of viable fetuses

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments.

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STOT - single exposure

No data available

STOT - repeated exposure**Components:****Lazertinib Mesylate Hydrate:**

Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Components:****Lazertinib Mesylate Hydrate:**

Species : Rat, male and female
NOAEL : 25 mg/kg
LOAEL : 50 mg/kg
Application Route : Oral
Exposure time : 4 weeks
Number of exposures : daily
Dose : 0,25,50,100/75 mg/kg/day

Species : Rat, male and female
NOAEL : 25 mg/kg
LOAEL : 50 mg/kg
Application Route : Oral
Exposure time : 13 weeks
Number of exposures : daily
Dose : 0,12.5,25,50 mg/kg/day

Species : Dog, male and female
LOAEL : 5 mg/kg
Application Route : Oral
Exposure time : 4 weeks
Number of exposures : daily
Dose : 0,5,10,20 mg/kg/day

Species : Dog, male
NOAEL : 4 mg/kg
Application Route : Oral
Exposure time : 13 weeks
Number of exposures : daily
Dose : 0,2,4,8 mg/kg/day

Species : Dog, female
LOAEL : 8 mg/kg
Application Route : Oral
Exposure time : 13 weeks
Number of exposures : daily
Dose : 0,2,4,8 mg/kg/day

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Aspiration toxicity

No data available

Experience with human exposure

No data available

Toxicology, Metabolism, Distribution

No data available

Neurological effects

No data available

Further information

No data available

Other health hazards

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Lazertinib Mesylate Hydrate:

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae/aquatic plants : Remarks: No data available

acetic acid:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 47 mg/l
Exposure time: 24 h

Persistence and degradability

Components:

Lazertinib Mesylate Hydrate:

Biodegradability : Remarks: No data available

Bioaccumulative potential

Components:

Lazertinib Mesylate Hydrate:

Bioaccumulation : Remarks: No data available

Partition coefficient: n- : Remarks: No data available

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octanol/water

Octadecanoic acid, magnesium salt:

Partition coefficient: n-octanol/water : Remarks: No data available

TITANDIOXIDE:

Partition coefficient: n-octanol/water : Remarks: No data available

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : In accordance with National, Federal, State and Local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

49 CFR

Not regulated as a dangerous good

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SECTION 15. REGULATORY INFORMATION

US State Regulations

Massachusetts Right To Know

microcrystalline cellulose 9004-34-6

Pennsylvania Right To Know

microcrystalline cellulose 9004-34-6
Lazertinib Mesylate Hydrate 2411549-88-5
D-Mannitol 69-65-8
acetic acid 64-19-7

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

New York City Hazardous Substances

acetic acid 64-19-7

California Permissible Exposure Limits for Chemical Contaminants

microcrystalline cellulose 9004-34-6

Other regulations

Restricted to professional users.

Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

This product is not subject to TSCA and TSCA 12(b) Export notification because Food, Drugs and cosmetic products are exempt.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH	:	US. ACGIH Threshold Limit Values
ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
J&J OEL/PBOEL HHC	:	J&J OEL/PBOEL HHC
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA P0	:	USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1
		Limits for Air Contaminants
ACGIH / TWA	:	Time weighted average
ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
J&J OEL/PBOEL HHC / STV	:	STV: Surface Target Value

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J&J OEL/PBOEL HHC / TWA : Time weighted average
J&J OEL/PBOEL HHC / : PBOEL-HHC
PBOEL-HHC
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour
workday during a 40-hour workweek
NIOSH REL / ST : STEL - 15-minute TWA exposure that should not be exceeded
at any time during a workday
OSHA P0 / TWA : 8-hour time weighted average
OSHA Z-1 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

For research use only.

Revision Date : 2025/02/28

Date and Number Formats

This document uses the following notation for printing dates and numbers:

Date: Dec 31th, 2012 as 2012/12/31

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Numbers: 123456,78 as 123,456.78

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