Version	Revision Date:	SDS Number:	Date of last issue: 2025/09/10
9.1	2025/09/11	100000014423	Date of first issue: 2018/11/14

SECTION 1. IDENTIFICATION

Substance name : BALVERSA 5 mg FC tablets
erdafitinib

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)

Eye irritation : Category 2A

Skin sensitisation : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - repeated exposure (Oral) : Category 1 (cartilage, eye - retina, vascular system, Mammary gland, lacrimal gland, glandular stomach)

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H361 Suspected of damaging fertility or the unborn child.
H372 Causes damage to organs (cartilage, eye - retina, vascular system, Mammary gland, lacrimal gland, glandular stomach) through prolonged or repeated exposure if swallowed.

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.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: 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

Chemical name	CAS-No.	Concentration (% w/w)
microcrystalline cellulose	9004-34-6	>= 50 - < 70
ERDAFITINIB	1346242-81-6	>= 1 - < 5
Octadecanoic acid, magnesium salt	557-04-0	>= 1 - < 5
titandioxide	13463-67-7	>= 1 - < 5

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 with soap and water.
If symptoms persist, call a physician.

In case of eye contact : Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
Remove contact lenses.
Consult a physician.

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 : No information available.

Notes to physician : Treat symptomatically.

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	:	Avoid dust formation. Avoid breathing dust. Evacuate personnel to safe areas. 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.
Environmental precautions	:	Should not be released into the environment.
Methods and materials for containment and cleaning up	:	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. Small spills: Moisten a towel, cover the spill, pick up the spill or use HEPA vacuum. 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	:	To avoid thermal decomposition, do not overheat. Use personal protective equipment as required. Keep away from heat and sources of ignition. Avoid inhalation, ingestion and contact with skin and eyes. Do not break, crush or spill this Finished Pharmaceutical Product.
Conditions for safe storage	:	Keep containers tightly closed in a cool, well-ventilated place. Keep away from heat and sources of ignition. Store in original container. To maintain product quality, do not store in heat or direct sunlight.
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	Control	Basis

		(Form of exposure)	parameters / Permissible concentration	
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
ERDAFITINIB	1346242-81-6	TWA	0.0051 mg/m3	J&J OEL/PBOEL HHC
		STV	0,010 mg/100cm²	J&J OEL/PBOEL HHC
		PBOEL-HHC	3 A	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 3A., 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 HHC
		TWA	10 mg/m3	ACGIH

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 personal respiratory protective equipment normally required.
Hand protection		
Remarks	:	Disposable gloves
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	:	brown
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	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
Relative density	:	No data available
Density	:	No data available

Solubility(ies)

Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available

Viscosity

Viscosity, kinematic	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	None reasonably foreseeable.
Chemical stability	:	Stable under normal 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.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method

Components:

ERDAFITINIB:

Acute oral toxicity : LD50 (Rat, male): > 1,000 mg/kg
Method: Acute oral toxicity
GLP: no

LD50 (Dog, male and female): > 45 mg/kg
Method: Acute oral toxicity
GLP: no

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation

Components:

ERDAFITINIB:

Remarks : No data available

Serious eye damage/eye irritation

Components:

ERDAFITINIB:

Result : Corrosive to eyes
Method : In vitro BCOP (Bovine Corneal Opacity and Permeability) assay (OECD 437)
GLP : no

Respiratory or skin sensitisation

Components:

ERDAFITINIB:

Species : Mouse
Method : Local Lymph Node Assay (LLNA) in mice (OECD 429)
Result : The product is a skin sensitiser, sub-category 1B.
GLP : yes

Germ cell mutagenicity

Components:

ERDAFITINIB:

Genotoxicity in vitro : Method: Bacterial Reverse Mutation Test OECD 471
Result: negative
GLP: yes

Test system: human lymphoblastoid cells

Method: In Vitro Mammalian Cell Micronucleus Test OECD 487
Result: negative
GLP: yes

Genotoxicity in vivo : Species: Rat
Method: In vivo Mammalian Erythrocyte Micronucleus Test OECD 474
Result: negative
GLP: yes

Germ cell mutagenicity - Assessment : No evidence of mutagenicity based on in vitro and in vivo studies and expert judgment.

Carcinogenicity

Components:

ERDAFITINIB:

Remarks : No data available

Carcinogenicity - Assessment : No information available.

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:

ERDAFITINIB:

Effects on fertility : Remarks: May result in reproductive system adverse effects based on therapeutic class.

Effects on foetal development : Species: Rat, female
Application Route: Oral
Dose: 0, 1, 4, 8 mg/kg body weight
General Toxicity Maternal: NOAEL: 4 mg/kg body weight
Teratogenicity: NOAEL: 1 mg/kg body weight
Developmental Toxicity: NOAEL: 1 mg/kg body weight
Embryo-foetal toxicity: NOAEL: 1 mg/kg body weight
Method: OECD Test Guideline 414
GLP: yes

Reproductive toxicity - Assessment : No information available.

Teratogenicity - Assessment : Limited evidence of adverse effects on development in animal studies and/ or human studies.

STOT - single exposure

Components:

ERDAFITINIB:

Remarks : No data available

STOT - repeated exposure

Components:

ERDAFITINIB:

Exposure routes : Oral
Target Organs : cartilage, eye - retina, vascular system, Mammary gland, lacrimal gland, glandular stomach
Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

ERDAFITINIB:

Species : Rat, male and female
NOAEL : 4 mg/kg
Application Route : Oral
Exposure time : 1 month
Number of exposures : daily
Dose : 4 - 8 - 16 mg/kg
Subsequent observation period : 1 month
GLP : yes

Species : Dog, male and female
NOAEL : 0.5 mg/kg
Application Route : Oral
Exposure time : 1 month
Number of exposures : daily
Dose : 0,25 - 0,5 - 1 mg/kg
Subsequent observation period : 1 month
GLP : yes

Species : Rat, male
NOAEL : 4 mg/kg
Application Route : Oral
Exposure time : 3 months
Number of exposures : daily

Dose	:	4 - 8 mg/kg
GLP	:	yes

Species	:	Rat, female
NOAEL	:	< 4 mg/kg
Application Route	:	Oral
Exposure time	:	3 months
Number of exposures	:	daily
Dose	:	4 - 8 mg/kg
GLP	:	yes

Species	:	Dog, male and female
NOAEL	:	< 0.5 mg/kg
Application Route	:	Oral
Exposure time	:	3 months
Number of exposures	:	daily
Dose	:	0,5 - 0,75 mg/kg
GLP	:	yes

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

Components:

ERDAFITINIB:

Test Type	:	in vitro assay
Remarks	:	Evidence of phototoxicity was observed
Test Type	:	in vivo assay
Remarks	:	No evidence of phototoxicity was observed

Other health hazards

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

ERDAFITINIB:

Toxicity to fish : Remarks: No data available

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

Persistence and degradability

Components:

ERDAFITINIB:

Biodegradability : Remarks: No data available

Bioaccumulative potential

Components:

ERDAFITINIB:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : log Pow: 4.39
pH: 12

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

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
D-Mannitol	69-65-8

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

California Permissible Exposure Limits for Chemical Contaminants

microcrystalline cellulose	9004-34-6
Octadecanoic acid, magnesium salt	557-04-0

Other regulations
Restricted to professional users.

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
J&J OEL/PBOEL HHC / STV	:	STV: Surface Target Value
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
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

Revision Date : 2025/09/11

Date and Number Formats

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

Date:	Dec 31th, 2012	as	2012/12/31
Numbers:	123456,78	as	123,456.78

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.

US / EN