



SAFETY DATA SHEET

100-1650 - Enzalutamide

Revision Date 20-Feb-2024

Revision Number 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name Enzalutamide

Other means of identification

Catalog Number 100-1650

UN/ID no. 3077

Document Number 10000027383

Synonym ASP-9785, MDV3100
4-(3-(4-Cyano-3-(trifluoromethyl)phenyl)-5,5-dimethyl-4-oxo-2-thioxoimidazolidin-1-yl)-2-fluoro-N-methylbenzamide

Recommended use of the chemical and restrictions on use

Recommended Use Laboratory chemical

Details of the supplier of the safety data sheet

Manufacturer/Supplier

STEMCELL Technologies Canada Inc.
Suite 500 - 1618 Station Street
Vancouver, British Columbia V6A 1B6 Canada

Emergency telephone number

Emergency Telephone 1-800-667-0322

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity - Oral	Category 4
Reproductive toxicity	Category 1B
Specific target organ toxicity (repeated exposure)	Category 2

Hazards not otherwise classified (HNOC)

Not applicable



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Label elements

Danger

Hazard statements

Harmful if swallowed

May damage fertility or the unborn child

May cause damage to organs through prolonged or repeated exposure



Appearance Powder

Physical state Solid

Odor No data available

Precautionary Statements - Prevention

Obtain special instructions before use

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

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

Wash face, hands and any exposed skin thoroughly after handling

Do not eat, drink or smoke when using this product

Do not breathe dust/fume/gas/mist/vapors/spray

Precautionary statements - Response

IF exposed or concerned: Get medical advice/attention

IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell

Rinse mouth

Precautionary Statements - Storage

Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other Information

Toxic to aquatic life with long lasting effects

Toxic to aquatic life

Unknown acute toxicity

0 % of the mixture consists of ingredient(s) of unknown toxicity

0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

100 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)



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0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance

Synonym

ASP-9785, MDV3100.

4-(3-(4-Cyano-3-(trifluoromethyl)phenyl)-5,5-dimethyl-4-oxo-2-thioxoimidazolidin-1-yl)-2-fluoro-N-methylbenzamide.

Chemical name	CAS No.	Weight-%
4-[3-[4-cyano-3-(trifluoromethyl)phenyl]-5,5-dimethyl-4-oxo-2-sulfanylideneimidazolidin-1-yl]-2-fluoro-N-methylbenzamide	915087-33-1	100

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

Description of first aid measures

General advice

Show this safety data sheet to the doctor in attendance.

Inhalation

Remove to fresh air.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

Skin contact

Wash skin with soap and water.

Ingestion

Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.

Most important symptoms and effects, both acute and delayed

Symptoms

No information available.

Indication of any immediate medical attention and special treatment needed

Note to physicians

Treat symptomatically.

5. FIRE-FIGHTING MEASURES



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Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	CAUTION: Use of water spray when fighting fire may be inefficient.
Specific hazards arising from the chemical	No information available.
Explosion data	
Sensitivity to Mechanical Impact	None.
Sensitivity to Static Discharge	None.
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions	Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas.
Other Information	Refer to protective measures listed in Sections 7 and 8.

Environmental precautions

Environmental precautions	See Section 12 for additional Ecological Information.
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Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Pick up and transfer to properly labeled containers.
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling	Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Handle in accordance with good industrial hygiene and safety practice. Ensure adequate ventilation.
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Conditions for safe storage, including any incompatibilities

Storage Conditions Store in accordance with information listed on the Product Information Sheet (PIS).

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Limits The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection No special protective equipment required.

Hand protection Wear suitable gloves.

Skin and body protection Wear suitable protective clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state Solid
Appearance Powder
Color white
Odor No data available



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Odor threshold No data available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	No data available	None known
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability limit:	No data available	
Lower flammability limit:	No data available	
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Relative density	No data available	None known
Water solubility	No data available	None known
Solubility in other solvents	No data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Explosive properties	No data available	
Oxidizing properties	No information available	
<u>Other Information</u>		
Softening point	No information available	
Molecular weight	464.4	
Molecular formula	C21H16F4N4O2S	
VOC Content (%)	No information available	
Liquid Density	No information available	
Bulk density	No information available	

10. STABILITY AND REACTIVITY

Reactivity No information available.

Chemical stability Stable under recommended transport or storage conditions.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid None known based on information supplied.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition products Carbon dioxide (CO₂). Carbon monoxide. Hydrogen cyanide. Hydrogen fluoride. Hydrogen sulfide. Nitrogen oxides (NO_x).



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11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available. Harmful if swallowed. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	No information available.
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Numerical measures of toxicity

Acute toxicity

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral)	500.00 mg/kg
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Unknown acute toxicity	0 % of the mixture consists of ingredient(s) of unknown toxicity
	0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
	100 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity
	100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
	100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)
	0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

Product Information

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

Skin corrosion/irritation	No information available.
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Product Information

Serious eye damage/eye irritation	No information available.
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Product Information

Respiratory or skin sensitization	No information available.
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Product Information



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Germ cell mutagenicity No information available.

Product Information

Carcinogenicity No information available.

Reproductive toxicity Classification based on data available for ingredients.

Product Information

STOT - single exposure No information available.

Product Information

STOT - repeated exposure May cause damage to organs.

Product Information

Aspiration hazard No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity The environmental impact of this product has not been fully investigated.

Product Information

Persistence and degradability No information available.

Bioaccumulation There is no data for this product.

Other adverse effects No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

14. TRANSPORT INFORMATION

Note: When sold in quantities of less than or equal to 1 mL, or 1 g, with an Excepted Quantity



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Code of E1, E2, E4, or E5, this item meets the De Minimis Quantities exemption, per IATA 2.6.10. Therefore packaging does not have to be labeled as Dangerous Goods/Excepted Quantity.

DOT

UN/ID no. 3077
 Proper shipping name Environmentally hazardous substance, solid, n.o.s.(MDV 3100)
 Hazard class 9 Miscellaneous dangerous substances and articles
 Packing Group III

TDG

Not regulated

MEX

Not regulated

ICAO (air)

Not regulated

IATA

UN Number 3077
 UN proper shipping name Environmentally hazardous substance, solid, n.o.s.(MDV 3100)
 Transport hazard class(es) 9 Miscellaneous dangerous substances and articles
 Packing Group III

IMDG

UN Number 3077
 UN proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (MDV 3100)
 Transport hazard class(es) 9 Miscellaneous dangerous substances and articles
 Packing Group III

RID

Not regulated

ADR

Not regulated

ADN

Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA Does not comply
 DSL/NDL Does not comply
 EINECS/ELINCS Does not comply
 ENCS Does not comply
 IECSC Does not comply
 KECL Does not comply
 PICCS Does not comply
 AICS Does not comply

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
 DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List



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EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute health hazard	Yes
Chronic Health Hazard	Yes
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable



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16. OTHER INFORMATION, INCLUDING DATE OF PREPARATION OF THE LAST REVISION

Prepared By, Quality Control. STEMCELL Technologies Canada Inc.

Revision Date 20-Feb-2024

Revision Note No information available.

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. STEMCELL Technologies Inc. shall not be held liable for any damage resulting from handling or from contact with the product.

End of Safety Data Sheet