

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: XTANDI® (enzalutamide) Capsules

CAS No: 915087-33-1

Chemical Name of Active Ingredient: 4-{3-[4-Cyano-3-(trifluoromethyl)phenyl]-5,5-dimethyl-4-oxo-2-sulfanylideneimidazolidin-1-yl}-2-fluoro-N-methylbenzamide

Chemical Formula of Active Ingredient: C₂₁H₁₆F₄N₄O₂S

1.2. Intended Use of the Product

Use of the substance/mixture: Androgen receptor inhibitor indicated for the treatment of patients with cancer. For professional use only.

1.3. Name, Address, and Telephone of the Responsible Party

Company

Astellas US LLC

2375 Waterview Drive

Northbrook, IL 60062

Tel.: 800-888-7704

www.us.astellas.com

1.4. Emergency Telephone Number

Emergency Number : 800-727-7003 Medical Communications

SECTION 2: HAZARDS IDENTIFICATION

This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) It is in solid, final form for direct administration to the patient. Therefore, it is exempt from labeling, as defined in the 29 CFR 1910.1200(b)(5)(iii).

Potential to cause seizures, especially in those predisposed to seizure activity. The toxicological, physical and other potential hazards associated with this compound have not been fully characterized. Should avoid ingestion, inhalation, skin and eye contact.

Given anti-androgen effects of the compound, histopathological changes have been observed in endocrine and reproductive organs in rats and dogs. As teratogenicity was induced at a low dose level (10 mg/kg) in the embryo-fetal development study in mice, pregnant women and women suspected to be pregnant should avoid contact with this material.

ADI=300 µg/day

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) It is in solid, final form for direct administration to the patient. Therefore, it is exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(6)(vii).

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label if possible).

First-aid Measures After Inhalation: Remove to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Gently wash with plenty of soap and water. Obtain medical attention if irritation develops or persists.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if pain, blinking, or redness persist.

First-aid Measures After Ingestion: Do not induce vomiting. Rinse mouth. Immediately call a POISON CENTER or doctor/physician.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/Injuries: Pharmaceutical. When handling in workplace settings, in quantities that are most likely above the therapeutic dose, this product may be harmful if absorbed through the eyes, skin, or respiratory tract.

Symptoms/Injuries After Inhalation: Exposure to capsule contents: May cause respiratory irritation.

Symptoms/Injuries After Skin Contact: Exposure to capsule contents: May cause skin irritation.

Symptoms/Injuries After Eye Contact: Exposure to capsule contents: May cause eye irritation.

Symptoms/Injuries After Ingestion: Ingestion may cause nausea, vomiting and diarrhea.

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Chronic Symptoms: Potential to cause seizures, especially in those predisposed to seizure activity. May cause cancer. May damage fertility or the unborn child. May damage organs through prolonged or repeated exposure.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If you feel unwell, seek medical advice (show the label where possible).

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: Do not use carbon dioxide. Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Other Information: Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Use only as directed.

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions

Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

6.3. Methods and Material for Containment and Cleaning Up

For Containment: Contain and collect as any solid.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal. If a capsule is accidentally crushed, immediately wipe up using a wet cloth or paper towel and discard. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Heading 8. Exposure controls and personal protection. For further information refer to section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Avoid breaking or crushing capsules.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Store in a dry, cool and well-ventilated place. Keep container closed when not in use. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Products: Oxidizers.

Storage Temperature: 20 - 25 °C (68 °F - 77 °F). Excursions permitted from 15 °C - 30 °C (59 °F - 86 °F).

7.3. Specific End Use(s)

Androgen receptor inhibitor indicated for the treatment of patients with cancer. For professional use only.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), or OSHA (PEL).

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Enzalutamide (915087-33-1)		
Internally derived drug substance OEL:	Internal TWA (mg/m ³) for an 8-hour day	30 µg/m ³
2,6-Di-tert-butyl-p-cresol (128-37-0)		
USA ACGIH	ACGIH TWA (mg/m ³)	2 mg/m ³ (inhalable fraction and vapor)
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	10 mg/m ³
Glycerin (56-81-5)		
USA OSHA	OSHA PEL (TWA) (mg/m ³)	15 mg/m ³ (mist, total particulate) 5 mg/m ³ (mist, respirable fraction)
Titanium dioxide (13463-67-7)		
USA ACGIH	ACGIH TWA (mg/m ³)	10 mg/m ³
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA IDLH	US IDLH (mg/m ³)	5000 mg/m ³
USA OSHA	OSHA PEL (TWA) (mg/m ³)	15 mg/m ³ (total dust)
Ethyl alcohol (64-17-5)		
USA ACGIH	ACGIH STEL (ppm)	1000 ppm
USA ACGIH	ACGIH chemical category	Confirmed Animal Carcinogen with Unknown Relevance to Humans
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	1900 mg/m ³
USA NIOSH	NIOSH REL (TWA) (ppm)	1000 ppm
USA IDLH	US IDLH (ppm)	3300 ppm (10% LEL)
USA OSHA	OSHA PEL (TWA) (mg/m ³)	1900 mg/m ³
USA OSHA	OSHA PEL (TWA) (ppm)	1000 ppm
Isopropyl alcohol (67-63-0)		
USA ACGIH	ACGIH TWA (ppm)	200 ppm
USA ACGIH	ACGIH STEL (ppm)	400 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	980 mg/m ³
USA NIOSH	NIOSH REL (TWA) (ppm)	400 ppm
USA NIOSH	NIOSH REL (STEL) (mg/m ³)	1225 mg/m ³
USA NIOSH	NIOSH REL (STEL) (ppm)	500 ppm
USA IDLH	US IDLH (ppm)	2000 ppm (10% LEL)
USA OSHA	OSHA PEL (TWA) (mg/m ³)	980 mg/m ³
USA OSHA	OSHA PEL (TWA) (ppm)	400 ppm

8.2. Exposure Controls

Appropriate Engineering Controls

: Ensure adequate ventilation, especially in confined areas. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure all national/local regulations are observed.

Personal Protective Equipment

: Not generally required. The use of personal protective equipment may be necessary as conditions warrant.

Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear chemically resistant protective gloves.

Eye Protection

: Chemical goggles or safety glasses.

Skin and Body Protection

: Wear suitable protective clothing.

Respiratory Protection

: None required under normal product handling conditions.

Environmental Exposure Controls

: Do not allow the product to be released into the environment.

Consumer Exposure Controls

: Do not eat, drink or smoke during use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State

: Solid

Appearance

: **40 mg:** off-white, oblong soft gelatin capsule, imprinted in black ink with "ENZ"

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Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
Evaporation Rate	: No data available
Melting Point	: 201 °C (394 °F)
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20 °C	: No data available
Relative Density	: No data available
Solubility	: Practically insoluble in water, somewhat soluble in isopropanol (13 mg/mL) and acetonitrile (90 mg/mL)
Partition Coefficient: N-Octanol/Water	: 3.0 (was experimentally established for the ERA)
Viscosity	: No data available
Molecular Weight Of Active Ingredient	: 464.44 g/mol

9.2. Other Information No additional information available.

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. Chemical Stability:** Enzalutamide is stable if stored at 20°C - 25°C (68°F - 77°F).
- 10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. Conditions to Avoid:** Direct sunlight. Extremely high or low temperatures. Ignition sources. Incompatible materials.
- 10.5. Incompatible Materials:** Oxidizers.
- 10.6. Hazardous Decomposition Products:** Carbon oxides (CO, CO₂). Nitrogen oxides. Sulfur dioxide. Fluorine compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

Enzalutamide (915087-33-1)	
Lethal Dose Oral Mouse	400 mg/kg
Butylated hydroxyanisole (25013-16-5)	
LD50 Oral Rat	2 g/kg
2,6-Di-tert-butyl-p-cresol (128-37-0)	
LD50 Oral Rat	> 2930 mg/kg (Species: Sprague-Dawley)
LD50 Dermal Rat	> 2000 mg/kg
D-Glucitol (50-70-4)	
LD50 Oral Rat	15.9 g/kg
Glycerin (56-81-5)	
LD50 Oral Rat	23000 mg/kg
LD50 Dermal Rabbit	> 10 g/kg
LC50 Inhalation Rat	> 570 mg/m ³ (Exposure time: 1 h)
Titanium dioxide (13463-67-7)	
LD50 Oral Rat	> 10000 mg/kg
Ethyl alcohol (64-17-5)	
LD50 Oral Rat	10470 mg/kg
LD50 Dermal Rat	20 ml/kg
LC50 Inhalation Rat	124.7 mg/l/4h
1,2-Propylene glycol (57-55-6)	
LD50 Oral Rat	20 g/kg
LD50 Dermal Rabbit	20800 mg/kg

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Isopropyl alcohol (67-63-0)	
LD50 Oral Rat	4710 mg/kg
LD50 Dermal Rabbit	4059 mg/kg
LC50 Inhalation Rat	72.6 mg/l/4h (Exposure time: 4 h)
Polyethylene glycol (25322-68-3)	
LD50 Oral Rat	47000 mg/kg
LD50 Dermal Rabbit	> 20 ml/kg
Ammonium hydroxide (1336-21-6)	
LD50 Oral Rat	350 mg/kg
Skin Corrosion/Irritation: Not classified	
Enzalutamide (915087-33-1)	
Additional information	Negative phototoxicity in vitro.
Serious Eye Damage/Irritation: Not classified	
Respiratory or Skin Sensitization: Not classified	
Germ Cell Mutagenicity: Not classified	
Enzalutamide (915087-33-1)	
Additional information	Enzalutamide was negative in the in vitro Ames Bacterial Reverse Mutation Assay and the Mouse Lymphoma Assay. Enzalutamide was also negative in the in vivo Mouse Micronucleus Assay.
Carcinogenicity: May cause cancer.	
Enzalutamide (915087-33-1)	
Additional information	<p>In a 6-month study in transgenic rasH2 mice, enzalutamide did not show carcinogenic potential (absence of neoplastic findings) at doses up to 20 mg/kg per day.</p> <p>Daily oral dosing of rats with enzalutamide at 10 to 100 mg/kg/day for 2 years increased the incidence of neoplastic findings (compared to control) that was considered related to the primary pharmacology of enzalutamide. These included benign thymoma, fibroadenoma in the mammary glands, and benign Leydig cell tumor in the testes in males; benign granulosa cell tumor in the ovaries in females; adenoma in the pars distalis of the pituitary in both sexes. In addition, urothelial papilloma and carcinoma of urinary bladder in male rats were observed at the 100 mg/kg/day dose and were considered secondary to the irritation caused by the increased urinary crystal/calculi which is known to occur in rodent species., Leydig cell tumors in rats are generally not considered relevant to humans based on experience with other anti-androgens. The human relevance of thymoma, pituitary adenoma and fibroadenoma in rats is unclear, but a potential relevance cannot be ruled out.</p>
Butylated hydroxyanisole (25013-16-5)	
IARC group	2B
National Toxicology Program (NTP) Status	Reasonably anticipated to be Human Carcinogen.
OSHA Hazard Communication Carcinogen List	In OSHA Hazard Communication Carcinogen list.
2,6-Di-tert-butyl-p-cresol (128-37-0)	
IARC group	3
Titanium dioxide (13463-67-7)	
IARC group	2B
OSHA Hazard Communication Carcinogen List	In OSHA Hazard Communication Carcinogen list.
Ethyl alcohol (64-17-5)	
IARC group	1
OSHA Hazard Communication Carcinogen List	In OSHA Hazard Communication Carcinogen list.
Isopropyl alcohol (67-63-0)	
IARC group	3

Reproductive Toxicity: May damage fertility or the unborn child.

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Enzalutamide (915087-33-1)	
Additional information	An effect on male fertility may be expected given the anti-androgen effects of the compound. Similarly, potential to cause birth defects (in particular, the feminization of male offspring) may exist. Embryo-fetal development study in mice: NOAEL = 1 mg/kg based on increased post-implantation loss and shortened anogenital distance. In dams, spontaneous abortion was observed at a dose of 30 mg/kg. In a rabbit embryo-fetal development study, the maternal NOAEL was 10 mg/kg and in fetuses the NOAEL was 10 mg/kg.

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): May cause damage to organs through prolonged or repeated exposure.

Enzalutamide (915087-33-1)	
Additional information	<p>Convulsions were observed in mice at doses > 100 mg/kg/day and in dogs at doses of 60 mg/kg/day. In addition, in the 39-week dog study, 1 animal at the 45 mg/kg/day dose was observed to have convulsions.</p> <p>Mild hematological effects (slight reduction in red blood cell parameters) and an increase in plasma testosterone occurred in dogs at oral doses of 15 to 60 mg/kg/day. Changes in male reproductive organ weights may be related to the pharmacologic action of this androgen receptor inhibitor.</p> <p>26-week repeated dose rat study: MTD 100 mg/kg/day, PO based on the following findings in males - decreased weights of prostate, epididymis and seminal vesicle, decreased prostate and seminal vesicle secretions. The following findings were observed in female reproductive organs – lumen dilation of the uterine glands and dilation of mammary gland. In addition, mild decreases in red blood cell counts and parameters, mild elevated cholesterol, increased liver and pituitary weights were reported. Histopathological findings included hepatocellular hypertrophy, hyperplasia/hypertrophy in the pituitary, thyroid follicular cell hyperplasia/hypertrophy, mammary gland hyperplasia in females, mammary gland atrophy in males, and slight to mild chronic progressive renal nephropathy.</p> <p>39-week repeated dose dog study: decreased prostate and epididymis weight, atrophy in the prostate, hypertrophy and/or hyperplasia of the Leydig cells in the testes, and atrophy and/or epithelial vacuolation, atrophy in the epididymides at 5 mg/kg/day and greater, atrophy and oligospermia/germ cell debris in the epididymis, and hypospermatogenesis consistent with pharmacological effects.</p>

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Exposure to capsule contents: May cause respiratory irritation.

Symptoms/Injuries After Skin Contact: Exposure to capsule contents: May cause skin irritation.

Symptoms/Injuries After Eye Contact: Exposure to capsule contents: May cause eye irritation.

Symptoms/Injuries After Ingestion: Ingestion may cause nausea, vomiting and diarrhea.

Chronic Symptoms: Potential to cause seizures, especially in those predisposed to seizure activity. May cause cancer. May damage fertility or the unborn child. May damage organs through prolonged or repeated exposure.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : This material is hazardous to the aquatic environment. Keep out of sewers and waterways.

Ecology - Water : Harmful to aquatic life. Harmful to aquatic life with long lasting effects.

Butylated hydroxyanisole (25013-16-5)	
EC50 Daphnia 1	2.3 mg/l
2,6-Di-tert-butyl-p-cresol (128-37-0)	
EC50 Daphnia 1	0.84 mg/l
EC50 Other Aquatic Organisms 2	0.43 mg/l (Exposure time: 72 h - Species: Desmodesmus subspicatus)

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Glycerin (56-81-5)	
LC50 Fish 1	54000 (51000 - 57000) mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
Ethyl alcohol (64-17-5)	
EC50 Daphnia 1	9268 - 14221 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC 50 Fish 2	> 100 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
ErC50 (algae)	1000 mg/l
1,2-Propylene glycol (57-55-6)	
LC50 Fish 1	51600 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	10000 mg/l (Exposure time: 24 h - Species: Daphnia magna)
LC 50 Fish 2	41 - 47 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 2	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
Isopropyl alcohol (67-63-0)	
LC50 Fish 1	9640 mg/l (Exposure time: 96 h - Species: Pimephales promelas [flow-through])
EC50 Daphnia 1	13299 mg/l (Exposure time: 48 h - Species: Daphnia magna)
EC50 Other Aquatic Organisms 1	1000 mg/l (Exposure time: 96 h - Species: Desmodesmus subspicatus)
LC 50 Fish 2	11130 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Other Aquatic Organisms 2	1000 mg/l (Exposure time: 72 h - Species: Desmodesmus subspicatus)
Ammonium hydroxide (1336-21-6)	
LC50 Fish 1	8.2 mg/l (Exposure time: 96 h - Species: Pimephales promelas)
EC50 Daphnia 1	0.66 mg/l (Exposure time: 48 h - Species: water flea)
EC50 Daphnia 2	0.66 mg/l (Exposure time: 48 h - Species: Daphnia pulex)

12.2. Persistence and Degradability No additional information available.

12.3. Bioaccumulative Potential

2,6-Di-tert-butyl-p-cresol (128-37-0)	
BCF fish 1	230 - 2500
Log Pow	4.17
Glycerin (56-81-5)	
BCF fish 1	(no bioaccumulation)
Log Pow	-1.76
Ethyl alcohol (64-17-5)	
Log Pow	-0.32
Bioaccumulative Potential	Not established.
1,2-Propylene glycol (57-55-6)	
BCF fish 1	< 1
Log Pow	-0.92
Isopropyl alcohol (67-63-0)	
Log Pow	0.05 (at 25 °C)

12.4. Mobility in Soil No additional information available.

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of contents and container according to local, regional, national, and international regulations.

Ecology – Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

14.1. In Accordance with DOT Not regulated for transport.

14.2. In Accordance with IMDG Not regulated for transport.

14.3. In Accordance with IATA Not regulated for transport.

SECTION 15: REGULATORY INFORMATION

15.1 US Federal Regulations Not applicable

15.2 US State Regulations Not applicable

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SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : 07/31/2019

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.