

ZYTIGA

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			Date of first issue: 2016/04/14

SECTION 1. IDENTIFICATION

Product name : ZYTIGA
Substance name : Zytiga 500mg tablet (Film coated)
abiraterone acetate 500MG/TABLET

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: Endocrine therapy
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)**

Serious eye damage : Category 1

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (male reproductive organs, female reproductive organs, Mammary gland, Pituitary gland, Adrenal gland)

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Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H318 Causes serious eye damage.
H360 May damage fertility or the unborn child.
H373 May cause damage to organs (male reproductive organs, female reproductive organs, Mammary gland, Pituitary gland, Adrenal gland) through prolonged or repeated exposure if swallowed.
H410 Very toxic to aquatic life with long lasting effects.

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/ fume/ gas/ mist/ vapours/ spray.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards

Refer to the pharmacotherapeutic group (section 1.2) and the patient packaging insert to evaluate the possible workplace hazards when this Finished Pharmaceutical Product is accidentally leaking, broken or crushed.

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SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Solid

Components

Chemical name	CAS-No.	Concentration (% w/w)
ABIRATERONE ACETATE	154229-18-2	>= 30 - < 50
Cellulose	9004-34-6	>= 10 - < 20
DODECYL SODIUM SULPHATE	151-21-3	>= 5 - < 10
HYDROXYPROPYLMETHYLCELLULOSE (HPMC)	9004-65-3	>= 1 - < 5
Octadecanoic acid, magnesium salt	557-04-0	>= 1 - < 5
COLLOIDAL ANHYDROUS SILICA	112945-52-5	>= 1 - < 5
TITANDIOXIDE	13463-67-7	>= 0.1 - < 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 with plenty of 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 : Consult the patient packaging insert for more information
about this Finished Pharmaceutical Product.
Fatigue
joint pain
Diarrhoea
Cough
hypertension
confusion
urinary tract infection
Vomiting
Shortness of breath
Oedema

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Notes to physician : Treat symptomatically.
Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Specific hazards during firefighting : 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.
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 (intact) or vacuum with HEPA filter (broken or crushed) 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 : Avoid inhalation, ingestion and contact with skin and eyes.
Do not break, crush or spill this Finished Pharmaceutical Product.
Keep away from heat and sources of ignition.
To avoid thermal decomposition, do not overheat.
Use personal protective equipment as required.

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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 dry, cool and well-ventilated place.
Keep away from heat and sources of ignition.
Keep locked up.

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
ABIRATERONE ACETATE	154229-18-2	TWA	0.012 mg/m ³	J&J OEL/PBOEL HHC
		STV	0,120 mg/100cm ²	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 SKIN: has the potential for absorption via the skin.			
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0
DODECYL SODIUM SULPHATE	151-21-3	TWA	0.5 mg/m ³	J&J OEL/PBOEL HHC

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		PBOEL-HHC	1 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 1B., Notation DSEN: has the potential to cause delayed allergic skin reaction (sensitization), such as wheals and rashes, Notation RSEN: has the potential to cause delayed allergic reactions (sensitization), such as shortness of breath, asthma and anaphylaxis.			
HYDROXYPROPYLMETHYLCELLULOSE (HPMC)	9004-65-3	TWA	10 mg/m3	ACGIH
Octadecanoic acid, magnesium salt	557-04-0	TWA (Inhalable particulate matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH
COLLOIDAL ANHYDROUS SILICA	112945-52-5	TWA (Dust)	20 Million particles per cubic foot (Silica)	OSHA Z-3
		TWA (Dust)	80 mg/m3 / %SiO ₂ (Silica)	OSHA Z-3
		TWA	6 mg/m3 (Silica)	NIOSH REL
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.

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Hand protection	:	Disposable gloves
Remarks	:	
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	:	purple
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
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not classified as a flammability hazard
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
Relative density	:	No data available
Density	:	No data available

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Solubility(ies)

Water solubility : No data available

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

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : Not applicable

Viscosity, kinematic : Not applicable

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.
Exposure to light.
Protect from frost, heat and sunlight.

Incompatible materials : None known.

Hazardous decomposition products : None known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity : Acute toxicity estimate: 4,594 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 28.12 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

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

Components:**ABIRATERONE ACETATE:**

Acute oral toxicity : LD50 (Mouse, male and female): > 2,000 mg/kg
Method: Acute oral toxicity
GLP: no

LD50 (Rat, male): > 400 mg/kg
Method: Acute oral toxicity
GLP: yes
Assessment: The substance or mixture has no acute oral toxicity
Remarks: No adverse effect has been observed in acute toxicity tests.

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

DODECYL SODIUM SULPHATE:

Acute oral toxicity : LD50 Oral (Rat): 1,200 mg/kg
Method: OECD Test Guideline 401
Assessment: The component/mixture is moderately toxic after single ingestion.

Acute inhalation toxicity : Assessment: The component/mixture is moderately toxic after short term inhalation.

Acute dermal toxicity : LD50 Dermal (Rabbit): > 2,000 mg/kg

COLLOIDAL ANHYDROUS SILICA:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

Skin corrosion/irritation**Components:****ABIRATERONE ACETATE:**

Remarks : No data available

Cellulose:

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Species : Rabbit
Remarks : No skin irritation

DODECYL SODIUM SULPHATE:

Species : Rabbit
Method : OECD Test Guideline 404
Result : Skin irritation

COLLOIDAL ANHYDROUS SILICA:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation**Components:****ABIRATERONE ACETATE:**

Remarks : No data available

Cellulose:

Species : Rabbit
Remarks : No eye irritation

DODECYL SODIUM SULPHATE:

Species : Rabbit
Result : Corrosive to eyes
Method : OECD Test Guideline 405

COLLOIDAL ANHYDROUS SILICA:

Species : Rabbit
Result : No eye irritation

Respiratory or skin sensitisation**Components:****ABIRATERONE ACETATE:**

Remarks : No data available

Cellulose:

Species : Guinea pig
Remarks : Did not cause sensitisation on laboratory animals.

DODECYL SODIUM SULPHATE:

Result : Not a sensitizer

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Germ cell mutagenicity**Components:****ABIRATERONE ACETATE:**

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

Test system: Human lymphocytes
Method: In vitro Mammalian Chromosome Aberration Test
OECD 473
Result: negative
GLP: yes

Genotoxicity in vivo : Species: Rat
Application Route: Oral
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.

DODECYL SODIUM SULPHATE:

Genotoxicity in vitro : Method: OECD Test Guideline 471
Result: negative

Carcinogenicity**Components:****ABIRATERONE ACETATE:**

Species : Mouse, male and female
Application Route : Oral
Exposure time : 26 w
Dose : 125-375-750 mg/kg body weight
Result : No evidence of carcinogenicity in animal studies.
GLP : yes

Species : Rat, male
Application Route : Oral
Exposure time : 104 w
Dose : 5-15-50 mg/kg body weight
Result : positive
GLP : yes
Remarks : The observed tumors do not appear to be relevant for men.

Species : Rat, female
Application Route : Oral
Exposure time : 104 w

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Dose : 15-50-150 mg/kg body weight
 Result : negative
 GLP : yes

Carcinogenicity - Assessment : The observed tumors do not appear to be relevant for men.

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:****ABIRATERONE ACETATE:**

Effects on fertility : Species: Rat, male
 Application Route: Oral
 Dose: 30 - 300 mg/kg
 General Toxicity - Parent: NOAEL: < 30 mg/kg
 GLP: yes
 Remarks: Adverse effects on sexual function and fertility.

Species: Rat, female
 Application Route: Oral
 Dose: 30 - 300 mg/kg
 General Toxicity - Parent: NOAEL: < 30 mg/kg
 GLP: yes
 Remarks: Adverse effects on sexual function and fertility.

Effects on foetal development : Species: Rat
 Application Route: Oral
 Dose: 10 - 30 - 100 mg/kg
 General Toxicity Maternal: NOAEL: < 10 mg/kg
 Teratogenicity: NOAEL: > 100 mg/kg
 Method: Developmental Toxicity
 GLP: yes
 Remarks: Did not show teratogenic effects in animal experiments.

Reproductive toxicity - Assessment : Sufficient evidence of reprotoxicity based on animals.

Teratogenicity - Assessment : No evidence of adverse effects on development.

DODECYL SODIUM SULPHATE:

Effects on fertility : Remarks: negative

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STOT - single exposure**Components:****ABIRATERONE ACETATE:**

Remarks : No data available

DODECYL SODIUM SULPHATE:

Exposure routes : Inhalation
Assessment : The substance or mixture is classified as specific target organ toxicant, single exposure, category 3 with respiratory tract irritation.

STOT - repeated exposure**Components:****ABIRATERONE ACETATE:**

Exposure routes : Oral
Target Organs : male reproductive organs, female reproductive organs, Mammary gland, Pituitary gland, Adrenal gland
Assessment : The substance or mixture is classified as specific target organ toxicant, repeated exposure, category 2.

Repeated dose toxicity**Components:****ABIRATERONE ACETATE:**

Species : Rat, male and female
NOAEL : < 50 mg/kg
Application Route : Oral
Exposure time : 3m
Dose : 10d 250-750-2000->50-250-750
Subsequent observation period : 1m
GLP : yes

Species : Rat, male
NOAEL : < 50 mg/kg
Application Route : Oral
Exposure time : 6m
Dose : 50-150-400 mg/kg
GLP : yes

Species : Rat, female
NOAEL : 50 mg/kg
Application Route : Oral
Exposure time : 6m
Dose : 50-150-400 mg/kg
GLP : yes

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Species : Monkey, male and female
NOAEL : < 250 mg/kg
Application Route : Oral
Exposure time : 3m
Dose : 250-750-200mg/kg
Subsequent observation period : 1m
GLP : yes

Species : Monkey, male and female
NOAEL : < 250 mg/kg
Application Route : Oral
Exposure time : 9m
Dose : 250-500-1000mg/kg
Subsequent observation period : 4w
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

No data available

Other health hazards

No data available

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****ABIRATERONE ACETATE:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0.13 mg/l
Exposure time: 96 h
Test Type: semi-static test
Method: OECD Test Guideline 203
GLP: yes

NOEC (Oncorhynchus mykiss (rainbow trout)): 0.065 mg/l
Exposure time: 96 h
Test Type: semi-static test

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Method: OECD Test Guideline 203
GLP: yes

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): 0.25 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202
GLP: yes

Toxicity to algae/aquatic plants : ErC50 (*Pseudokirchneriella subcapitata* (green algae)): > 1.0 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: Growth inhibition
Method: OECD Test Guideline 201
GLP: yes

EbC50 (*Pseudokirchneriella subcapitata* (green algae)): > 1.0 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: Growth inhibition
Method: OECD Test Guideline 201
GLP: yes

NOEC (*Pseudokirchneriella subcapitata* (green algae)): 1.0 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: Growth inhibition
Method: OECD Test Guideline 201
GLP: yes

M-Factor (Acute aquatic toxicity) : 1

Toxicity to fish (Chronic toxicity) : NOEC (*Pimephales promelas* (fathead minnow)): 0.0011 mg/l
Exposure time: 32 d
Test Type: Fish early-life stage (FELS) toxicity test (OECD 210)
Method: OECD Test Guideline 210
GLP: yes

NOEC (*Pimephales promelas* (fathead minnow)): 0.000013 mg/l
Exposure time: 119 d
Test Type: Fish partial life cycle toxicity test
Method: OECD Test Guideline 229
GLP: yes

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (*Daphnia magna* (Water flea)): 0.00047 mg/l
Exposure time: 21 d
Test Type: Daphnia reproduction test

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Method: OECD Test Guideline 211
GLP: yes

M-Factor (Chronic aquatic toxicity) : 1,000

Toxicity to microorganisms : NOEC (activated sludge): > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
GLP: yes

EC50 (activated sludge): > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
GLP: yes

NOEC (Soil microorganisms): 250
Exposure time: 28 d
Test Type: Nitrogen transformation
Method: OECD Test Guideline 216
GLP: yes

Toxicity to soil dwelling organisms : Test Type: Acute toxicity
NOEC (*Eisenia fetida* (earthworms)): 500 mg/kg
Exposure time: 14 d
Method: OECD Test Guideline 207
GLP: yes

Test Type: Acute toxicity
EC50 (*Eisenia fetida* (earthworms)): > 1,000 mg/kg
Exposure time: 14 d
Method: OECD Test Guideline 207
GLP: yes

Test Type: Reproduction Test
NOEC (Springtail (*Collembola*)): 500 mg/kg
Exposure time: 28 d
Method: ISO 11267
GLP: yes

Test Type: Reproduction Test
EC50 (Springtail (*Collembola*)): 670 mg/kg
Exposure time: 28 d
Method: ISO 11267
GLP: yes

Plant toxicity : NOEC: 100 mg/kg
Exposure time: 14 d
Species: Terrestrial plants
Method: OECD Test Guideline 208
GLP: yes

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EC50: > 100 mg/kg
Exposure time: 14 d
Species: Terrestrial plants
Method: OECD Test Guideline 208
GLP: yes

Cellulose:

Toxicity to fish : Remarks: No data available

DODECYL SODIUM SULPHATE:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 29 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other : LC50 (Ceriodaphnia dubia (water flea)): 5.55 mg/l
aquatic invertebrates
Exposure time: 48 h
Test Type: flow-through test

Toxicity to algae/aquatic : EC50 (Desmodesmus subspicatus (green algae)): > 120 mg/l
plants
Exposure time: 72 h

Toxicity to fish (Chronic :
toxicity)

Toxicity to daphnia and other : NOEC: 1 mg/l
aquatic invertebrates
(Chronic toxicity)

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

Toxicity to fish : Remarks: No data available

COLLOIDAL ANHYDROUS SILICA:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10,000 mg/l
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
aquatic invertebrates
Exposure time: 24 h

Persistence and degradability**Components:****ABIRATERONE ACETATE:**

Biodegradability : aerobic
Inoculum: activated sludge
Result: Not readily biodegradable.
Exposure time: 28 d
Method: OECD Test Guideline 301B
GLP: yes

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Stability in water : Test Type: aerobic
Degradation half life (DT50): 2.3 Days
Method: OECD Test Guideline 308
GLP: yes
Remarks: Fresh water 1

Test Type: aerobic
Degradation half life (DT50): 2.3 Days
Method: OECD Test Guideline 308
GLP: yes
Remarks: Fresh water 2

Test Type: aerobic
Degradation half life (DT50): 4.9 Days
Method: OECD Test Guideline 308
GLP: yes
Remarks: total system 1

Test Type: aerobic
Degradation half life (DT50): 3.3 Days
Method: OECD Test Guideline 308
GLP: yes
Remarks: total system 2

DODECYL SODIUM SULPHATE:

Biodegradability : Result: Readily biodegradable.

Biochemical Oxygen : > 60 %(m)
Demand (BOD)

Dissolved organic carbon : > 70 %(m)
(DOC)

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

Biodegradability : Remarks: No data available

COLLOIDAL ANHYDROUS SILICA:

Biodegradability : Remarks: No data available

Bioaccumulative potential**Components:****ABIRATERONE ACETATE:**

Bioaccumulation : Species: Oncorhynchus mykiss (rainbow trout)
Bioconcentration factor (BCF): 625
Exposure time: 18 d
Method: OECD Test Guideline 305
GLP: yes

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Species: Oncorhynchus mykiss (rainbow trout)
 Bioconcentration factor (BCF): 576
 Exposure time: 18 d
 Method: OECD Test Guideline 305
 GLP: yes

Partition coefficient: n-octanol/water : log Pow: > 6.20
 Method: OECD Test Guideline 117
 GLP: yes

DODECYL SODIUM SULPHATE:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : log Pow: 0.83 (68 °F / 20 °C)

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

Bioaccumulation : Remarks: No data available

Octadecanoic acid, magnesium salt:

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

COLLOIDAL ANHYDROUS SILICA:

Bioaccumulation : Remarks: No data available

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

TITANDIOXIDE:

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

Mobility in soil**Components:****ABIRATERONE ACETATE:**

Distribution among environmental compartments : Adsorption/Soil
 Koc: 269470 - 363061
 Method: OECD Test Guideline 106

Adsorption/Activated sludge
 Koc: 7705 - 11806
 Method: OECD Test Guideline 106

Stability in soil : Test Type: Aerobic transformation in soil
 Dissipation time: 18 Days
 Method: OECD Test Guideline 307

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GLP: yes
Remarks: soil 1

DODECYL SODIUM SULPHATE:

Mobility : Remarks: No data available

Distribution among environmental compartments : Remarks: No data available

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

Distribution among environmental compartments : Remarks: No data available

COLLOIDAL ANHYDROUS SILICA:

Distribution among environmental compartments : Remarks: No data available

Other adverse effects**Components:****ABIRATERONE ACETATE:**

Results of PBT and vPvB assessment : Non-classified PBT substance

DODECYL SODIUM SULPHATE:

Environmental fate and pathways : No data available

Results of PBT and vPvB assessment : Substance is not persistent, bioaccumulative, and toxic (PBT).

Additional ecological information : No data available

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

Results of PBT and vPvB assessment : No information available.

Additional ecological information : No data available

COLLOIDAL ANHYDROUS SILICA:

Results of PBT and vPvB assessment : No information available.

Additional ecological information : No data available

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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**

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

Class : 9

Packing group : III

Labels : 9

IATA-DGR

UN/ID No. : UN 3077

Proper shipping name : Environmentally hazardous substance, solid, n.o.s. (abiraterone acetate)

Class : 9

Packing group : III

Labels : 9

Packing instruction (cargo aircraft) : 956

Packing instruction (LQ) : Y956

Packing instruction (EQ) : E1

Packing instruction (passenger aircraft) : 956

Packing instruction (LQ) : Y956

Remarks : Special Provision A197: Environmentally hazardous substances, classified under UN 3077 or UN 3082, when transported in single or combination packagings containing a net quantity per single or inner packaging of 5 L or less for liquids or having a net mass of 5 kg or less for solids, are not subject to any other provisions of the IATA DGR provided the packagings meet the general provisions of IATA DGR 5.0.2.4.1, 5.0.2.6.1.1 and 5.0.2.8., This substance can be shipped under 'de minimi's quantities' provisions if the net quantity per inner package <= 1mL for liquids or <= 1g for solids and the net quantity per outer package does not exceed 100mL for liquids or 100g for solids and provided packaging provisions of IATA DGR §2.6.10 are met.

IMDG-Code

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UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (abiraterone acetate)

Class : 9

Packing group : III

Labels : 9

EmS Code : F-A, S-F

Marine pollutant : yes

Remarks : 2.10.2.7: Environmentally Hazardous Substances/Marine Pollutants, classified under UN 3077 or UN 3082, packaged in single or combination packagings containing a net quantity per single of inner packaging of 5L or less for liquids or having a net mass per single of inner packaging of 5kg or less for solids are not subject to the IMDG provided the packagings meet the general requirements of 4.1.1.1, 4.1.1.2, and 4.1.1.4 to 4.1.1.8., This substance can be shipped under 'de minimi's quantities' provisions if the net quantity per inner package <= 1mL for liquids or <= 1g for solids and the net quantity per outer package does not exceed 100mL for liquids or 100g for solids and provided packaging provisions of ADR/RID/ADN/IMDG §3.5.1.4 are met.

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

UN/ID/NA number : UN 3077

Proper shipping name : Environmentally hazardous substance, solid, n.o.s. (abiraterone acetate)

Class : 9

Packing group : III

Labels : 9

ERG Code : 171

Marine pollutant : yes

Remarks : 49 CFR 171.4 - Marine Pollutant Exception: Except when transporting aboard a vessel, the requirements of this subchapter do not apply to non-bulk packagings transported by motor vehicles, rail cars, and aircraft., This substance can be shipped under 'de minimi's quantities' provisions if the net quantity per inner package <= 1mL for liquids or <= 1g for solids and the net quantity per outer package does not exceed 100mL for liquids or 100g for solids and provided packaging provisions of 49 CFR 173.4b are met.

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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SECTION 15. REGULATORY INFORMATION**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**

This material does not contain any components with a section 302 EHS TPQ.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations**Massachusetts Right To Know**

Cellulose	9004-34-6
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Pennsylvania Right To Know

ABIRATERONE ACETATE	154229-18-2
alpha-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-, hydrate (1:1)	5989-81-1
Cellulose	9004-34-6
	74811-65-7
DODECYL SODIUM SULPHATE	151-21-3

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 Prop. 65

WARNING: This product can expose you to chemicals including ABIRATERONE ACETATE, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California Permissible Exposure Limits for Chemical Contaminants

Cellulose	9004-34-6
Octadecanoic acid, magnesium salt	557-04-0
COLLOIDAL ANHYDROUS SILICA	112945-52-5

Other regulations

Restricted to professional users.

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

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

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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
OSHA Z-3	:	USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
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
OSHA Z-3 / 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,

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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 : 2025/02/24

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.

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