Version	Revision Date:	SDS Number:	Date of last issue: 2017/03/28
4.21	2017/03/30	100000009070	Date of first issue: 2014/08/20

SECTION 1. IDENTIFICATION

Product name : ZYTIGA
Substance name : ZYTIGA (ABIRATERONE ACETATE)
abiraterone acetate 250MG/TABLET

Manufacturer or supplier's details

Company name of supplier : Janssen Pharmaceuticals, Inc.

Address : 1125 Trenton-Harbourton Rd
Titusville NJ 08560
US

Telephone : (609) 730-2000
E-mail address Responsible/issuing person : SDSJanssen@its.jnj.com

Emergency telephone number : CHEMTREC US: 1-800-424-9300
CHEMTREC International: +1 703-527-3887

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

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)

Acute aquatic toxicity : Category 1

Chronic aquatic toxicity : Category 1

GHS label elements

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

Hazard pictograms :

Signal word : Danger

Hazard statements : H318 Causes serious eye damage.
H360F May damage fertility.
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

May be absorbed via the skin.
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 accidently leaking, broken or crushed.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical name	CAS-No.	Concentration (%)
ABIRATERONE ACETATE	154229-18-2	>= 30 - < 50

Cellulose	9004-34-6	>= 10 - < 20
DODECYL SODIUM SULPHATE	151-21-3	>= 1 - < 5
Octadecanoic acid, magnesium salt	557-04-0	>= 1 - < 5
COLLOIDAL ANHYDROUS SILICA	112945-52-5	>= 1 - < 5

SECTION 4. FIRST AID MEASURES

If inhaled : 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.
Consult 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
Cough
Diarrhoea
confusion
urinary tract infection
Vomiting
Shortness of breath
Oedema
hypokalemia
peripheral edema

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 : Risk of dust explosion in case of organic fine powder.

Hazardous combustion products : No hazardous combustion products are known

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. Do not break, crush or spill this Finished Pharmaceutical Product.
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	:	Large spills: 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	:	None known.
Advice on safe handling	:	Avoid formation of dust and aerosols. To avoid thermal decomposition, do not overheat. 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. Use personal protective equipment as required.
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	:	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	0.008 mg/m3	J&J OEL/PBOEL HHC
		STV	0,080 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 SKIN: has the potential for absorption via the skin.			
Cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
			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
		PEL (Total dust)	10 mg/m3	CAL PEL
		PEL (respirable dust fraction)	5 mg/m3	CAL PEL
DODECYL SODIUM SULPHATE	151-21-3	TWA	0.5 mg/m3	J&J OEL/PBOEL HHC
		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.			
Octadecanoic acid, magnesi-	557-04-0	TWA	10 mg/m3	ACGIH

um salt				
		PEL	10 mg/m3	CAL PEL
COLLOIDAL ANHYDROUS SILICA	112945-52-5	TWA (Dust)	20 Million particles per cubic foot (Silica)	OSHA Z-3
		TWA (Dust)	80 mg/m3 / %SiO2 (Silica)	OSHA Z-3
		TWA	6 mg/m3 (Silica)	NIOSH REL
		PEL	6 mg/m3	CAL PEL

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.
Engineering controls should always be the primary method of controlling exposures.
If respiratory protective equipment is needed for certain activities, the type as well as the corresponding protection factor will depend upon the risk assessment and air concentrations, hazards, physical and warning properties of substances present.

Hand protection

Remarks : Skin protection required for pregnant women or women of child bearing age. Gloves are recommended as a good hygiene measure if there is direct contact with the tablets.

Eye protection : No special precautions required.

Skin and body protection : No special precautions required.

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 : uncoated, tablet

Colour : white, off-white

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)	:	No information available.
Upper explosion limit	:	No data available
Lower explosion 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
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: 4,853 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 10 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity : Remarks: May be harmful if absorbed through skin.

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

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): 1,288 mg/kg
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
Species: Rabbit
Remarks: No skin irritation

DODECYL SODIUM SULPHATE
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
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

Germ cell mutagenicity

Components:

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

: Species: 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
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 identified as a carcinogen or potential carcinogen by OSHA.

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
Sex: male
Dose: 30 - 300 mg/kg
Application Route: Oral
NOAEL: < 30 mg/kg,
GLP: yes
Remarks: Adverse effects on sexual function and fertility.

Species: Rat
Sex: female
Dose: 30 - 300 mg/kg
Application Route: Oral
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
NOAEL Teratogenic effects > 100 mg/kg
NOAEL Maternal effects < 10 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

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: May cause damage to organs through prolonged or repeated exposure.

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

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

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
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 : 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

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
Method: OECD Test Guideline 211
GLP: yes

Toxicity to bacteria : 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 (Terestrial plants): 100 mg/kg
Exposure time: 14 d
Method: OECD Test Guideline 208
GLP: yes

EC50 (Terestrial plants): > 100 mg/kg
Exposure time: 14 d
Method: OECD Test Guideline 208
GLP: yes

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

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

Toxicity to fish (Chronic toxicity) :

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

COLLOIDAL ANHYDROUS SILICA

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

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

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 : Remarks: No data available

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

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

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

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 : 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

Mobility in soil

Components:

ABIRATERONE ACETATE

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

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

Stability in soil : Test Type: Aerobic transformation in soil
Method: OECD Test Guideline 307
GLP: yes
Remarks: soil 1

DODECYL SODIUM SULPHATE

Mobility : Remarks: No data available

Distribution among environmental compartments : Remarks: No data available

COLLOIDAL ANHYDROUS SILICA

Distribution among environmental compartments : Remarks: No data available

Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Components:

ABIRATERONE ACETATE

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

Components:

DODECYL SODIUM SULPHATE

Environmental fate and pathways	:	No data available
Results of PBT and vPvB assessment	:	This substance is not considered to be persistent, bioaccumulating and toxic (PBT).
Additional ecological information	:	No data available

Components:

COLLOIDAL ANHYDROUS SILICA

Results of PBT and vPvB assessment	:	No information available.
Additional ecological information	:	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

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

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	:	no
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.

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know Act

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

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.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know

Cellulose	9004-34-6	10 - 20 %

Pennsylvania Right To Know

ABIRATERONE ACETATE	154229-18-2	30 - 50 %
alpha-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-, hydrate (1:1)	5989-81-1	20 - 30 %
Cellulose	9004-34-6	10 - 20 %
	74811-65-7	5 - 10 %
PVP K30 (KOLLIDON 30)	Not Assigned	5 - 10 %
DODECYL SODIUM SULPHATE	151-21-3	1 - 5 %

New Jersey Right To Know

ABIRATERONE ACETATE	154229-18-2	30 - 50 %
alpha-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-, hydrate (1:1)	5989-81-1	20 - 30 %

Cellulose	9004-34-6	10 - 20 %
	74811-65-7	5 - 10 %
PVP K30 (KOLLIDON 30)	Not Assigned	5 - 10 %

California Prop 65 WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

ABIRATERONE ACETATE	17-(3-pyridyl)androsta-5,16-dien-3-beta-ol acetate(ester)

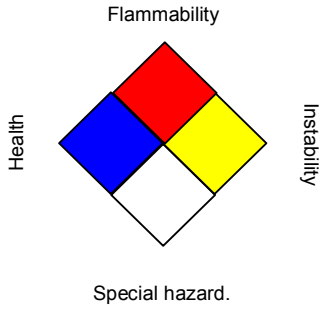
Other regulations : Restricted to professional users.

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

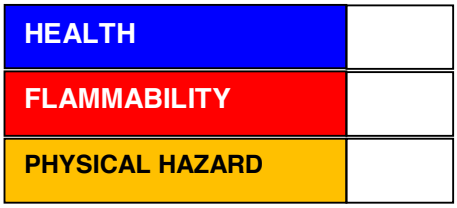
SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS III:



0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

Revision Date : 2017/03/30

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