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Print Date 2013-05-23

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

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

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : 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.

1.3 Details of the supplier of the safety data sheet

Company : Janssen Pharmaceutica NV
Turnhoutseweg 30
2340 Beerse
Belgium
Telephone : +3214602111
Telefax : +3214602841
E-mail address : RA-JANBE-SAFETYDA@JANBE.JNJ.COM

1.4 Emergency telephone number +32 14 602444

2. Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 1B	H360FD: May damage fertility. May damage the unborn child.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure if swallowed.
Acute aquatic toxicity, Category 1	H400: Very toxic to aquatic life.
Chronic aquatic toxicity, Category 1	H410: Very toxic to aquatic life with long lasting effects.

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Classification (67/548/EEC, 1999/45/EC)

Toxic to Reproduction Category 1
Toxic to Reproduction Category 1
Harmful

Dangerous for the environment

R60: May impair fertility.
R61: May cause harm to the unborn child.
R48/22: Harmful: danger of serious damage to health by prolonged exposure if swallowed.
R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements : H360FD May damage fertility. May damage the unborn child.
H373 May cause damage to organs through prolonged or repeated exposure if swallowed.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust or mist.
P281 Use personal protective equipment as required.
Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
Storage:
P405 Store locked up.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.
Hazardous components which must be listed on the label:

154229-18-2 ABIRATERONE ACETATE

2.3 Other hazards

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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 accidentally leaking, broken or crushed.

3. Composition/information on ingredients

3.2 Mixtures

Hazardous components

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration [%]
ABIRATERONE ACETATE	154229-18-2	Repr.Cat.1; R60 Repr.Cat.1; R61 Xn; R48/22 N; R50/53	Repr. 1B; H360FD STOT RE 2; H373 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	>= 25 - < 50

For the full text of the R-phrases mentioned in this Section, see Section 16.

For the full text of the H-Statements mentioned in this Section, see Section 16.

4. First aid measures

4.1 Description of 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 5 minutes.
Remove contact lenses.
If eye irritation persists, consult a specialist.
- If swallowed : If swallowed, rinse mouth with water (only if the person is
conscious).
Call a physician immediately.

4.2 Most important symptoms and effects, both acute and delayed

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Symptoms : Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

4.3 Indication of any immediate medical attention and special treatment needed

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

5. Firefighting measures

5.1 Extinguishing media

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

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting : Risk of dust explosion in case of organic fine powder.

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Further information : Avoid dust formation.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Do not break, crush or spill this Finished Pharmaceutical Product.
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.

6.2 Environmental precautions

Environmental precautions : Should not be released into the environment.
Do not flush into surface water or sanitary sewer system.

6.3 Methods and materials for containment and cleaning up

Methods for cleaning up : Large spills: Vacuum with HEPA filter or via wet cleaning into suitable containers for disposal. Pick up and arrange without

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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".

6.4 Reference to other sections

For disposal information, see section 13

7. Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Do not break, crush or spill this Finished Pharmaceutical Product.
Avoid formation of dust and aerosols.
Ensure all equipment is electrically grounded before beginning transfer operations.
To avoid thermal decomposition, do not overheat.
For personal protection see section 8.
Keep away from heat and sources of ignition.
Avoid inhalation, ingestion and contact with skin and eyes.

Advice on protection against fire and explosion : Avoid dust formation.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : 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.

Storage temperature : 15 - 30 °C

7.3 Specific end use(s)

Specific use(s) : Consult the patient packaging insert for more information about this Finished Pharmaceutical Product., Consult the technical guidelines for the use of this substance/mixture.

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8. Exposure controls/personal protection

8.1 Control parameters

Components	CAS-No.	Value	Control parameters	Update	Basis
ABIRATERONE ACETATE	154229-18-2	TWA	0,007 mg/m ³		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.			
Further information	:	Notation SKIN: has the potential for absorption via the skin.			
Further information	:	Notation REPRO: has the potential to have adverse effects on reproduction and fetal development			

PNEC

ABIRATERONE ACETATE : Fresh water
Value: 0,0013 µg/l

8.2 Exposure controls

Personal protective equipment

- Respiratory protection : 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.
No personal respiratory protective equipment normally required.
- Hand protection : 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.
- Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.
- Protective measures : The type of protective equipment must be selected based on

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the Environmental Health and Safety risk assessment.
Consult a Environmental Health and Safety expert if
necessary.

Environmental exposure controls

General advice : Should not be released into the environment.
Do not flush into surface water or sanitary sewer system.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : tablet, uncoated

Colour : white, off-white

9.2 Other information

10. Stability and reactivity

10.1 Reactivity

None reasonably foreseeable.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Further information: Risk of dust explosion in case of organic
fine powder.

10.4 Conditions to avoid

Conditions to avoid : To avoid thermal decomposition, do not overheat.
Heat, flames and sparks.
Exposure to light.
Protect from frost, heat and sunlight.

10.5 Incompatible materials

Materials to avoid : None known.

10.6 Hazardous decomposition products

Hazardous decomposition : None known.

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products

11. Toxicological information

11.1 Information on toxicological effects

Product

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

Components:

ABIRATERONE ACETATE :

Acute oral toxicity : LD50: > 400 mg/kg, rat

: LD50: 800 mg/kg, mouse

Acute inhalation toxicity : no data available

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

Skin corrosion/irritation : May irritate skin.

Serious eye damage/eye irritation : May irritate eyes.

Respiratory or skin sensitisation : no data available

Germ cell mutagenicity

Genotoxicity in vitro : Ames test, with and without metabolic activation, Result: negative

: Chromosome aberration test in vitro, Human lymphocytes, Result: negative

Genotoxicity in vivo : In vivo micronucleus test, rat, Oral, negative

Germ cell mutagenicity (Assessment) : Animal testing did not show any mutagenic effects.

STOT - single exposure : Remarks: no data available

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

12. Ecological information

12.1 Toxicity

Components:

ABIRATERONE ACETATE :

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13. Disposal considerations

13.1 Waste treatment methods

- Product : 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

14.1 UN number

- ADR : 3077
- RID : 3077
- IMDG : 3077
- IATA : 3077

14.2 Proper shipping name

- ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (abiraterone acetate)
- RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (abiraterone acetate)
- IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (abiraterone acetate)
- IATA : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (abiraterone acetate)

14.3 Transport hazard class

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Labels : 9
Packing instruction (CAO) : 956
Packing instruction (PAX and CAO) : 956

14.5 Environmental hazards

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA

Environmentally hazardous : yes

14.6 Special precautions for user

For personal protection see section 8.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

no data available

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15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Other regulations : Restricted to professional users., According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment is not applicable (mixture)

16. Other information

Full text of R-phrases referred to under sections 2 and 3

R48/22	Harmful: danger of serious damage to health by prolonged exposure if swallowed.
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R60	May impair fertility.
R61	May cause harm to the unborn child.

Full text of H-Statements referred to under sections 2 and 3.

H360FD	May damage fertility. May damage the unborn child.
H373	May cause damage to organs through prolonged or repeated exposure if swallowed.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

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.

SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006



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