FINASTERIDE

MATERIAL SAFETY DATA SHEET

In accordance with Regulation (CE) 1907/2006, (CE) 1272/2008 and (EU) 453/2010 (Annex I)

Revision no. 4 - Revision date: April 5, 2012

SECTION 1.
IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

1.1. Substance identifier

Substance name:	**FINASTERIDE**
Other names (if available): Name in Annex VI-CLP: Name reported in the inventory of harmonized classification and labelling:	(5α,17β)-N-(1,1-Dimethylethyl)-3-oxo-4-aza-androst-1-ene-17-carboxamide N-(1,1-dimethylethyl)-3-oxo- 4-Aza-5α -androst-1-ene-17 β -carboxamide. N-tert-Butyl-3-oxo-4-aza-5 α -androst-1-ene-17 β -carboxamide unlisted not available
CAS number	98319-26-7
REACH registration number	Exempt of registration

1.2. Relevant identified uses of the substance and uses advised against

Relevant use(s)	5-alpha reductase inhibitor - API (Active Pharmaceutical Ingredient)
Uses advised against	none

1.3. Details of the supplier of the safety data sheet

Manufacturer/Distributor:
Company name: **STERLING S.r.l**
Address : **Via della Carboneria, 30 Solomeo**
06073 Corciano (PG) – Italy
Phone number : 075/5294001
Fax number: 075/5294000

Competent person responsible for the safety data sheet:
Aragona Anna Alessandra
e-mail: aragona@sterling.it

1.4. Emergency telephone number

02 66101029 (Centro Antiveleni Niguarda Ca' Granda – Milano)

SECTION 2
HAZARDS IDENTIFICATION

2.1 Classification of the substance

- **Classification of the substance in accordance with Regulation (CE) n. 1272/2008:**

Hazard class	Class code and hazard category	Hazard statement	Hazard warning
Acute toxicity	**Ac. Oral cat. 4**	**H302**	**Harmful if swallowed**
Reproductive toxicity	**Repr. Cat. 1B**	**H360FD**	**May damage fertility or the unborn child**

- **Classification in accordance with Directive 67/548/CEE :**

Classification	Risk phrases	
Xn, R22	**R22**	**Harmful if ingested**
Repr. Cat 2, R60, R61	**R60**	**May impair fertility**
	R61	**May cause harm to the unborn child.**
R52/53	**R52/53**	**Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment**

Main adverse effects

Physico-chemical effects — No adverse effects known.

Health effects — Adverse effects may include skin rash, swelling of lips, abdominal pain, back pain, breast enlargement or tenderness, decreased libido, impotence, decreased volume of ejaculate, diarrhea, dizziness, and headache. Possible allergic reaction to material if inhaled, ingested, or in contact with skin. May damage fertility or the unborn child.

Environmental effects — Because it can interfere with the metabolism of testosterone in fish it may be harmful to aquatic organisms.

See also sections from 9 to 12

2.2 Label elements

- **Labelling in accordance with regulation n. 1272/2008/EC**

Warning		
Signal Word	Danger	
Hazard indication (H)[1]	H302	H360FD
Safety statements (P)[1]	P202, P281 P301+312, P308+313 P405 P501	
- *Prevention*		
- *Reaction*		
- *Storage*		
- *Disposal*		

[1] For the explanation of H and P statements: see Section 16

2.3 Other hazards (which do not results in the classification)

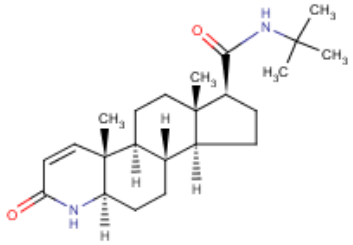
The substance satisfies the PBT criteria	YES	NO

- PBT		X
- vPvB		X

- Health hazards: May be harmful if inhaled or in contact with skin. May be irritant or sensitizer.
- Environmental hazards: not known
- Physico-chemical hazards: none
- Specific effects: Unknown

SECTION 3
COMPOSITION/INFORMATION ON INGREDIENTS

Description: active pharmaceutical principle

Name of the component	Finasteride
Concentration	Pure substance
Structural formula	
Chemical formula	$C_{23}H_{36}N_2O_2$
Molecular weight	372.54 g/mol
Substance with Community OEL	No
CAS name	(5alpha,17beta)-(1,1-Dimethylethyl)-3-oxo-4-azaandrost-1-ene-17-carboxamide
CAS number	98319-26-7
IUPAC name	4-Azaandrost-1-ene-17-carboxamide, N-(1,1-dimethylethyl)-3-oxo-, (5alpha,17beta)-
EC number	not assigned
Index number	not assigned
Impurity/ies (if classified)	-
Additive/ies (if classified)	-

SECTION 4
FIRST AID MEASURES

4.1 Description of the first aid measures

- *Eye contact*: Wash immediately with large amounts of water or normal saline. Keep eyelid open during the washing. Get medical advice if adverse symptoms will appear.
- *Skin contact*: Remove contaminated clothes (eventually shoes). Wash affected area with soap or mild detergent and large amount of water until no evidence of substance remains. Get medical advice if adverse symptoms will appear.
- *Ingestion*: If swallowed wash mouth with large amounts of water provided person is conscious. If victim is conscious and alert, give milk or water. Get medical advice and show the label/container.

- Inhalation	Remove the person from the exposed area to fresh air immediately. If breathing has stopped perform artificial respiration, keep person warm and at rest. Get medical advice if the exposure was significant in terms of quantity or time.

4.2 Most important symptoms and effects (acute and delayed)

- Acute effects	Possible eye, skin, gastrointestinal, and/or respiratory tract irritation
- Delayed effects:	The most frequently reported adverse reactions were related to sexual function. Possible hypersensitization .

4.3 Indication of any immediate medical attention and special treatment needed

- Medical monitoring:	In case of ingestion or prolonged exposure
- Antidotes, if known	unknown
- Contraindications	unknown
- Immediate treatment at workplace	not known

SECTION 5
FIREFIGHTING MEASURES

5.1 Extinguishing media

- Suitable estinguishing media	Water spray or chemical foam, dry foam, CO_2.
- Unsuitable estinguishing media	not known

5.2 Special hazards arising from the substance

- Hazardous combustion products	May generate toxic fumes of Cox and NOx.
- Other special hazards	not known

5.3 Advice fo firefighters

- Technical actions for protection	Keep containers cool with water.
- Special protective equipment for firefighters	Wear boots, overalls, gloves, eye and face protection and breathing apparatus. Equipment must be conformed with EN criteria and used in highest condition of protection on the basis of the information reported in the previous sub-sections

SECTION 6
ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel

Wear appropriate protective equipment (see Section 8) to prevent contamination of the skin, eyes and personal clothing.
In case of fire and/or and explosions avoid breathing fumes and vapors. Use a self-contained breathing apparatus (SCBA) and appropriate protective clothing. The fumes can be eliminated by spraying with water.
See also section 8

- **For emergency responders**
See section 8.

6.2 Environmental precautions

In case of accidental release in the environment avoid that the substance can reach drains, surface water and ground water. Contact local authorities in case of environmental release.

6.3 Methods and material for containment and clearing up

- *Containment procedures:*	Coverage of the discharges
- *Cleaning up procedures:*	Recover the substance for suction or other mechanical means and wash the area with plenty of water and detergents. Store the material into a company that specializes pending disposal. Containers must be cleaned up and disposed of as waste remediation above.

6.4 Reference to other sections

See also section 8 and 13.

SECTION 7
HANDLING AND STORAGE

7.1. Precautions for safe handling

- *Recommandation for handling:*	Handle away from sparkles and flames - sources of ignition Handle in a well ventilated place Avoid contact with incompatible materials Wear suitable Personal Protection Equipment (see section 8) Keep the substance away from drains, surface or ground waters
- *Recommandation for personal hygiene:*	Do not absolutely eat, drink and smoke in the working areas Wash hands after handling the substance Remove contaminated clothing and protective equipment before entering eating areas

7.2. Condition for safe storage including any incompatibilities

The substance is not classified for any physical and chemical properties and no risk management is foreseen.

Other advice

	Store at controlled room temperature
- *Ventilation requirements*	Use in a well ventilated place at room temperature
- *Containers*	Keep containers tightly closed and correctly labeled
- *Specific design of storage rooms*	Not requested on the base of the classification
- *Quantity limits for storage*	Not requested on the base of the classification
- *Packaging compatibilities*	See also section 10.5

7.3. Specific end use(s)

- Recommendation for specific final use(s): Active Pharmaceutical Principle

	YES	NO
- Exposure scenario attached		X
- Chemical Safety Assessment (CSA) attached		X
- Industry or sector specific guidance available and attached		X

SECTION 8
EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

- National/European Occupational Exposure Limits	unknow
- Other National/European Occupational Exposure Limits	unknow
- Recommended monitoring procedures	The measurement of substances in the workplace must be carried out with standardized methods (eg EN 689:1997: Workplace atmospheres - Guide for assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy; UNI EN 482:2006: atmospheres in the workplace - General requirements for the provision of procedures for the measurement of chemical agents) or, failing that, with appropriate methods.
- DNEL values (components)	unknow
- PNEC values (components)	unknow

8.2. Exposure controls

	YES	NO
- Exposure scenario attached		X
- Chemical Safety Assessment (CSA) attached		X

8.2.1. Appropriate engineering controls

The adoption of the most appropriate technical controls is also based on the local Risk Assessment done by the employer in its workplace conditions (use of the substance) when a unique and standardized exposure scenario described in a dossier registered REACH is not available.

8.2.2. Individual protection measures, such as Personal Protective Equipment (PPE)

a) Eye and Face protection	Safety goggles as for EN 166; facial shield
b) Skin protection	
- *hands protection*	Wear protective gloves. Gloves resistant to chemical agents as for the EN 374, parts 1, 2 e 3 and the European Directive 89/89/CEE. The glove material has to be made of rubber or polyethylene impermeable and resistant to the substance. Make the choice of the glove material on consideration of the penetration times, rates of diffusion and degradation. The selection of suitable gloves not only depends on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- *other, body protection*	Select the suitable protective equipment based on the activity of use and possible exposure. Wear gauntlets, boots, bodysuit and other devices in accordance with EN 13982.

c) Respiratory protection	Dust mask with approved dust filter. Use only devices approved by the Competent Authorities such as NIOSH (USA) and CEN (EU) In the case of brief exposure or minimal exposure use respiratory filter; in case of intensive and sustained exposition wear self-contained breathing. Where risk assessment shows air-purifying respirators are appropriate use a dust mask type P3 (EN 143) respirator
d) Thermal hazards	Not foreseen in the standard use. Assess possible Personal Protection Equipment on the basis of specific uses of the substance.

8.2.3 Environmental exposure controls

	YES	NO
- Exposure scenario attached		X
- Chemical Safety Assessment (CSA) attached		X

SECTION 9
PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance:	white or whitish solid (Crystalline powder)
Odor:	-
Odour threshold:	-
pH:	Data not available in the literature search carried out
Melting point/freezing point:	252 ÷ 254 °C (1)
Boiling point:	576.6 °C at 760 mmHg (predicted) (2)
Flash point:	177.4 °C (predicted) (2)
Auto-ignition temperature:	Data not available in the literature search carried out
Surface tension:	37.7 dyne/cm (predicted) (2)
Vapour pressure:	7.47x 10^{-12} mmHg at 25°C (predicted) (1)
Relative density:	1,065 g/cm³ (predicted) (2)
Water solubility:	Slightly soluble; 11.7 mg/l (1)
Organic solvent solubility:	soluble in chloroform and in lower alcohol solvents
Partition coefficient Octonol/water (Log Kow):	3.03 (1)
Explosive properties:	Data not available in the literature search carried out
Oxidising properties:	Data not available in the literature search carried out

9.2. Other information

Henry's Law Constant (25°C):	3.77 x 10^{-11} atm-m³/mole (predicted) (1)

SECTION 10
STABILITY AND REACTIVITY

10.1. Reactivity

Stable in normal conditions of storage.

10.2. Chemical stability

The substance is stable at the normal condition of temperature and pressure and if stored in closed containers in well ventilated and cool place.

	NO	YES	Used stabiliser
- Stabilisers:	X	-	
- Change in physical appearance	X	-	

10.3. Possibility of hazardous reactions

	NO	YES
- Possibility of an exothermic reaction:	X	-
- Possibility of a reaction releasing excessive pressure	X	-
- Possible degradation with instable product formation	X	-

10.4. Condition to avoid

Keep protected from light, humidity and high temperatures.

10.5. Incompatible materials

Strong oxidizing agents

10.6. hazardous decomposition products

If heated at high temperatures, decomposes re leasing fumes and toxic gases of COx and NOx.

SECTION 11
INFORMATION ON TOXICOLOGICAL EFFECTS

- **Exposure routes:**	YES	NO
- Inhalation:	X	
- Ingestion:	X	
- Skin contact:	X	
- Eye contact:	X	

- Effects (acute, delayed, chronic) following the exposure (short and/or prolonged):

- *Inhalation:* May be damage fertility or the unborn child.
  May be harmful or sensitizing by inhalation
- *Ingestion:* Harmful if swallowed
- *Skin contact:* May be irritant or sensitizing.
- *Eye contact:* May be irritant

-Toxico-kinetics information (ADME=Adsorption,**D**istribution,**M**etabolism,**E**xcretion**):** [3]

Absorption: In a study of 15 healthy young subjects, the mean bioavailability of finasteride 5 mg tablets was 63% (range 34 to 108 %), based on the ratio of area under the curve (AUC) relative to an intravenous (IV) reference dose. Maximum finasteride plasma concentration averaged 37 ng/mL (range, 27 to 49 ng/mL) and was reached 1 to 2 hours postdose. Bioavailability of finasteride was not affected by food.

Distribution: Approximately 90% of circulating finasteride is bound to plasma proteins. There is a slow accumulation phase for finasteride after multiple dosing. Finasteride has been shown to cross the blood brain barrier but does not appear to distribute preferentially to the CSF.

The amount of finasteride in semen was estimated to be 50- to 100-fold less than the dose of finasteride (5 mcg) that had no effect on circulating DHT levels in men.

Metabolism: Finasteride is extensively metabolized in the liver, primarily via the cytochrome P450 3A4 enzyme subfamily. Two metabolites, the t-butyl side chain monohydroxylated and monocarboxylic acid metabolites, have been identified that possess no more than 20% of the 5α-reductase inhibitory activity of finasteride

Elimination**:** mean elimination half-life in plasma was 6-8 hours . Following an oral dose in man, a mean of 39% was excreted in the urine in the form of metabolites; 57% (range, 51 to 64 %) was excreted in the feces.

- Acute toxicity effects:

- *Oral:* [1]	LD50 Orale - ratto 418 mg/kg Effects: Behavioral - somnolence (general depressed activity). Gastrointestinal - Ulceration or bleeding from stomach. Respiratory depression. LD50 Orale - mouse 486 mg/kg Note: Behavioral - somnolence (general business depression), ataxia. Lungs, thorax or respiration – respiratory depression LD50 oral dog > 1000 mg/kg Effects: Gastrointestinal: nausea or vomiting
- *Dermal:*	Data not available in the literature search carried out
- *Inhalation:*	Data not available in the literature search carried out
- *Other effects* [1]	LD50 Intraperitoneal Rat 885 mg/kg Effects: Behavioral - somnolence (general depressed activity). Gastrointestinal - Ulceration or bleeding from small intestine, peritonitis LD50 Intraperitoneal mouse 372 mg/kg Effects: Behavioral - somnolence (general depressed activity), ataxia. Lungs, thorax or respiration – respiratory depression LD50 subcutaneous mouse/rat > 2000 mg/kg
RTECS no.:	**CL5245000**

- Corrosion/Irritation effects: Data not available in the literature search carried out

- Severe ocular lesion *:* Data not available in the literature search carried out

- Sensitisation: Data not available in the literature search carried out

- **Repeated dose toxicity** (experimental.): Data not available in the literature search carried out

- CMR effects:

- **Germinal cell mutagenicity** [2]:

No evidence of mutagenicity was observed in an in vitro bacterial mutagenesis assay, a mammalian cell mutagenesis assay, or in an in vitro alkaline elution assay. In an in vitro chromosome aberration assay, using Chinese hamster ovary cells, there was a slight increase in chromosome aberrations. These concentrations correspond to 4000 to 5000 times the peak plasma levels in man given a total dose of 5 mg. In an in vivo chromosome aberration assay in mice, no treatment-related increase in chromosome aberration was observed with finasteride at the maximum tolerated dose of 250 mg/kg/day (228 times the human exposure) as

determined in the carcinogenicity studies.

- **Carcinogenicity** [3]:

No evidence of a tumorigenic effect was observed in a 24-month study in Sprague-Dawley rats receiving doses of finasteride up to 160 mg/kg/day in males and 320 mg/kg/day in females. These doses produced respective systemic exposure in rats of 111 and 274 times those observed in man receiving the recommended human dose of 5 mg/day. All exposure calculations were based on calculated AUC for animals and mean AUC for man (0.4 mcg•hr/mL).

In a 19-month carcinogenicity study in CD-1 mice, a statistically significant ($p \leq 0.05$) increase in the incidence of testicular Leydig cell adenomas was observed at a dose of 250 mg/kg/day (228 times the human exposure). In mice at a dose of 25 mg/kg/day (23 times the human exposure, estimated) and in rats at a dose of ≥40 mg/kg/day (39 times the human exposure) an increase in the incidence of Leydig cell hyperplasia was observed. A positive correlation between the proliferative changes in the Leydig cells and an increase in serum LH levels (2- to 3-fold above control) has been demonstrated in both rodent species treated with high doses of finasteride. No drug related Leydig cell changes were seen in either rats or dogs treated with finasteride for 1 year at doses of 20 mg/kg/day and 45 mg/kg/day (30 and 350 times, respectively, the human exposure) or in mice treated for 19 months at a dose of 2.5 mg/kg/day (2.3 times the human exposure, estimated).

- **Reproductive toxicity** [2]:

Because of the ability of Type II 5α-reductase inhibitors to inhibit the conversion of testosterone to DHT, finasteride may cause abnormalities of the external genitalia of a male fetus of a pregnant woman who receives finasteride.

In female rats, low doses of finasteride administered during pregnancy have produced abnormalities of the external genitalia in male offspring.

Administration of finasteride to pregnant rats at doses ranging from 100 mcg/kg/day to 100 mg/kg/day (1 to 1000 times the recommended human dose of 5 mg/day) resulted in dose-dependent development of hypospadias in 3.6 to 100% of male offspring. Pregnant rats produced male offspring with decreased prostatic and seminal vesicular weights, delayed preputial separation and transient nipple development when given finasteride at ≥30 mcg/kg/day and decreased anogenital distance when given finasteride at ≥3 mcg/kg/day. The critical period during which these effects can be induced in male rats has been defined to be days 16 to 17 of gestation. The changes described above are expected pharmacological effects of drugs belonging to the class of Type II 5α-reductase inhibitors and are similar to those reported in male infants with a genetic deficiency of Type II 5α-reductase. No abnormalities were observed in female offspring exposed to any dose of finasteride in utero .

No developmental abnormalities have been observed in first filial generation (F) male or female offspring resulting from mating finasteride-treated male rats with untreated females. Administration of finasteride at 3 mg/kg/day during the late gestation and lactation period resulted in slightly decreased fertility in F male offspring. No effects were seen in female offspring.

No evidence of malformations has been observed in rabbit fetuses exposed to finasteride in utero from days 6 to 18 of gestation at doses up to 100 mg/kg/day. However, effects on male genitalia would not be expected since the rabbits were not exposed during the critical period of genital system development.

In the rhesus monkey (gestation days 20 to 100), a species more predictive of human development than rats or rabbits. Intravenous administration of finasteride to pregnant monkeys at doses as high as 800 ng/day resulted in no abnormalities in male fetuses. In confirmation of the relevance of the rhesus model for human fetal development, oral administration of a dose of finasteride to pregnant monkeys resulted in external genital abnormalities in male fetuses.

No other abnormalities were observed in male fetuses and no finasteride-related abnormalities were observed in female fetuses at any dose.

- Specific Target Organ Toxicity (STOT)-single exposure:

Data not available in the literature search carried out

- Specific Target Organ Toxicity (STOT)- repeated exposure :

Data not available in the literature search carried out

- Aspiration hazards: Data not available in the literature search carried out

- Epidemiological information: [3]

It is not known whether finasteride is excreted in human milk.

SECTION 12
ECOLOGICAL INFORMATION

12.1. Toxicity

Daphnia magna LC50: 21 mg/L/48 hr
Rainbow trout LC50: 19.6 mg/L/96 hr

12.2. Persistence and degradability

Data not available in the literature search carried out

12.3. Bioaccumulative potential

BCF= 169.98 (predicted) [2]
Log Pow = 3.03 (predicted) [1]

12.4. Mobility in soil

Data not available in the literature search carried out

12.5. Results of PBT e vPvB assessment

Assessment is not available - in relation to the value of logPow a; on the basis of ecotoxicological values the substance is not classified dangerous for the environment and a low bioaccumulation potential is expected.
Because it can interfere with the metabolism of testosterone in fish it may be harmful to aquatic organisms.

12.6. Other adverse effects

Not known

SECTION 13
DISPOSAL CONSIDERATION

13.1. Waste treatment methods

	Incineration	Recycling	Landfilling
- Mixture wastes:	X		
- Contaminated packaging:		X	

Should never be disposed through wastewater.
Refers to Community/National/Local requirements concerning the waste disposal.

SECTION 14
TRANSPORT INFORMATION

The substance is not classified for transport.

SECTION 15
REGULATORY INFORMATION

15.1 Safety, Health and Environmental regulation/legislation specific for the mixture or its ingredients

Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work and following amendment and National reinforcements..

Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to the personal protective equipment

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) Official Journal L 131 , 05/05/1998 P. 0011 - 0023

Regulation (EC) no 689/2008 of the european parliament and of the council of 17 June 2008 concerning the export and import of dangerous chemicals.

15.2. Chemical Safety Assessment

	YES	NO
- Exposure scenario attached		X
- Chemical Safety Assessment (CSA) attached		X

SECTION 16
OTHER INFORMATION

Revisions:

- **Revision n. 03 dated** January 2011 (regarding all sections in according to Regulation no. 453/2010).

Bibliographic sources:

(1) ChemIDplus Lite data base, search for Finasteride
(2) Chemspider data base, search for Exemestane
(3) Daily Med, Current Medication Information, FINASTERIDE tablet

Acronyms

- ACGIH: American Conference of Governmental Industrial Hygienists
- ADR: Agreement concerning the carriage of dangerous goods by Road
- BCF: Bioaccumulative factor
- BEI : Biological Esposure Indices (Indici di esposizione biologica)
- CAS: Chemical Abstract Service (division of the American Chemical Society
- CLP: Classification, Labelling and Packaging
- CMR: Carcinogens, Mutagens, Toxic for re production substances
- EINECS: European Inventory of existing Commercial Substances

- EPA: US Environmental Protection Agency
- GHS: Globally Harmonised System
- IARC: International Agency for Research on Cancer
- IATA: International Air Transport Association Code
- IMDG: International Maritime Dangerous Goods Code
- IUPAC: International Union of Pure and Applied Chemistry
- LOEL: Lowest Observed Effect Level
- NOAEL: No Observed Adverse Effect Level)
- NTP: National Toxicology Program
- OEL: Occupational Exposure Limit
- OSHA: Occupational Safety and Health Administration
- PPE : Personal protective Equipment
- PBT: Persistent, Bioaccumulative and Toxic substances
- RID: Regulation concerning the International carriage of Dangerous goods by rail
- TLV/TWA: Threshold Limit Value/Threshold Weighted Average
- vPvB: very Persistent, very Bioaccumulative

Information related to the regulation CE/1272/2008

List of hazards statements

H360FD:	**May damage fertility or the unborn child**

List of P statements

Prevention	
P202	**Do not handle until all safety precautions havebeen read and understood.**
P281	**Use personal protective equipment as required.**
Reaction	
P301+312	**IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.**
P308+P313:	**IF exposed or concerned: Get medical advice/attention.**
Storage	
P405	**Store locked up.**
Disposal	
P501:	**Dispose of contents/container in accordance with local/regional/ national/international regulation.**

Information related to the Directive 67/ 548/ CEE, Directive 1999/45/CE and Regulation (CE) n. 1907/2006

R phrases

R22	**Harmful if ingested.**
R60:	**May impair fertility.**
R61:	**May cause harm to the unborn child.**
R52/53	**Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment**

Information on workers training
Follow criteria of Directive 98/24/CE, its amendments and National reinforcements
Restriction of use : None
Substance under authorisation : no

DISCLAIMER
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mentioned in section 1, unless they are given adequate written information received on how to handle the material. The provider of this document can not provide any warnings about the dangers of ' use or interaction with other chemicals or materials. And 'the user's safe use of the product, the product suitability for the purpose for which it is applied and proper disposal. The information below should not be considered a declaration or guarantee, either expressed or implied, of merchantability, fitness for a particular purpose, quality, or any other. The information contained in this SDS are in accordance with Annex I of Regulation No 453/2010/EU.

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