MOMETASONE FUROATE MONOHYDRATE

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:	Mometasone Furoate Monohydrate
Other names (if available): Name in Annex VI-CLP: Name reported in the inventory of harmonized classification and labelling:	Pregna-1,4-diene-3,20-dione,9,21-dichloro-17-[(2'-furanylcarbonyl)oxy]-11-hydroxy-16-methyl-(11β,16a) unlisted not available
CAS number	141646-00-6
REACH registration number	Exempt of registration

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

Relevant use(s)	Anti infiammatory - 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
Reproductive toxicity	**Repr. Cat. 2**	**H361d**	**Suspected of damaging the unborn child.**

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

Classification	Risk phrases	
Repr. Cat 3, R63	**R63**	**Possible risk of harm to the unborn child.**

Main adverse effects

Physico-chemical effects — No adverse effects known.

Health effects — This material is a potent topical steroid. The incidence of adverse effects from therapeutic use of corticosteroids increases with dose and duration of exposure; effects are rare with administration of less than three weeks.
Glucocorticoid effects may include bone fractures, back pain, joint pain or stiffness, weakness, high blood sugar, high blood pressure, increased appetite, infection, delayed wound healing, thinning skin, bruising, purple lines on skin, increased hair growth, acne, redistribution of body fat, menstrual irregularities, impotence, headache, increased sweating, eye pain, change in vision, and mental or behavioral changes. The mineralocorticoid actions of this material may cause disruption of fluid and electrolyte imbalance, causing swelling, increased blood pressure, confusion, lightheadedness, nausea, vomiting, numbness, and tremors. Causes depression of the respiratory system, dry nose.
Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Environmental effects — No adverse effects known.

See also sections from 9 to 12

2.2 Label elements

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

Warning	
Signal Word	**Warning**
Hazard indication (H))[1]	**H361d - Suspected of damaging the unborn child.**
Safety statements (P)[1]	
- Prevention	**P201, P202, P281**
- Reaction	**P308+313**
- Storage	**P405**
- Disposal	**P501**

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

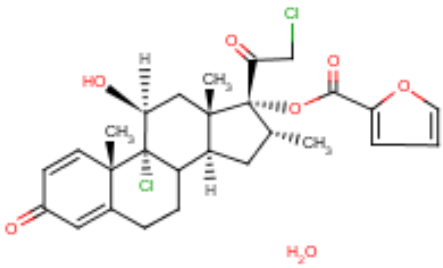
2.3 Other hazards (which do not results in the classification)

	YES	NO
The substance satisfies the PBT criteria		
- PBT		X
- vPvB		X

- Health hazards: May be harmful if ingested, 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; synthetic corticosteroid.

Name of the component	Mometasone Furoate Monohydrate
Concentration	Pure substance
Structural formula	
Chemical formula	$C_{27}H_{30}Cl_2O_6 \cdot H_2O$
Molecular weight	539,44 g/mol
Substance with Community OEL	No
CAS name	Pregna-1,4-diene-3,20-dione, 9,21-dichloro-17-[(2-furanylcarbonyl)oxy]-11-hydroxy-16-methyl-, hydrate (1:1), (11.beta.,16.alpha.)-
CAS number	141646-00-6
IUPAC name	Pregna-1,4-diene-3,20-dione, 9,21-dichloro-17-((2- furanylcarbonyl)oxy)-11-hydroxy-16-methyl-, monohydrate, (11beta,16alpha)-
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 if adverse symptoms will appear.
- 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. Possible allergic reaction to material if inhaled, ingested or in contact with skin. Causes depression of the respiratory system, dry nose.
- Delayed effects:	Possible hypersensitization, acne or other skin problems, hip or shoulder pain, fullness in face, swelling of feet or lower legs, menstrual irregularities, nausea, vomiting, irregular heartbeat, muscle cramps, weakness, osteoporosis, increased susceptibility to infection, psychosis, and eye problems.

4.3 Indication of any immediate medical attention and special treatment needed

Medical monitoring:	In case of prolonged exposure
- Antidotes, if known	unknow
- Contraindications	unknow
- 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 Cl^-.
- 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
	Store in the original package
- *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:	Odourless
Odour threshold:	-
pH:	Data not available in the literature search carried out
Melting point/freezing point:	220 °C
Boiling point:	Data not available in the literature search carried out

Flash point:	Data not available in the literature search carried out
Auto-ignition temperature:	Data not available in the literature search carried out
Surface tension:	Data not available in the literature search carried out
Vapour pressure:	Data not available in the literature search carried out
Density:	Data not available in the literature search carried out
Water solubility:	Insoluble
Organic solvent solubility:	Soluble in acetone and dichloromethane. Slightly soluble in ethanol (96%)
Partition coefficient Octonol/water (Log Kow):	Data not available in the literature search carried out
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

Molar Volume:	Data not available in the literature search carried out
Polarizability:	Data not available in the literature search carried out

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 Cl^-.

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: Suspected of damaging the unborn child.
May be harmful or sensitizing by inhalation. May causes depression of the respiratory system, dry nose.

- Ingestion: May be 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**):** (1)

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle and the integrity of the epidermal barrier. Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

Absorption: Following a inhaled dose of mometasone furoate (anhydrous) inhalation powder to healthy human subjects, plasma concentrations were shown to be near or below the lower limit of quantitation for the assay.The mean peak plasma concentrations at steady state ranged from approximately 94 to 114 pcg/mL and the mean time to peak levels ranged from approximately 1.0 to 2.5 hours.

Distribution: Based on the study employing a 1000 mcg inhaled dose of tritiated mometasone furoate (anhydrous) inhalation powder in humans, no appreciable accumulation of mometasone furoate in the red blood cells was found. Following an intravenous 400 mcg dose of mometasone furoate, the plasma concentrations showed a biphasic decline, with a mean terminal half-life of about 5 hours and t he mean steady-state volume of distribution of 152 L. The in vitro protein binding for mometasone furoate was reported to be 98% to 99% (in a concentration range of 5–500 ng/mL).

Metabolism: Studies have shown that mometasone furoate (anhydrous) is primarily and extensively metabolized in the liver of all species investigated and undergoes extensive metabolism to multiple metabolites. In vitro studies have confirmed the primary role of CYP 3A4 in the metabolism of this compound; however, no major metabolites were identified.

Excretion: Following an intravenous dosing, the terminal half-life was reported to be about 5 hours. Following an inhaled dose, the radioactivity is excreted mainly in the feces (a mean of 74%), and to a small extent in the urine (a mean of 8%) up to 7 days. No radioactivity was associated with unchanged mometasone furoate (anhydrous) in the urine.

- Acute toxicity effects:

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

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

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

- Other effects: (2) LD_{50} subcutaneous – rat = 300 mg/kg (respiratory depression, body temperature decrease – for mometasone furoate anhydrous)
LDLo subcutaneous – mouse = 1 gm/kg (for mometasone furoate anhydrous)

RTECS Number: TU3822000 (mometasone furoate anhydrous)

- 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.): (2)

TDLo administration onto the skin – rat = 10.920 mg/kg/52W-C	Changes in lungs, thorax or respiration. Endocrine - Adrenal cortex hypoplasia. Blood - Changes in spleen.	for mometasone furoate anhydrous
TDLo administration onto the skin – dog = 36.400 mg/kg/52W-C	Changes in liver and blood. Endocrine - Adrenal cortex hypoplasia	for mometasone furoate anhydrous

- CMR effects:

- **Germinal cell mutagenicity** (1): Mometasone furoate anhydrous increased chromosomal aberrations in an in vitro Chinese hamster ovary cell assay, but did not increase chromosomal aberrations in an in vitro Chinese hamster lung cell assay. Mometasone furoate was not mutagenic in the Ames test or mouse lymphoma assay, and was not clastogenic in an in vivo mouse micronucleus assay, a rat bone marrow chromosomal aberration assay, or a mouse male germ-cell chromosomal aberration assay. Mometasone furoate also did not induce unscheduled DNA synthesis in vivo in rat hepatocytes.

- **Carcinogenicity** (1):

In a 2-year carcinogenicity study in Sprague Dawley rats, mometasone furoate anhydrous demonstrated no statistically significant increase in the incidence of tumors at inhalation doses up to 67 mcg/kg (approximately 8 times the maximum recommended daily inhalation dose in adults on an AUC basis and 2 times the maximum recommended daily inhalation dose in pediatric patients based on an mcg/m basis). In a 19-month carcinogenicity study in Swiss CD-1 mice, mometasone furoate demonstrated no statistically significant increase in the incidence of tumors at inhalation doses up to 160 mcg/kg (approximately 10 times the maximum recommended daily inhalation dose in adults on an AUC basis and 2 times the maximum recommended daily inhalation dose in pediatric patients based on an mcg/m basis).

- **Reproductive toxicity** (1):

In reproductive studies in rats, impairment of fertility was not produced by subcutaneous doses up to 15 mcg/kg (approximately 6 times the maximum recommended daily inhalation dose in adults on an AUC basis).

Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. However, experience with oral corticosteroids suggests that rodents are more prone to teratogenic effects from corticosteroid exposure than humans.

When administered to pregnant mice, rats, and rabbits, mometasone furoate increased fetal malformations and decreased fetal growth (measured by lower fetal weights and/or delayed ossification). Dystocia and related complications were also observed when mometasone furoate was administered to rats late in gestation.
In a mouse reproduction study, subcutaneous mometasone furoate produced cleft palate at approximately one third of the maximum recommended daily human dose (MRHD) for adults on an mcg/m basis and decreased fetal survival at approximately 1 time the MRHD. No toxicity was observed at approximately one-tenth of the MRHD.
In a rat reproduction study, mometasone furoate produced umbilical hernia at topical dermal doses approximately 6 times the MRHD and delays in ossification at approximately 3 times the MRHD.
In another study, rats received subcutaneous doses of mometasone throughout pregnancy or late in gestation. Treated animals had prolonged and difficult labor, fewer live births, lower birth weight, and reduced early pup survival at a dose that was approximately 6 times the MRHD for adults on an area under the curve (AUC) basis. Similar effects were not observed at approximately 3 times the MRHD.
In rabbits, mometasone furoate caused multiple malformations (e.g., flexed front paws, gallbladder agenesis, umbilical hernia, hydrocephaly) at topical dermal doses approximately 3 times the maximum recommended daily inhalation dose in adults on an mcg/m basis. In an oral study, mometasone furoate increased resorptions and caused cleft palate and/or head malformations (hydrocephaly and domed head) at a dose less than the MRHD for adults based on AUC. At a dose approximately 2 times the

MRHD in adults based on AUC, most litters were aborted or resorbed.

Pregnancy category C: There are no adequate and well-controlled studies in pregnant women. Animal reproduction studies in mice, rats, and rabbits revealed evidence of teratogenicity.

- 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: (1)
There are no adequate and well-controlled studies of mometasone furoate use in pregnant women.
Hypoadrenalism may occur in infants born to women receiving corticosteroids during pregnancy.
It is not known if mometasone furoate is excreted in human milk. Because other corticosteroids are excreted in human milk, caution should be used when mometasone furoate is administered to nursing women.
Orally inhaled corticosteroids, including mometasone furoate, may cause a reduction in growth velocity when administered to pediatric patients.
In clinical trials glaucoma, increased intraocular pressure, and cataracts have been reported in 8 of 3007 patients following the administration of mometasone furoate.
Decreases in bone mineral density (BMD) have been observed with long-term administration of products containing inhaled corticosteroids, including mometasone furoate. The clinical significance of small changes in BMD with regard to long-term outcomes is unknown.

SECTION 12
ECOLOGICAL INFORMATION

12.1. Toxicity

Data not available in the literature search carried out

12.2. Persistence and degradability

Data not available in the literature search carried out

12.3. Bioaccumulative potential

Data not available in the literature search carried out

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

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** February 2011 (regarding all sections in according to Regulation no. 453/2010).

Bibliographic sources:

(1) Daily Med, Current Medication Information, ASMANEX (mometasone furoate - anhydrous) inhalant
(2) RTECS Database for CAS 83919-23-7.

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

H361d:	**Suspected of damaging the unborn child.**

List of P statements

Prevention

P201	**Obtain special instructions before use.**
P202	**Do not handle until all safety precautions have been read and understood.**
P281	**Use personal protective equipment as required.**

Reaction

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
R63: **Possible risk of harm to the unborn child.**

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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