

DROSPIRENONE CRS

Safety Data Sheet

Safety Data Sheet in accordance with Regulation (EC) No. 1907/2006, as amended.

Date of issue: 27/06/2013

Revision date: 27/06/2013

Supersedes: 01/12/2009

Version: 3.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Substance
Trade name : DROSPIRENONE CRS
EC no : 266-679-2
CAS No : 67392-87-4
Product code : Y0001105
Other means of identification : RTECS No : WH1299000

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

1.2.1. Relevant identified uses

Main use category : The product is intended for research, analysis and scientific education.
Use of the substance/mixture : For professional use only
Function or use category : Laboratory chemicals

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare
EDQM, Council of Europe
F-67081 Strasbourg
T +33(0)388412035 - F +33(0)388412771

1.4. Emergency telephone number

Emergency number : +44(0)1235239670

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Repr. 1B H360F
Repr. 1B H360D
Acute Tox. 4 (Oral) H302
Carc. 2 H351
Lact H362
Aquatic Chronic 2 H411

Full text of H-phrases: see section 16

Classification according to Directive 67/548/EEC or 1999/45/EC

Carc.Cat.3; R40
Repr.Cat.2; R60
Repr.Cat.2; R61
Xn; R22
N; R51/53
R64

Full text of R-phrases: see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

DROSPIRENONE CRS

Safety Data Sheet

Safety Data Sheet in accordance with Regulation (EC) No. 1907/2006, as amended.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



Signal word (CLP) :

Danger

Hazard statements (CLP) :

H302 - Harmful if swallowed
H351 - Suspected of causing cancer
H360D - May damage the unborn child
H360F - May damage fertility
H362 - May cause harm to breast-fed children
H411 - Toxic to aquatic life with long lasting effects

Precautionary statements (CLP) :

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
P263 - Avoid contact during pregnancy/while nursing
P264 - Wash hands and other exposed areas thoroughly after handling
P273 - Avoid release to the environment
P281 - Use personal protective equipment as required
P301+P312 - IF SWALLOWED: call a POISON CENTER or doctor/physician if you feel unwell
P308+P313 - IF exposed or concerned: Get medical advice/attention
P330 - Rinse mouth
P391 - Collect spillage
P501 - Dispose of contents/container to : Hazardous waste. Comply with applicable regulations

2.3. Other hazards

Other hazards not contributing to the classification

: Exposure may produce an allergic reaction.

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Directive 67/548/EEC
DROSPIRENONE (Main constituent)	(CAS No)67392-87-4 (EC no)266-679-2	≤ 100	Carc.Cat.3; R40 Repr.Cat.2; R60 Repr.Cat.2; R61 Xn; R22 N; R51/53 R64

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
DROSPIRENONE (Main constituent)	(CAS No)67392-87-4 (EC no)266-679-2	≤ 100	Repr. 1B, H360F Repr. 1B, H360D Acute Tox. 4 (Oral), H302 Carc. 2, H351 Lact, H362 Aquatic Chronic 2, H411

Full text of R-, H- and EUH-phrases: see section 16

3.2. Mixture

Not applicable

DROSPIRENONE CRS

Safety Data Sheet

Safety Data Sheet in accordance with Regulation (EC) No. 1907/2006, as amended.

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures general : If you feel unwell, seek medical advice (show the label where possible). Delayed adverse effects possible. Active component. Pharmaceuticals. For further information refer to Summary of Product Characteristics.
- First-aid measures after inhalation : Move to fresh air in case of accidental inhalation. Assure fresh air breathing. Obtain medical attention if breathing difficulty persists.
- First-aid measures after skin contact : Rinse skin with water/shower. Wash with plenty of soap and water.
- First-aid measures after eye contact : Rinse with water while holding the eyes wide open. Contact lenses should be removed. Obtain medical attention if pain, blinking or redness persist.
- First-aid measures after ingestion : Rinse mouth out with water. The following symptoms may occur: (see section(s) : 2, 4.2). If you feel unwell, seek medical advice. Prolonged medical observation may be indicated. (see section(s) : 4.3). The affected person must rest and be kept under medical observation.

4.2. Most important symptoms and effects, both acute and delayed

- Symptoms/injuries : See Heading 2. Endocrine disorders. Nervous system disorders. Reproductive system and breast disorders. Excitement/restlessness.

4.3. Indication of any immediate medical attention and special treatment needed

In all cases of doubt, or when symptoms persist, seek medical attention. If possible show this sheet, if not available show packaging or label. If the occupational exposure limit is exceeded : Specific medical surveillance.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Small amounts: Use extinguishing media appropriate for surrounding fire. Extinguishing blanket. Carbon dioxide. Dry powder. Large amounts: Not applicable.
- Unsuitable extinguishing media : Water may be ineffective in firefighting due to low solubility.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

- Precautionary measures fire : Small amounts: Use normal individual fire protective equipment. Large amounts: Not applicable.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Avoid raising dust. Wear suitable protective clothing, gloves and eye or face protection. Avoid any direct contact with the product. Evacuate unnecessary personnel. Large amounts: Not applicable.

6.1.1. For non-emergency personnel

- Protective equipment : See Headings 7 and 8.
- Emergency procedures : Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection. Wear suitable protective clothing and gloves.

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

No additional information available

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Ensure waste is collected and contained. Clean thoroughly. Poorly soluble in water. Clean with the help of detergents. Collect all waste in suitable and labelled containers and dispose according to local legislation. Wash the non-recoverable remainder with : Sodium hypochlorite solution.

6.4. Reference to other sections

(see section(s) : 8, 13).

DROSPIRENONE CRS

Safety Data Sheet

Safety Data Sheet in accordance with Regulation (EC) No. 1907/2006, as amended.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Additional hazards when processed : Small amounts: See Heading 1. When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us. The attention of the user is drawn to the risks possibly incurred by using the product for any other purpose than that for which it was intended. Avoid contact during pregnancy/while nursing.
- Precautions for safe handling : Handle and open container with care. See Heading 8. Do not handle until all safety precautions have been read and understood. Avoid any direct contact with the product. Obtain special instructions before use.
- Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures. Small amounts: Material should be handled in a laboratory hood whenever possible.

7.2. Conditions for safe storage, including any incompatibilities

- Technical measures : Comply with applicable regulations.
- Storage conditions : To guarantee the quality and properties of the product, keep : dry, Keep in a cool, well-ventilated place away from heat. Store in original container. Store according to local legislation.
- Incompatible products : Strong oxidizing agents.

7.3. Specific end use(s)

See Heading 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

- Appropriate engineering controls : Material should be handled in a laboratory hood whenever possible.
- Personal protective equipment : Gloves. Safety glasses. Protective clothing. Dust production: dust mask with filter type P3.



- Hand protection : Gloves. Chemical resistant PVC gloves (to European standard EN 374 or equivalent).
- Eye protection : Wear eye protection. DIN EN 166.
- Skin and body protection : Lab coat. Wear suitable protective clothing. DIN EN 13034.
- Respiratory protection : Quarter mask (DIN EN 140). Wear appropriate breathing apparatus if air renewal not sufficient to maintain dust/vapour under TLV.

DROSPIRENONE CRS

Safety Data Sheet

Safety Data Sheet in accordance with Regulation (EC) No. 1907/2006, as amended.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: white. whitish. Powder.
Colour	: No data available
Odour	: Not applicable. See Heading 2, 4.2, 8.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 199 - 201 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Self ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Acetone. Methanol. Water: < 1 mg/l
Log Pow	: 3,08 at 20°C
Log Kow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions.

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

Small amounts: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us. Large amounts: Not applicable.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

Small amounts: None under normal use. Large amounts: Not applicable.

10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes. Large amounts: Not applicable.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Harmful if swallowed.

DROSPIRENONE CRS(67392-87-4)	
LD50 oral rat	500 - 2000 mg/kg
ATE (oral)	500,000 mg/kg

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified

DROSPIRENONE CRS

Safety Data Sheet

Safety Data Sheet in accordance with Regulation (EC) No. 1907/2006, as amended.

Germ cell mutagenicity	: Not classified
Carcinogenicity	: Suspected of causing cancer.
Reproductive toxicity	: May damage fertility. May damage the unborn child. May cause harm to breast-fed children.
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Potential Adverse human health effects and symptoms	: Avoid any direct contact with the product. Small amounts: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us. See first aid section of this material safety data sheet. Large amounts: Not applicable.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Small amounts: See Heading 2. Poorly soluble in water. No data available on ecotoxicity. Hazardous waste. Use suitable disposal containers. Large amounts: Not applicable.

DROSPIRENONE CRS(67392-87-4)

LC50 fishes 1	7 mg/l LC50-96 Hour - fish
EC50 Daphnia 1	> 7,8 mg/l EC50 - 48 Hour - Daphnia magna

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

DROSPIRENONE CRS(67392-87-4)

Log Pow	3,08 at 20°C
---------	--------------

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.
Waste disposal recommendations : Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point.

SECTION 14: Transport information

In accordance with ADR / RID / ADNR / IMDG / ICAO / IATA

14.1. UN number

UN-No : 3077
UN-No.(IATA) : 3077
UN-No. (IMDG) : 3077

14.2. UN proper shipping name

Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
Transport document description : UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, (E)

14.3. Transport hazard class(es)

Class (UN) : 9
Class (IATA) : 9
Class (IMDG) : 9
Hazard labels (UN) : 9



DROSPIRENONE CRS

Safety Data Sheet

Safety Data Sheet in accordance with Regulation (EC) No. 1907/2006, as amended.

14.4. Packing group

Packing group (UN) : III
Packing group (IMDG) : III

14.5. Environmental hazards

Dangerous for the environment :



Other information : No supplementary information available.

14.6. Special precautions for user

14.6.1. Overland transport

Hazard identification number (Kemler No.) : 90
Classification code (UN) : M7
Orange plates :



Tunnel restriction code : E
LQ : LQ27
Excepted quantities (ADR) : E1

14.6.2. Transport by sea

Ship Safety Act : Miscellaneous dangerous substances & articles
MFAG-No : 171

14.6.3. Air transport

Civil Aeronautics Law : Miscellaneous dangerous substances & articles

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

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

No REACH Annex XVII restrictions

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

DROSPIRENONE CRS

Safety Data Sheet

Safety Data Sheet in accordance with Regulation (EC) No. 1907/2006, as amended.

Full text of R-, H- and EUH-phrases::

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
Carc. 2	Carcinogenicity, Category 2
Lact	Reproductive toxicity, Additional category, Effects on or via lactation
Repr. 1B	Reproductive toxicity, Category 1B
Repr. 1B	Reproductive toxicity, Category 1B
H302	Harmful if swallowed
H351	Suspected of causing cancer
H360D	May damage the unborn child
H360F	May damage fertility
H362	May cause harm to breast-fed children
H411	Toxic to aquatic life with long lasting effects
R22	Harmful if swallowed
R40	Limited evidence of a carcinogenic effect
R51/53	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
R64	May cause harm to breastfed babies
N	Dangerous for the environment
Xn	Harmful

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product