

Product Name:
Issued:

Duphaston
Aug-08-2011



SAFETY DATA SHEET

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

1.1 Product Identifier

Product Name: Duphaston
Synonyms: Dydrogesterone tablets
List Number: 234915

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

Recommended use: Pharmaceuticals

1.3 Details of the supplier of the safety data sheet

Supplier: Abbott Products Operations AG
Hegenheimermattweg 127
4123 Allschwil
Switzerland

E-mail Address: Abbott.SDS@abbott.com

1.4 Emergency telephone number

Emergency Telephone: CHEMTREC: 1(800) 424-9300 (in USA and Canada)
or +1-703-527-3887 (international)

Section 2. Hazards identification

2.1 Classification of the substance or mixture

Regulation (EC) No 1272/2008

Specific target organ systemic toxicity (repeated exposure) Category 2

None

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Indication of danger: Xn - Harmful

Risk Phrases: R22 - Harmful if swallowed
R48 - Danger of serious damage to health by prolonged exposure

2.2 Label elements

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Section 2. Hazards identification



Signal Word: Warning

Hazard Statements: H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary Statements: P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P314 - Get medical advice/attention if you feel unwell
P501 - Dispose of contents/container to an approved waste disposal plant

2.3 Other hazards

Not determined

Section 3. Composition/information on ingredients

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Lactose 63-42-3	70-90	200-559-2		Not classified	No data available
Starch 9005-25-8	5-15	232-679-6		Not classified	No data available
Dydrogesterone 152-62-5	5-15	205-806-8	T; R48/25, N; R51-53	STOT RE 1 (H372) Aquatic Chronic 2 (H411)	No data available
Hydroxypropyl Methylcellulose 9004-65-3	1-5	NA		Not classified	No data available
Silica, Amorphous 112926-00-8	1-5	NA		Not classified	No data available
Titanium dioxide 13463-67-5	0.1-1	236-675-5		Not classified	No data available
Magnesium Stearate 557-04-0	0.1-1	209-150-3		Not classified	No data available

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

Section 4. First aid measures

4.1 Description of first aid measures

Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

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Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Protection of First-aiders: Use personal protective equipment

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms: None known from occupational exposure.

Medical Conditions Aggravated by Exposure: None known from occupational exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Notes To Physician: Treat symptomatically

Section 5. Firefighting measures

5.1 Extinguishing Media

Suitable Extinguishing Media: Use extinguishing agent suitable for type of surrounding fire

Unsuitable Extinguishing Media: Not determined

5.2 Special hazards arising from the substance or mixture

Special Exposure Hazards: Not determined

5.3 Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus and full protective gear

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal Precautions: Use personal protective equipment identified in Section 8.

6.2. Environmental precautions

Environmental Precautions: Should not be released into the environment.

6.3. Methods and material for containment and cleaning up

Methods for Cleaning Up: Recover product and place in an appropriate container for disposal.

Incompatibilities: Not determined.

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6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

Section 7. Handling and storage

7.1. Precautions for safe handling

Avoid contact with skin, eyes and clothing

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions.

7.3. Specific end use(s)

Recommended use: Pharmaceuticals

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	Abbott EEL	Skin Notation
Lactose 63-42-3	Not Applicable	None
Starch 9005-25-8	Not Applicable	None
Dydrogesterone 152-62-5	2.5 mcg/m ³	None
Hydroxypropyl Methylcellulose 9004-65-3	Not Applicable	None
Silica, Amorphous 112926-00-8	Not Applicable	None
Titanium dioxide 13463-67-5	Not Applicable	None
Magnesium Stearate 557-04-0	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Lactose 63-42-3	10 mg/m ³ total dust, 3 mg/m ³ respirable dust				
Starch 9005-25-8	10 mg/m ³ total dust for Starch			10 mg/m ³ (TWA) 4 mg/m ³ (TWA) 10 mg/m ³ (TWA)	
Hydroxypropyl Methylcellulose 9004-65-3	10 mg/m ³ total dust; 3 mg/m ³ respirable dust				
Silica, Amorphous 112926-00-8	10 mg/m ³				
Magnesium Stearate 557-04-0	10 mg/m ³ total dust				

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Starch 9005-25-8		10 mg/m ³ (VLA-ED)	3 mg/m ³ (MAK)	30 mg/m ³ (STEL) 12 mg/m ³ (STEL) 30 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)
Silica, Amorphous 112926-00-8			4 mg/m ³ (MAK)	

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8.2. Exposure controls

Engineering Controls: No special provisions are required under normal product use conditions. Use inside a process enclosure when handling the bulk formulation.

Respiratory Protection: Respiratory protection is not needed during normal product use. When handling the bulk formulation, an approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

Eyes: Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.

Gloves: Not needed during typical product use conditions. Wear impervious gloves when handling the bulk formulation.

Other PPE Data: Wear appropriate body coverings if contact may occur.

Environmental Exposure Controls: Not determined

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance: White Tablet

Odor: Not determined.

Odor Threshold: Not determined

pH: Not determined.

Boiling Pt. @ 760 mm Hg (°C): Not determined.

Melting/Freezing Point (°C): Not determined

Flash Point (°C): Not determined.

Evaporation Rate at 20°C: Not determined.

Flammability (Solid): Not determined.

Lower Explosive Limit: Not determined.

Upper Explosive Limit: Not determined.

Vapor Pressure (mm Hg): Not determined.

Vapor Density (Air = 1): Not determined.

Specific Gravity: Not determined.

Solubility(ies): Not determined.

Partition coefficient: n-octanol/water Not determined.

Autoignition Temp. (°C): Not determined.

Decomposition temperature (°C): Not Determined

Viscosity (centipoise): Not determined.

Explosion Severity: Not determined.

Oxidizer Properties: Not determined.

9.2. Other information

Not determined

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Section 10. Stability and reactivity

10.1. Reactivity

Not determined

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Hazardous reactions: Not determined.

Self-Heating Tendency: Not determined.

10.4. Conditions to avoid

None known

10.5 Incompatible materials

Not determined

10.6 Hazardous decomposition products

Carbon oxides, Nitrogen oxides (NO_x)

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Clinical Route
Dermal: Not determined.
Inhalation: Not determined.

Acute Toxicity - Oral: Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Lactose 63-42-3	LD50 >	5000	mg/kg	Mice Rats
Dydrogesterone 152-62-5	LD50 >	4640 7200 500	mg/kg	Rats Mice Dogs
Hydroxypropyl Methylcellulose 9004-65-3	LD50 >	2250	mg/kg	Rats

Acute Toxicity - Dermal: Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Dydrogesterone 152-62-5	LD50 >	2000	mg/kg	Rats

Acute Toxicity - Inhalation: Data for component (s) given below.

Chemical Name	Test	Value	Units	Species
Magnesium Stearate 557-04-0	LC 50 >	2000	mg/m ³ , 1 hour	Rats

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Other Toxicology Data: Data for component (s) given below:

Chemical Name	Test Type	Value	Units	Species	Comments
Dydrogesterone 152-62-5	LD 50 (sc) >	4640	mg/kg	Rats	

Corrosivity: Not determined.

Dermal Irritation: Did not produce skin irritation in rabbits.

Eye Irritation: Produced mild eye irritation in animal testing. Recovery after 48 hours.

Sensitization: Not determined.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: Not determined.

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Dydrogesterone 152-62-5	Uterus Mammary Gland	Rats Rabbits	0.6 0.3	mg/kg	Oral	2 years 12 months

Reproductive Effects: Not determined.

Carcinogenicity: Not determined.

Chemical Name	Site of Tumors	Species	Dosage	Route	Units	Duration
Dydrogesterone 152-62-5	None	Rats	36	Oral	mg/kg	2 years

Mutagenicity: Data for component (s) given below.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Dydrogesterone 152-62-5	Negative	Negative	Negative	Negative
Magnesium Stearate 557-04-0	No Data.	Negative	No Data.	No Data.

Aspiration hazard: Not determined

Notes:

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

Section 12. Ecological information

12.1. Toxicity

Data for component (s) given below.

Chemical Name	Percent	LC 50 (mg/l)	Species	Duration
Dydrogesterone 152-62-5	5-15	4.8 mg/L 5.2 mg/L	Zebra Fish Daphnia magna	96 Hours 48 Hours

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Chemical Name	Percent	EC 50 (mg/l)	Species	Duration
Dydrogesterone 152-62-5	5-15	8.9 mg/l	Algae	72 hours

12.2. Persistence and degradability

Data for component (s) given below.

Chemical Name	Percent	% Degradation	Duration
Dydrogesterone 152-62-5	5-15	7%	28 days

12.3. Bioaccumulative potential

Data for components given below.

Chemical Name	Percent	Log Po/w
Dydrogesterone 152-62-5	5-15	> 3

12.4. Mobility in soil

Not determined.

12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

Section 13. Disposal considerations

13.1 Waste treatment methods

Waste Disposal Methods: Disposal should be made in accordance with country, federal, state and local regulations.

Section 14. Transport information

ADR, DOT, ICAO/IATA, IMDG/IMO

Status: Not regulated

- 14.1. UN Number:** Not applicable
14.2. Proper shipping name: Not applicable
14.3. Hazard class: Not applicable
14.4. Packing group: Not applicable
14.5. Environmental hazard: Not applicable
14.6. Special Provisions: Not applicable

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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

International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Lactose 63-42-3	200-559-2	X	X	Not listed.	X
Starch 9005-25-8	232-679-6	X	X	Not listed.	X
Dydrogesterone 152-62-5	205-806-8	-	-	Not listed.	-
Hydroxypropyl Methylcellulose 9004-65-3	-	X	X	Not listed.	X
Silica, Amorphous 112926-00-8	-	-	X	Not listed.	X
Titanium dioxide 13463-67-5	-	-	-	Not listed.	-
Magnesium Stearate 557-04-0	209-150-3	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Lactose 63-42-3	-	8-(4)-389	X	X	KE-17416	
Starch 9005-25-8	(8)-98	-	X	X	KE-32128	
Dydrogesterone 152-62-5	(4)-1299	7-(1)-101 7-(1)-222	-	-	-	
Hydroxypropyl Methylcellulose 9004-65-3	(8)-196	-	X	X	KE-05368	
Silica, Amorphous 112926-00-8	(1)-548	-	X	X	KE-32733	
Titanium dioxide 13463-67-5	-	-	-	-	-	
Magnesium Stearate 557-04-0	(2)-611	-	X	X	KE-26390	

Legend

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

ISHL - Japan Industrial Safety and Health Law

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

Carcinogenicity Rating:

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Lactose	70-90	Not Listed	Not Listed	Not Listed
Starch	5-15	Not Listed	Not Listed	Not Listed
Dydrogesterone	5-15	Not Listed	Not Listed	Not Listed
Hydroxypropyl Methylcellulose	1-5	Not Listed	Not Listed	Not Listed
Silica, Amorphous	1-5	Not Listed	Not Listed	Not Listed

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Chemical Name	Percent	NTP:	IARC:	ACGIH:
Titanium dioxide	0.1-1	Not Listed	Not Listed	Not Listed
Magnesium Stearate	0.1-1	Not Listed	Not Listed	Not Listed

SARA 313 Information

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Lactose	70-90	No	Not Applicable	Not applicable
Starch	5-15	No	Not Applicable	Not applicable
Dydrogesterone	5-15	No	Not Applicable	Not applicable
Hydroxypropyl Methylcellulose	1-5	No	Not Applicable	Not applicable
Silica, Amorphous	1-5	No	Not Applicable	Not applicable
Titanium dioxide	0.1-1	No	Not Applicable	Not applicable
Magnesium Stearate	0.1-1	No	Not Applicable	Not applicable

Immediate Health: No
Delayed Health: No
Fire: No
Sudden Pressure: No
Reactivity: No

RCRA Status: Not determined.

Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

WHMIS Hazard Class: Not determined.

NFPA Rating:
 Health: 0
 Fire: 1
 Reactivity: 0

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

Section 16. Other information

Risk Phrases: R22 - Harmful if swallowed, R48 - Danger of serious damage to health by prolonged exposure

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

H315 - Causes skin irritation, H319 - Causes serious eye irritation, H332 - Harmful if inhaled, H372 - Causes damage to organs (a,b,c) through prolonged or repeated exposure if inhaled, H411 - Toxic to aquatic life with long lasting effects

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