

MATERIAL SAFETY DATA SHEET

Product:	Absorica™ (Isotretinoin) Capsules
Print Date:	Sept. 20, 2012

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name:	Absorica™ (Isotretinoin) Capsules
Company:	GALEPHAR Pharmaceutical Research, INC.
Address:	
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2. COMPOSITION/ INFORMATION OF INGREDIENTS

<i>Active Ingredient</i>	
Chemical name:	3,7-Dimethyl-9-(2,6,6-trimethyl-1-cyclohexen-1-yl)2-cis-4-trans-6-trans-8-trans-nonatetraenoic acid
CAS No:	[4759-48-2]

Other Ingredients

Stearoyl Macrogol Glycerides (Gelucire 50/13)	[9011-21-6]
Soybean Oil, USP	[8001-22-7]
Sorbitan Monooleate, NF (Span 80)	[1338-43-8]
Propyl Galate, NF	[121-79-9]

3. HAZARD IDENTIFICATION

Absorica™ must not be used by female patients who are or may become pregnant. May cause harm to the unborn child. Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

4. FIRST AID MEASURES

General Advice:	Remove contaminated clothing. First aid personnel should pay attention to their own safety.
Inhalation:	Keep patient calm. Remove to fresh air. Seek medical attention.
Skin:	Wash thoroughly with soap and water.
Eyes:	Immediately wash affected eyes for at least 15 minutes under running water with eyelids held open. Consult an eye specialist.
Ingestion:	Rinse mouth immediately and then drink plenty of water. Seek medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing measures:	Water spray. Dry extinguishing media.
Protective equipment:	Wear self-contained breathing apparatus and chemical-protective clothing.
Other Information:	Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:	Absorica is contraindicated in females who are or may become pregnant.
Environmental precautions:	Do not discharge into drains/surface waters/groundwater.
Cleaning up or taking up methods:	Pick up with suitable appliance and dispose of.

7. HANDLING AND STORAGE

Store at 20°C - 25°C, excursion permitted between 15°C - 30°C. Protect against heat. Protect content from light.
Keep Absorica™ out of reach of children and females that are or may become pregnant.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

General safety and hygiene measures:	Under no circumstances should the product come into contact with the skin of pregnant women. Hands and/or face should be washed immediately after product contact.
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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Hard Gelatin Capsule with a yellowish paste.
Melting range:	Approx. 60 °C
Solubility in water:	Sparingly Soluble
Solubility:	Slightly Soluble in methanol and in ethanol.
Solubility (qualitative) solvent(s):	Organic Solvents Soluble

MATERIAL SAFETY DATA SHEET**10. STABILITY AND REACTIVITY**

Conditions to avoid:	> 60°C
Thermal decomposition:	> 60°C
Substances to avoid:	Oxygen
Hazardous reactions:	No hazardous reactions when stored and handled according to instructions.
Hazardous decomposition products:	No hazardous decomposition products if stored and handled as prescribed /indicated.

11. TOXICOLOGICAL INFORMATION

LD 50(oral-rat):	5,000 mg/kg
LD 50(derma-rabbit):	> 2,500 mg/kg
Primary skin irritation-rabbit:	non-irritant (Draize test)
Primary irritations of the mucous membrane-	non-irritant (Draize test)
Other:	In animal studies the substance showed a developmental toxic/teratogenic effect.

12. ENVIRONMENTAL INFORMATION*Ecotoxicity*

Toxicity to fish:	OECD Guide-line 203 semistatic Brachydanio rerio/LC50 (96h): 0,2 mg/l The statement of the toxic effect relates to the analytically determined concentration. The product has not been tested. The statement has been derived from products of a similar structure and composition.
Aquatic invertebrates:	OECD Guideline 202, part 1 static Daphnia magna/EC50 (48 h); >0,1 < 0,3 mg/l The product has low solubility in the test medium. An eluate has been tested. The statement of the toxic effect relates to the analytically determined concentration.
Microorganisms/Effet on activates sludge:	OECD Guide-line 209 aerobic activated sludges/E20 (180 min): approx. 1,000 mg/l
Assessment of aquatic toxicity:	Very toxic (acute effect) to aquatic organisms. Toxic effects occur within the range of solubility. The inhibition of the degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriate low concentrations.

*Persistence and degradability**Elimination information*

Test methods:	OECD 301B; ISO 9439; 92/69/EEC, C.4C-C (aerobic), activated sludge
Method of analysis:	CO2 formation relative to the theoretical value.
Degree of elimination:	90 - 100% (28 d)
Assessment:	Not easily biodegradable (by OECD criteria). Biodegradable.

Bioaccumulation potential

Accumulation in organisms is expected.

The product has not been tested. The statement has been derived from products of a similar structure and composition.

13. DISPOSAL INFORMATION

Methods of Disposal:	Observe national and local legal requirements.
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14. TRANSPORT INFORMATION

Proper shipping name:	Absorica™ (Isotretinoin) Capsules
IMDG IMO:	Not regulated
ADR/RID:	Not regulated
IATA:	Not regulated
UN No:	Not regulated

15. REGULATORY INFORMATION*International Regulatory Information**Hazard Symbols(s)*

T	Toxic
N	Dangerous to the environment

Risk Phrases

R61:	May cause harm to the unborn child.
R50/53:	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety Phrases

S53:	Avoid exposure - obtain special instructions before use.
S61:	Avoid release to the environment. Refer to special instructions/safety data sheets.

16. OTHER INFORMATION

Use:	Pharmaceutical
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The above information is believed to be correct but does not support to be all inclusive and shall be used only as a guide. Galephar Pharmaceutical Research, Inc. shall not be held liable for any damage resulting from handling or from contact with the above product.