

SAFETY DATA SHEET FENOFIBRATE CAPSULES

In conformity with Decree 2004-725 dated 22 juillet 2004 & Directive 2001/58/CE transposed under Legislation dated 9 November 2004

1 - IDENTIFICATION OF THE PREPARATION & OF THE COMPANY RESPONSIBLE FOR ITS MARKETING

<u>CHEMICAL PREPARATION</u>	Capsules	c
<u>UTILIZATION OF THE PREPARATION:</u>		
<u>IDENTIFICATION OF THE COMPANY:</u>	ETHYPHARM	
<u>Address:</u>	194, bureaux de la Colline	
<u>Tel. No.</u>	01 41 12 17 20	
<u>Telecopy No.</u>	01 41 12 17 30	
<u>EMERGENCY TELEPHONE No.</u>	(33) 01 43 73 70 78	

2 - COMPOSITION / INFORMATION CONCERNING INGREDIENTS:

<u>NAME OF SUBSTANCE PRESENTING DANGER:</u>	FENOFIBRATE
<u>CAS No.</u>	49 562 - 28 - 9
<u>RISK PHRASES</u>	R 22: dangerous if swallowed R36/37/38: irritant for eyes, respiratory tract and the skin
<u>SAFETY ADVICE:</u>	S22: do not inhale dust particles S24/25: avoid skin & eye contact S36/37: wear appropriate clothing & goggles S46: if swallowed, obtain medical advice
<u>CONCENTRATION IN PREPARATION:</u>	64%

3 - IDENTIFICATION OF DANGER POINTS OF THE PREPARATION:

<u>PRINCIPAL DANGER POINTS:</u>	Preparation is not classified as dangerous
<u>HEALTH EFFECTS:</u>	HYPO-LIPEMIANT, HYPO-CHOLESTEROLEMIANT Medicine

4 - FIRST AID:

INFORMATION:

INHALATION: Remove victim from contaminated zone. Make victim breathe fresh air. Consult a doctor if necessary

SKIN CONTACT: Wash abundantly with clear water for 10 minutes. Remove soiled clothing. Consult a doctor if irritation persists.

EYE CONTACT: Wash abundantly with water during 10 to 15 minutes. Consult an ophthalmologist if there is discomfort, pain or redness.

INGESTION: Consult a doctor

5 - FIRE-FIGHTING / PREVENTION OF EXPLOSIONS & FIRE

<u>MEANS OF EXTINCTION:</u>	Water atomization, CO2, powder
<u>PROTECTION OF FIRE-FIGHTERS:</u>	Wear insulated respiratory apparatus

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6 - MEASURES TO BE TAKEN IN CASE OF ACCIDENTAL SPILLING:

<u>INDIVIDUAL PRECAUTIONS</u>	Wear a mask, gloves & goggles.
<u>PRECAUTIONS FOR PROTECTION OF THE ENVIRONMENT:</u>	Do not throw down drains nor in natural environment
<u>CLEANING METHODS:</u>	Recuperate the product for reconditioning in suitable airtight containers. Destruction in authorized elimination centres.

7 - MANIPULATION & STORAGE:

<u>MANIPULATION:</u>	
Prevention of exposure of workers:	Wear suitable individual protection. Vacuum sources of emission é ventilate premises.
Prevention of fire & explosion:	Take all necessary precautions to avoid accumulation of static electricity & production of sparks or hot points during manipulation.
<u>STORAGE:</u>	
Storage conditions:	Store away from humidity in a ventilated area at ambient temperature in hermetically closed recipients.
Packaging materials:	Plastic bags + plastic drums

8 - EXPOSURE CONTROL / INDIVIDUAL PROTECTION :

<u>EXPOSURE LIMIT VALUES (FENOFIBRATE) :</u>	DL 50 (oral): 3200 mg/kg (rat)
<u>EXPOSURE CONTROL / INDIVIDUAL PROTECTION:</u>	
Respiratory protection	Wear Type P3 mask if manipulation generates dust
Protection of the hands:	na
Protection of the eyes:	na
Protection of the skin & of body parts other than the hands:	Appropriate working clothes
<u>SPECIFIC HYGIENE MEASURES:</u>	Wash body parts in contact with the product

9 - PHYSICAL & CHEMICAL PROPERTIES:

<u>GENERAL INFORMATION:</u>	
<u>Physical state:</u>	Capsules
<u>Colour:</u>	Green & white
<u>Odour:</u>	None
<u>INFORMATION RELATING TO HEALTH, SAFETY, SECURITY & THE ENVIRONMENT:</u>	
<u>pH:</u>	Undetermined
<u>Sparking point:</u>	Undetermined
<u>Self-inflammable temperature:</u>	Undetermined
<u>Explosure characteristics:</u>	Product does not present any danger from explosion
<u>Melting point:</u>	Undetermined
<u>Mass volume:</u>	Undetermined
<u>Solubility (capsule):</u>	Soluble in alcohol & in water

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10 - STABILITY / REACTIVITY:

<u>CONDITIONS TO BE AVOIDED:</u>	Avoid dust formation
<u>MATERIALS TO BE AVOIDED:</u>	
<u>Stability:</u>	Stable under normal conditions of utilization
<u>PRODUCTS OF DANGEROUS DECOMPOSITION:</u>	CO, CO ₂ , HCl

11 - TOXICOLOGICAL INFORMATION

<u>Acute toxicity:</u>	DL 50 (oral, rat) > 3200 mg/kg
<u>Local effects:</u>	Hypolipidemiant

12 - ECOTOXICOLOGICAL INFORMATION:

<u>ECOTOXICITY:</u>	Not available.
<u>MOBILITY:</u>	Not available.
<u>PERSISTENCE & DEGRADABILITY:</u>	Not available.
<u>BIO-ACCUMULATION POTENTIAL :</u>	Not available..
<u>DIVERSE HARMFUL EFFECTS:</u>	Not available.

13 - CONSIDERATIONS RELATING TO ELIMINATION:

<u>Residue waste:</u>	Destruction by specialized authorized Company.
<u>Dirty packaging materials:</u>	Destruction by specialized authorized Company.

14 - INFORMATION RELATING TO TRANSPORTATION:

Not subject to the Transportation of Dangerous Materials Legislation in compliance with Regulation ADR/RID/IATA/IMDG

15 - REGULATORY INFORMATION:

<u>LABELING:</u>	Product not classified as dangerous
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16 - OTHER INFORMATION:

The information contained in this data sheet is based on our present knowledge relating to the product concerned at the date indicated.

This information is given in good faith.
The attention of users is nevertheless drawn to the risks that might be incurred
when a product is utilized for purposes other than those for which it has been conceived