



SOLARA
Active Pharma Sciences

Communication Address
Solara Active Pharma Sciences Limited
(Strides Chemicals merged with Solara)
Plot No. N-39 / N39-1, Anand Nagar MIDC,
Additional Ambarnath,
Ambarnath (East), District Thane,
Maharashtra, Mumbai - 421506, India.
Telefax : 91-251-2620466.
E-mail : info@solara.com
www.solara.co.in

MATERIAL SAFETY DATA SHEET

Complying with 1907/2006 / EEC Regulation of 18 December 2006
("REACH Regulation") & REGULATION (EC) No. 1272/2008(CLP)

Product Name	Pentoxifylline
Effective Date	NA
QA sign /date	<i>kmj</i> 06/02/2020
Replaces	NA

Section 1: Chemical Product and Company Identification:

Product name : Pentoxifylline
Common/important uses of the substance : Active Ingredient (API) in Pharmaceutical Industry
Company name : Solara Active Pharma Sciences Limited
Address : Plot No. N39/N39-1, Additional MIDC, Anand Nagar, Ambarnath (E), Pin - 421506, Dist -
Thane, Maharashtra, India Tel : +91-02517120404

Section 2: Hazards Identification:

According to EC Classification:

Most important Hazards
Harmful if swallowed R 22
Harmful by Inhalation R 20

Classification
Xn - Harmful

GHS (CLP) Classification :

Hazard Statements:
H302 Harmful if swallowed
H332 Harmful if inhaled

Acute Toxicity, Category 4, Oral
Acute Toxicity, Category 4, Inhalation

SIGNAL WORD :

Warning

See section 11 for more detailed information on health effects and symptoms

Section 3: Composition and Information on Ingredients:

Chemical Name: 1-(5-oxohexyl)Theobromine, Dimethyloxohexylxantine,3,7-Dihydro-3,7-Dimethyl-1-(5-oxohexyl)1H

Synonym: Trental, Vazofirin, Rentylin, Otypentifylline

Chemical Formula: C13-H18-N4-O3

CAS # 6493-05-6

EINECS : 229-374-5

RTECS : XH247500

EU 1272/2008 (CLP) - GHS Classification :

H 302, H 332

EU Classification :

Xn, R20/22

Section 4: First Aid Measures:

Inhalation : Remove to fresh air. If rapid recovery does not occur, obtain medical attention.

Skin : Remove contaminated clothing. Rinse with water for at least 15 minutes.

Eyes : Rinse immediately with plenty of water for at least 15 minutes. Obtain medical attention.

Ingestion : Do not induce vomiting. Give water to drink provided patient is conscious. Obtain medical attention.





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Section 5: Fire and Explosion Data

May form toxic gases on heating or in case of fire.

Suitable extinguishing media:

Dry chemical powder, carbon dioxide, alcohol resistant foam, water spray or foam.

Extinguishing media which shall not be used for safety reasons :

High volume water jets.

Protective equipment : Full protective clothing and self contained breathing apparatus.

Specific hazards during fire fighting :

His material may be combustible at high temperature.

Slightly flammable in presence of heat.

Non-flammable in presence of shocks.

Development of hazardous combustion gases possible in the event free.

Fire may cause evolution of carbon oxides (CO, CO₂), nitrogen oxides (NO, NO₂....)

Further information :

May form explosive dust air mixture during certain solids handling operations (f.ex.milling or sieving)

Remove container from danger zone and cool with water.

Prevent fire extinguishing water from contaminating surface water or ground water system.

Section 6: Accidental Release Measures

Personal Precautions : Avoid contact with skin, eyes by use of appropriate protective equipment. Wear impermeable gloves and boots. Dampen to avoid dust.

Environment precautions: Use appropriate containment to avoid environment contamination. Prevent from entering into ditches or rivers. Inform local authorities if this cannot be prevented. Ventilate area and wash spills site after material pick up is complete.

Section 7: Handling and Storage

Handling : Avoid contact with skin, eyes and clothing.

Handling temperatures : Ambient

Storage : Store in a cool, dry place.

Keep in original container, closed when not in use, protected from light, humidity and excessive heat. Store at 20-25°C, excursions of 15-30°C as well as spikes up to 40°C are permitted. temperatures below 30°C.





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Section 8: Exposure Controls/Personal Protection

Personal protective equipment

Respiratory protection : Use approved respirator (EN 149)
Hand Protection : Wear PVC, nitrile, neoprene or other gloves.
Eye protection : Wear safety spectacles or full face shield.
Skin protection : Minimize all forms of skin contact

Engineering Controls :

Use process enclosures, local ventilation, or other engineering controls to keep airborne levels below recommended exposure level.

Hygiene measures:

Immediately change contaminated clothing. Wash hands and face after working with substance.

Other information :

IOEL (internal occupational exposure level) > 250mcg/m³
PAI Hazard Category : 2

Section 9: Physical and Chemical Properties

Appearance: White powder

Odour: Odourless.

Taste: Not available.

Melting Point: 104°C - 108°C

Relative Density: Not available.

Solubility in organic solvent: Soluble in Benzene.

Solubility in Water: 77 (g/ml) at 25°C

pH (1% aq. Sol.): 5.0 - 7.5.

Section 10: Stability and Reactivity

Stability: Stable in normal conditions.

Conditions to avoid: Keep away from heat, flames and sparks

Hazardous decomposition products: Thermal decomposition may produce carbon monoxide, carbon dioxide and nitrogen oxides.

Hazardous polymerization will not occur.

Section 11: Toxicological Information

Acute toxicity, oral : Category 4

LD50 Mouse : 1385 mg/kg

LD50 Rat : 1772 mg/kg

Acute toxicity, Inhalation : Category 4

CMR Effects :

Carcinogenicity : Not reported

Mutagenic Effects : Not reported

Reproductive Effects : Not reported





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Product Name pentoxifylline

Section 12: Environmental Information

Ecotoxicity: EC50 (fenofibric acid) = 1.72 mg/l (Acute aquatic toxicity Cat II)
Mobility : Med
Persistence : High (water/Soil)
Degradability : Poor (waste water)
Bioaccumulative potential : Low
Further Information :
Do not allow to enter waters, soils
The products of degradation are less toxic.
Good water solubility.

Section 13: Disposal Considerations

Method Disposal:
Recover or recycle if possible.
Dispose of in accordance with official regulations.
Hazardous waste : Yes

Section 14: Transport Information

UN No: Not applicable
ADR/RID: Not regulated as hazardous material.
IATA: Not regulated as hazardous material.
IMDG: Not regulated as hazardous material

Section 15: Regulatory Information

Classification and labeling according to EU Directives 67/548/EEC and 1999/45/EC (including amendments) and take into account the intended substance use:

Hazard symbols: Xn

Risk Phrases: R20 Harmful by inhalation
R22 Harmful if swallowed

Safety Phrases : S22 Do not breathe dust
S20/21 When using do not eat, drink or smoke
S24/25 Avoid contact with eyes and skin
S40 If swallowed seek medical advice

Classification and labeling according to EU-Regulation (EC) 1272/2008 (CLP-Regulation) and Globally Harmonized System (GHS):
Signal Word: WARNING



Hazards Statements :
H302 :Harmful if swallowed
H332 :Harmful if inhaled

Precautionary Statements :
P202 :Do not handle until all safety precautions have been read and understood
P233 :Keep container tightly closed





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Product Name

pentoxifylline

P234 :Keep only in original container
P260 :Do not breathe dust/fume/gas/mist/vapours/spray
P270 :Do not eat, drink or smoke when using this product
P314 :Get material advice/attention if you feel unwell

Section 16: Other Information

Full text of R-phrases referred to in section 2 & 3
R 20/22 Harmful if inhaled or swallowed.

Full text of Hazard Statements referred to in section 2 & 3
H302 :Harmful if swallowed
H332 :Harmful if inhaled
References:

The above information is believed to be correct but does not purport to be all inclusive and shall be used as a guide

END



