

Safety Data Sheet

1. IDENTIFICATION

Product Identifier SOLVEASY TINEA CREAM (AUST R 166484)

Other Means of Identification Not applicable.

Recommended Uses and Restrictions on Use

For the treatment of tinea pedis (athlete's foot).

Suppliers Details

Ego Pharmaceuticals Pty Ltd
21-31 Malcolm Rd,
Braeside 3195,
Victoria, Australia

Emergency Phone Number

Ego Pharmaceuticals Pty Ltd
03 9586 8800
Poisons Information Centre
131 126

2. HAZARDS IDENTIFICATION

Hazard Classification

Not classified as hazardous according to the Australian Criteria for the classification of chemicals. This product has been approved for topical use as an unscheduled medicine by the TGA.

Label Elements & Precautionary Statements

Keep out of reach of children.

Not recommended for children under 12 years of age.

Seek medical advice in pregnancy or during breastfeeding before using this cream.

Avoid eyes.

For external use only.

If irritation develops, contact your pharmacy or doctor.

Store below 30°C.

Other Hazards

No other hazards are expected.

3. INFORMATION ON INGREDIENTS

<u>AAN</u>	<u>CAS Number</u>
Benzyl alcohol	100-51-6
Terbinafine hydrochloride	91161-71-6
Methyl hydroxybenzoate	99-76-3
Propyl hydroxybenzoate	94-13-3

4. FIRST AID MEASURES

Description of First Aid Measures

Inhalation

Not applicable.

Skin Contact

Not applicable, this product is intended to be in contact with human skin. If irritation occurs, wash affected area and discontinue use. Contact your doctor or pharmacist.

Eye Contact

May cause irritation. Rinse with clean water. Seek medical advice.

Ingestion

Swallowing a large amount of SolvEasy Tinea Cream, particularly by a child, may cause an upset stomach. Induce vomiting. Seek medical advice.

Symptoms Caused by Exposure

Inhalation

Not applicable.

Skin Contact

This product is intended for use on human skin. If irritation develops, seek medical advice.

Eye Contact

May cause irritation.

Ingestion

Swallowing a large amount of SolvEasy Tinea Cream, particularly by a child, may cause an upset stomach.

Medical Attention and Special Treatment

Seek medical advice.

5. FIRE FIGHTING MEASURES

Suitable Extinguishing Media

All types of extinguishers are suitable.

Physicochemical Hazards

None known.

Special Protective Equipment and Precautions for Fire Fighters

Fire fighters to wear self-contained breathing apparatus and suitable protective clothing if risk of exposure to vapour or products of combustion.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

All personnel involved in the containment and disposal procedure should wear eye protection.

Environmental Precautions

Stop and contain the spill by scooping up any product leaked from the packaging and dispose the product and damaged packs using an approved method. Prevent run-off into drains and waterways. Ensure that the surface (floor) is cleaned thoroughly with detergent and water as any product residue may leave the floor slippery.

Methods and Materials for Containment and Cleaning Up

See “Environmental Precautions”.

7. HANDLING AND STORAGE

Precautions for Safe Handling

No special requirements.

Conditions for Safe Storage and Incompatibilities

This product is intended for human use. Store below 30°C. Keep out of reach of children.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Exposure Standards

No special requirements.

Biological Monitoring

No special requirements.

Engineering Controls

No special requirements.

Personal Protective Equipment

No special requirements.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Firm white to off-white cream
Odour:	Typical of benzyl alcohol.
Odour Threshold:	No data available
pH:	Balanced
Melting Point/Freezing Point (°C):	No data available
Boiling Point/Boiling Range (°C):	No data available
Flash Point (°C):	No data available (not flammable)
Evaporation rate:	No data available
Flammability:	Not flammable
Upper/Lower Flammability or Explosive Limits:	No data available
Vapour Pressure:	No data available
Vapour Density:	No data available

Relative Density (g/mL): Approximately 0.93

Solubility: No data available

Partition Coefficient (n-octanol/water): No data available

Auto-ignition Temperature (°C): No data available

Decomposition Temperature (°C): No data available

10. STABILITY AND REACTIVITY

Chemical Stability

Stable under normal storage conditions.

Possibility of Hazardous Reactions

Hazardous reactions are not expected.

Conditions to Avoid

Heating above recommended storage temperature.

Incompatible Materials

None known.

Hazardous Decomposition Products

None known.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

No data available.

Skin Corrosion / Irritation / Sensitisation

Non-irritant, non-sensitiser.

Serious Eye Damage / Irritation

No data available. Seek medical advice.

Respiratory Sensitisation

No data available. Seek medical advice.

Germ Cell Mutagenicity

No data available.

Carcinogenicity

No data available.

Reproductive Toxicity

Seek medical advice in pregnancy or during breastfeeding, before using the cream.

Specific Target Organ Systemic Toxicity (STOST) – Single Exposure

No data available.

Specific Target Organ Systemic Toxicity (STOST) – Repeated Exposure

No data available.

Aspiration Hazard

No data available.

Other

Not recommended for children under 12 years of age.

Routes of Exposure***Swallowed***

Swallowing a large amount of the cream may cause an upset stomach.

Inhalation

No data available.

Skin Contact

This product is intended for use on human skin. However, some people may experience redness, itchiness or a stinging sensation in the areas where the product is applied. Although these symptoms are usually harmless, seek medical advice.

Eye Contact

No data available.

Early Onset Symptoms Related to Exposure

No data available.

Delayed Health Effects from Exposure

No data available.

Exposure Levels

No data available.

Interactive Effects

No data available.

12. ECOLOGICAL INFORMATION

Ecotoxicity	No data available.
Persistence and Degradability	No data available.
Bioaccumulative Potential	No data available.
Mobility in Soil	No data available.
Other Adverse Effects	No data available.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Disposal must be conducted in accordance with the local waste authority requirements. The product must be contained and not disposed into sewerage systems, drains or waterways.

14. TRANSPORT INFORMATION

UN Number	Not applicable
Proper Shipping / Technical Name	SolvEasy Tinea Cream
Transport Hazard Class(es)	Not applicable
Packing Group	Not applicable
Environmental Hazards for Transport Purposes	No data available.
Special Precautions for User	Seek medical advice in pregnancy or during breastfeeding before using SolvEasy Tinea Cream. SolvEasy Tinea Cream is not recommended for those under 12 years of age.
Additional Information	None
Hazchem / Emergency Action Code	Not applicable

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations

SolvEasy Tinea Cream AUST R 166484 has been approved for topical use as a unscheduled medicine by the TGA.

16. OTHER INFORMATION

Date of issue: 31-03-2011	SDS Version Number: 03
	Superseded Version Number: 02

<u>Abbreviation / Acronym</u>	<u>Definition</u>
TGA	Therapeutic Goods Administration of Australia
AAN Name	Australian Approved Name
CAS	Chemical Abstract Service
% w/w	Percentage weight by weight
<	Less than
>	Greater than
°C	degree Celsius
g/ml	grams per millilitre
mm	millimetre
UN	United Nations

-- END OF MSDS --