

Safety Data Sheet

1. IDENTIFICATION

Product Identifier Resolve Plus 1.0 AUST R 75601

Other Means of Identification None

Recommended Uses and Restrictions on Use Anti-inflammatory, anti-fungal cream for inflamed or itchy tinea

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

Emergency Phone Number

Ego Pharmaceuticals Pty Ltd

03 9586 8800

Australian Poisons Information Centre

13 11 26

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 a Schedule 3 – Pharmacist Only Medicine by the TGA

Label Elements & Precautionary Statements

Keep out of reach of children

Avoid eyes

Do not use on children under 2 years unless your doctor tells you to

Do not use on acne

Do not use under waterproof bandages or for more than 7 days unless your doctor tells you to

If irritation occurs, discontinue use

If symptoms persist seek medical advice

For external use only

Store below 25°C

Other Hazards

None

3. INFORMATION ON INGREDIENTS

<u>AAN</u>	<u>CAS Number</u>
Miconazole nitrate	22916-47-8
Hydrocortisone	50-23-7
Phenethyl alcohol	60-12-8

4. FIRST AID MEASURES

Symptoms and First Aid Measures

Inhalation

Not applicable

Skin Contact

This product is intended for contact with human skin. However, if irritation occurs, wash affected area and discontinue use

Eye Contact

May cause irritation. Rinse with clean water and seek medical advice

Ingestion

Slight stinging may occur. Give plenty of fluids. Seek medical advice

Medical Attention and Special Treatment

Seek medical advice

5. FIRE FIGHTING MEASURES

Suitable Extinguishing Media

All types of fire extinguishers are suitable

Physicochemical Hazards

Not known

Special Protective Equipment and Precautions for Fire Fighters

Fire fighters to wear self-contained breathing apparatus and suitable protective clothing if there are risks of exposure to vapours 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

Scoop up any product from the packaging and dispose of any packaged and unpackaged material that is damaged 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 away from dangerous chemicals. Store below 25°C (for product integrity)

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: White glossy cream

Odour: Slight and characteristic

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): Not applicable, not flammable

Evaporation rate: No data available

Flammability: Not flammable

Upper/Lower Flammability or Explosive Limits: Not flammable / explosive

Vapour Pressure: No data available

Vapour Density: No data available

Relative Density (g/ml): Approximately 0.96

Solubility: No data available

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

Auto-ignition Temperature (°C): Not applicable

Decomposition Temperature (°C): No data available

10. STABILITY AND REACTIVITY

Reactivity and Chemical Stability

Stable under the recommended storage conditions

Possibility of Hazardous Reactions

Hazardous reactions are not expected

Conditions to Avoid

Heating above recommended storage conditions

Incompatible Materials

No data available

Hazardous Decomposition Products

No data available

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

No data available

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

Routes of Exposure***Swallowed***

No data available

Inhalation

No data available

Skin Contact

This product is intended for use on human skin. If irritation occurs, wash affected area and discontinue use

Eye Contact

May cause irritation

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 be disposed into sewerage systems, drains or waterways

14. TRANSPORT INFORMATION

UN Number Not applicable

Proper Shipping / Technical Name Not applicable

Transport Hazard Class(es) Not applicable

Packing Group Not applicable

Environmental Hazards for Transport Purposes Not applicable

Special Precautions for User Store away from dangerous goods. As per section 2

Additional Information Shipment is considered non-dangerous as per IATA regulation.

Hazchem / Emergency Action Code Not applicable

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations

Resolve Plus 1.0 AUST R 75601 has been approved for topical use as a Schedule 3 – Pharmacist Only Medicine by the TGA

16. OTHER INFORMATION

Date of issue: 08-08-2013	SDS Version Number: 01
	Superseded Version Number: NA

Legend of Abbreviations and Acronyms Used:

Abbreviation / Acronym	Definition
TGA	Therapeutic Goods Administration
AAN	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
UN	United Nations
N/A	Not applicable.

-- END OF SDS --