SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

**Material**
RIDAURA CAPSULES

**Synonyms**
RIDAURA CAPSULES 3 MG * NDC NO. 0007-4879-18 * AURANOFIN, FORMULATED PRODUCT

**Company Name**
GlaxoSmithKline, Corporate Environment, Health & Safety
980 Great West Road
Brentford, Middlesex  TW8 9GS UK

General Information: +44-1920-884242
UK number, answer phone

Transport Emergency, UK: +44-1865-407333
UK number, available 24 hours

Medical Emergency +612-221-3999, Ext 221

Information and Advice: US number, available 24 hours
Multi-language response

GlaxoSmithKline, Corporate Environment, Health & Safety
2200 Renaissance Blvd, Suite 105
King of Prussia, PA 19406 US

General Information: +610-239-5229
US number, answer phone

Transport Emergency: +703-527-3887
except UK US number, available 24 hours
Multi-language response

2. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS RN</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>AURANOFIN</td>
<td>34031-32-8</td>
<td>1.9</td>
</tr>
<tr>
<td>NON-HAZARDOUS INGREDIENTS</td>
<td>Unassigned</td>
<td>98.1</td>
</tr>
</tbody>
</table>

3. HAZARDS IDENTIFICATION

**Fire and Explosion**
This product is expected to be non-combustible.

**Health**
Caution - Pharmaceutical agent.
May produce allergic skin reactions.
Exposure might occur via ingestion; skin; eyes.
Possible effects of overexposure in the workplace include: diarrhoea; vomiting; abdominal cramps; symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing). Health effects information is based on hazards of components. Not expected to be a health hazard during normal handling.
4. FIRST-AID MEASURES

Ingestion
Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.

Inhalation
Physical form suggests that risk of inhalation exposure is negligible.

Skin Contact
Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.

Eye Contact
Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment
Medical treatment in cases of overexposure should be treated as an overdose of auranofin. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

Medical Conditions Caused or Aggravated by Exposure
Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product.

Health Surveillance Procedures
Exposed individuals are encouraged to report symptoms of skin and respiratory irritation to an occupational health professional or line management. These symptoms may include, but are not limited to, skin conditions, bronchitis, asthma, or nasal irritation.

Antidotes
No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards
Not expected for the product, although the packaging is combustible.

Extinguishing Media
Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.

Special Firefighting Procedures
For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.

Hazardous Combustion Products
Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Spills
Wear protective clothing and equipment consistent with the degree of hazard.

Personal Precautions
For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods
Collect and place it in a suitable, properly labelled container for recovery or disposal.

Decontamination Procedures
Water can be used for clean-up and decontamination operations. No specific decontamination or detoxification procedures have been identified for this product.

7. HANDLING AND STORAGE

Handling
Avoid breaking or crushing capsules.

Storage
No storage requirements necessary for occupational hazards. Follow storage instructions described in the product insert to maintain efficacy.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

INGREDIENT
AURANOFIN

GSK Occupational Hazard Category
3

GSK Occupational Exposure Limit
7 MCG/M3 (8 HR TWA)

Other Equipment or Procedures
Wash hands and arms thoroughly after handling. None required for normal handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance
Brown/tan.

Physical Form
Gelatin capsule.

10. STABILITY AND REACTIVITY

Stability
This product is expected to be stable.

Conditions to Avoid
None for normal handling of this product.

11. TOXICOLOGICAL INFORMATION

Oral Toxicity
Not expected to be toxic following ingestion.

Acute: Rat
LD50: > 2000 mg/kg

Inhalation Toxicity
No studies have been conducted.

Skin Effects
Irritation is not expected following direct contact.

Eye Effects
Minor irritation might occur following direct contact with eyes.

Target Organ Effects
No specific target organ effects have been identified.

Sensitisation
Allergic skin reactions might occur following dermal exposure.

Genetic Toxicity
Not expected to be genotoxic under occupational exposure conditions.

Carcinogenicity
No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.

Reproductive Effects
Contains components which have been classified as: Known or presumed to cause toxicity in developing human offspring.

Pharmacological Effects
The active ingredient in this product is an anti-inflammatory. Adverse effects of overexposure might include: diarrhoea; vomiting; abdominal cramps; symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing).
12. ECOLOGICAL INFORMATION

Summary
No information is available about the potential of this product to produce adverse environmental effects. Local regulations and procedures should be consulted prior to environmental release.

13. DISPOSAL CONSIDERATIONS

Disposal Recommendations
Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

Regulatory Requirements
Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling
Transport Information
Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

EU Classification and Labelling
Classification(s)
None

Classification
This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.

Other US Regulations
TSCA Status
Exempt

16. OTHER INFORMATION

REFERENCES
GSK Hazard Determination

Date Approved/Revised 16-Dec-2002

SDS Sections Updated

Sections
ACCIDENTAL RELEASE MEASURES
COMPOSITION / INFORMATION ON INGREDIENTS
DISPOSAL CONSIDERATIONS
ECOLOGICAL INFORMATION
FIRE-FIGHTING MEASURES
FIRST-AID MEASURES

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Disposal Recommendations
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Summary
Extinguishing Media
Hazardous Combustion Products
Special Firefighting Procedures
Health Surveillance Procedures
Inhalation
The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.