SAFETY DATA SHEET

GlaxoSmithKline

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

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

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
AURANOFIN	34031-32-8	1.9
NON-HAZARDOUS INGREDIENTS	Unassigned	98.1

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.

Environment	No information is available about the potential of this product to produce adverse environmental effects.

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

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental 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

Colour	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).

Other Adverse Effects None known for this material in humans.

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

US OSHA Standard (29 CFR Part 1910.1200)

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 Version Number** 5

SDS Sections Updated

Sections	Subsections
ACCIDENTAL RELEASE MEASURES	Decontamination Procedures
COMPOSITION / INFORMATION ON INGREDIENTS	
DISPOSAL CONSIDERATIONS	Disposal Recommendations
	Regulatory Requirements
ECOLOGICAL INFORMATION	Summary
FIRE-FIGHTING MEASURES	Extinguishing Media
	Hazardous Combustion Products
	Special Firefighting Procedures
FIRST-AID MEASURES	Health Surveillance Procedures
	Inhalation

SDS Sections Updated

Sections	Subsections
FIRST-AID MEASURES	Medical Conditions Caused or Aggravated by Medical Treatment
HAZARDS IDENTIFICATION	Environment
	Eye Contact
	Health
	Ingestion
	Inhalation
	Skin Contact
IDENTIFICATION OF SUBSTANCE / PREPARATION AND	
PHYSICAL AND CHEMICAL PROPERTIES	
REGULATORY INFORMATION	European Union Classification and Labelling
STABILITY AND REACTIVITY	Conditions to Avoid
	Stability
TOXICOLOGY INFORMATION	Carcinogenicity
	Eye Effects
	Genetic Toxicity
	Oral Toxicity
	Other Adverse Effects
	Pharmacological Effects
	Reproductive Effects
	Sensitisation
	Skin Toxicity
	Target Organ Effects
TRANSPORT INFORMATION	Emergency Action Code
	Summary

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.