

## SAFETY DATA SHEET



GlaxoSmithKline

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

<b>Material</b>	<b>AGENERASE SOFTGEL CAPSULES</b>
<b>Synonyms</b>	AGENERASE CAPSULES * AGENERASE SOFTGEL CAPSULES 50MG * AGENERASE SOFTGEL CAPSULES 150MG * NDC NO. 0173-0672-00 * NDC NO. 0173-0679-00 * AMPRENAVIR, FORMULATED PRODUCT
<b>Company Name</b>	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 US number, available 24 hours except UK Multi-language response

### 2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
AMPRENAVIR	161814-49-9	6 to 7.4
NON-HAZARDOUS INGREDIENTS	Unassigned	92.6 to 94

### 3. HAZARDS IDENTIFICATION

<b>Skin Contact</b>	Allergic reaction and irritation are not expected following direct contact.
<b>Eye Contact</b>	Avoid contact with capsule contents. Minor irritation with redness or swelling might occur following direct contact.
<b>Inhalation</b>	Not expected to occur during normal handling of this product.
<b>Ingestion</b>	Possible effects of overexposure include nausea vomiting rash adverse effects on foetal development .

### 4. FIRST-AID MEASURES

**Material** AGENERASE SOFTGEL CAPSULES

<b>Ingestion</b>	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.
<b>Inhalation</b>	Using appropriate personal protective equipment, move exposed subject to fresh air. If breathing is difficult or ceases, ensure and maintain ventilation. Give oxygen as appropriate. The exposed subject should be kept warm and at rest. Obtain medical attention in cases of known or possible over exposure, or with symptoms including chest pain, difficulty breathing, loss of consciousness or other adverse effects, which may be delayed.
<b>Skin Contact</b>	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.
<b>Eye Contact</b>	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

**NOTES TO HEALTH PROFESSIONALS**

<b>Medical Treatment</b>	Medical treatment in cases of overexposure should be treated as an overdose of an anti-viral agent.
<b>Medical Conditions Caused or Aggravated by Exposure</b>	This material may cause or aggravate allergy to components in this product.
<b>Antidotes</b>	No specific antidotes are recommended.

**5. FIRE-FIGHTING MEASURES**

<b>Fire and Explosion Hazards</b>	Not expected for the product, although the packaging is combustible.
<b>Extinguishing Media</b>	This material is expected to be non-combustible, based on components present.
<b>Special Firefighting Procedures</b>	No special firefighting requirements. If leakage of this material occurs, contain and collect for later disposal.
<b>Hazardous Combustion Products</b>	Toxic or corrosive thermal decomposition products are expected when this material is exposed to fire.

**6. ACCIDENTAL RELEASE MEASURES**

<b>Spills</b>	
<b>Personal Precautions</b>	Wear protective clothing and equipment consistent with the degree of hazard.
<b>Environmental Precautions</b>	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
<b>Clean-up Methods</b>	Collect material and place it in a suitable, properly labelled container for recovery or disposal.
<b>Decontamination Procedures</b>	No specific decontamination or detoxification procedures have been identified for this product.

**7. HANDLING AND STORAGE**

<b>Handling</b>	No special control measures required for normal handling of this material. Normal room ventilation is expected to be adequate for routine handling of this material.
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**Storage** No storage requirements necessary for occupational hazards. Follow storage recommendations for the product.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<b>INGREDIENT</b>	AMPRENAVIR	
<b>GSK Occupational Hazard Category</b>	1	
<b>GSK Occupational Exposure Limit</b>	1000 mcg/m3 (8 HR TWA)	CARCINOGEN, REPRODUCTIVE HAZARD

### PERSONAL PROTECTIVE EQUIPMENT

**Eye Protection** Wear approved safety glasses with side shields or cover goggles if eye contact is possible.

**Gloves** The selection of gloves for a specific activity must be based on the material's properties and on possible permeation and degradation that may occur under the circumstances of use. Glove selection must take into account any solvents and other hazards present. Potential allergic reactions can occur with certain glove materials (e.g. Latex) and therefore these should be avoided. Care must be exercised if insufficient data are available and further guidance should be sought from your local EHS department.

**Other Equipment or Procedures** Wash hands and arms thoroughly after handling.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance</b>	
<b>Colour</b>	White/cream.
<b>Physical Form</b>	Soft capsule containing liquid.

## 10. STABILITY AND REACTIVITY

<b>Stability</b>	This material is expected to be stable.
<b>Conditions to Avoid</b>	None for normal handling of this product.

## 11. TOXICOLOGICAL INFORMATION

<b>Oral Toxicity</b>	Low toxicity expected following ingestion. Assessment based upon effects of individual components.
<b>Inhalation Toxicity</b>	Not applicable for this product.
<b>Skin Effects</b>	Irritation is not expected following direct contact. Assessment based upon effects of individual components.
<b>Eye Effects</b>	Minor irritation might occur following direct contact with eyes. Assessment based upon effects of individual components.
<b>Sensitisation</b>	Sensitisation (allergic skin reaction) is not expected. Assessment based upon effects of individual components.
<b>Genetic Toxicity</b>	Not expected to be genotoxic under occupational exposure conditions.
<b>Carcinogenicity</b>	Amprenavir, the active substance in this product, produced carcinogenic effects in a lifetime study in mice a lifetime study in rats .Not expected to produce cancer in humans under occupational exposure conditions.

<b>Reproductive Effects</b>	The active substance in this product is Not expected to impair human fertility under occupational exposure conditions. The active substance in this product is Known or presumed to cause toxicity in developing human offspring. The active substance in this product is Known or presumed to affect the quantity and quality of breast milk in humans.
<b>Other Adverse Effects</b>	Overexposure in the workplace might have the following effects: headache nausea ; vomiting ; symptoms of hypersensitivity (such as skin rash, hives, itching, and / or difficulty breathing).

## 12. ECOLOGICAL INFORMATION

<b>Summary</b>	This material contains an active pharmaceutical ingredient that has been tested, and no environmental effects have been identified. Local regulations and procedures should be consulted prior to environmental release.
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## 13. DISPOSAL CONSIDERATIONS

<b>Disposal Recommendations</b>	Collect for recycling or recovery if possible. The recommended method of disposal for this material is incineration. Wherever possible, disposal should be in an on-site licenced chemical incinerator, if allowed by the incinerator licence or permit. If no on-site incinerator is available, dispose of material in a licenced commercial chemical incinerator.
<b>Regulatory Requirements</b>	Observe all local and national regulations when disposing of this material.

## 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

<b>Transport Information</b>	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.
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## 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

<b>Classification(s)</b>	None
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### US OSHA Standard (29 CFR Part 1910.1200)

<b>Classification</b>	This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.
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### Other US Regulations

<b>TSCA Status</b>	Exempt
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## 16. OTHER INFORMATION

<b>References</b>	GSK Hazard Determination
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**Date Approved/Revised** 03-Jun-2002

**SDS Version Number** 5

### SDS Sections Updated

#### Sections

FIRST-AID MEASURES

REGULATORY INFORMATION

#### Subsections

Medical Conditions Caused or Aggravated by  
European Union Classification and Labelling

**SDS Sections Updated****Sections**

REGULATORY INFORMATION

**Subsections**

US OSHA Standard (29 CFR Part 1910.1200) -

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.