# SAFETY DATA SHEET

GlaxoSmithKline

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

**Material** **KWELLADA-P LOTION**

**Synonyms** KWELLADA-P LOTION (CANADA) * QUELLADA SCABIES (AUSTRALIA) * QUELLADA LOTION (UK) * LOTION KWELLADA * FORMULA NO. IB0841 * PERMETHRIN LOTION 5% * PERMETHRIN, FORMULATED PRODUCT

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

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|---|---|
| UK General Information: | +44-20-8047-5000 |
| Transport Emergency (EU) | +44-1865-407333 |
| Medical Emergency | +1-612-221-3999, Ext 221 |
| Information and Advice: | US number, available 24 hours<br>Multi-language response |

GlaxoSmithKline, Corporate Environment, Health & Safety
One Franklin Plaza, 200 N 16th Street
Philadelphia, PA 19102-1225 US

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|---|---|
| US General Information: | +1-888-825-5249 |
| Transport Emergency (non EU) | +1-703-527-3887<br>US number, available 24 hours<br>Multi-language response |

## 2. COMPOSITION / INFORMATION ON INGREDIENTS

| Ingredients | CAS RN | Percentage |
|---|---|---|
| PERMETHRIN | 52645-53-1 | 5.26 |
| NON-HAZARDOUS INGREDIENTS | Unassigned | 94.74 |

## 3. HAZARDS IDENTIFICATION

**Fire and Explosion** This product is classified as non-flammable.

**Health** Handling this product in its final form presents minimal risk from occupational exposure. Health effects information is based on hazards of components.

**Environment** Dangerous for the environment. Toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.

## 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.

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| **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**

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| **Medical Treatment** | None. |
| **Medical Conditions Caused or Aggravated by Exposure** | None for occupational exposure. |
| **Antidotes** | No specific antidotes are recommended. |

## 5. FIRE-FIGHTING MEASURES

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| **Fire and Explosion Hazards** | Not expected for the product, although the packaging is combustible. |
| **Extinguishing Media** | No special requirements needed. |
| **Special Firefighting Procedures** | For single units (packages): No special requirements needed.<br>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.<br>If leakage of this material occurs, contain and collect 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

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| **Personal Precautions** | Wear protective clothing and equipment consistent with the degree of hazard. |
| **Environmental Precautions** | Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas. |
| **Clean-up Methods** | Spread an inert absorbent on the spill and place in a suitable, properly labelled container for recovery or disposal. |
| **Decontamination Procedures** | Water can be used for clean-up and decontamination operations. The waste waters generated during decontamination should be directed to a waste water treatment system. |

## 7. HANDLING AND STORAGE

**HANDLING**

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| **General Requirements** | No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product. |
| **STORAGE** | No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy. |

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**

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| **Colour** | White. |
| **Physical Form** | Lotion. |

## 10. STABILITY AND REACTIVITY

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| **Stability** | This product is expected to be stable. |
| **Conditions to Avoid** | None for normal handling of this product. |

## 11. TOXICOLOGICAL INFORMATION

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| **Oral Toxicity** | Not expected to be toxic following ingestion. |
| **Inhalation Toxicity** | No studies have been conducted. |
| **Skin Effects** | Irritation is not expected following direct contact. |
| **Eye Effects** | Irritation is not expected following direct contact with eyes. |
| **Sensitisation** | Sensitisation (allergic skin reaction) is not expected. |
| **Genetic Toxicity** | Not expected to be genotoxic under occupational exposure conditions. |
| **Carcinogenicity** | Not expected to produce cancer in humans under occupational exposure conditions. No components are listed as carcinogens by GSK, IARC, NTP or US OSHA. |
| **Reproductive Effects** | Insufficient information available to classify for reproductive toxicity. |
| **Other Adverse Effects** | Overexposure in the workplace might have the following effects: toxicity in the nervous system. |

## 12. ECOLOGICAL INFORMATION

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| **Summary** | This product contains an active ingredient that has been tested and which may be harmful if released directly to the environment. Consult the MSDS of the active ingredient for specific information about potential environmental effects. Appropriate precautions should be taken to limit release of this mixture to the environment. Local regulations and procedures should be consulted prior to environmental release. |

**ECOTOXICITY**

**Aquatic**

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| **Microtox** | Microtox is a general toxicity test which utilizes a sensitive marine photo bacteria as the test species. This material contains an active pharmaceutical ingredient that is toxic to these microorganisms. |
| **Daphnid** | This mixture contains an active pharmaceutical ingredient that is very toxic to daphnids. |
| **Fish** | This mixture contains an active pharmaceutical ingredient that is very toxic to fish. |

**MOBILITY**

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| **Partitioning** | This mixture contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient may have the tendency to distribute into fats. |

**PERSISTENCE/DEGRADATION**

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| **Biodegradation** | This mixture contains an active pharmaceutical ingredient that has been tested and is expected to be biodegradable. |
| **BIOACCUMULATION** | This material contains an active pharmaceutical ingredient that will have a tendency to bioaccumulate in the food chain. |

## 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 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**

**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**

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

**US OSHA Standard (29 CFR Part 1910.1200)**

**Classification** This product 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** 17-Jan-2007 **SDS Version Number** 8

### SDS Sections Updated

**Sections** **Subsections**

COMPOSITION / INFORMATION ON INGREDIENTS

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.