

MATERIAL SAFETY DATA SHEET

according to Regulation (EC) No 1907/2006 (REACH)

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Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE

Product Name: LKM1 humAb IgG
Catalog Number: 36400/36401/36405
Relevant identified uses: For research use or IVD manufacturing only.
Emergency telephone number: Poison Control Center Freiburg, Germany
Tel. +49 761 19240 (24 hours)

Section 2: HAZARDS IDENTIFICATION

Classification: This substance does not need to be classified according to regulation (EC) No. 1272/2008, or directives 67/548/EEC and 1999/45/EC.
Label: This product does not need to be labeled in accordance with EC directives or respective national laws.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

General information: Aqueous solution of human chimeric monoclonal antibody against Cytochrome P450 2D6 (LKM1 hp).

Ingredients: According to regulation (EC) No. 1272/2008, hazardous and carcinogenic ingredients with a concentration of less than 1% and 0.1%, respectively, are not considered "relevant ingredients". Hazardous and carcinogenic ingredients that exceed these criteria are listed below.

| Ingredient | Cas No. | EC No. | Concentration |
|-----------------|-----------|-----------|---------------|
| Glycerol | 56-81-5 | 200-289-5 | 10% |
| Sodium Chloride | 7647-14-5 | 231-598-3 | < 2.0% |

Section 4: FIRST AID MEASURES

General information: Consult a physician and show this safety data sheet.
Inhalation: Remove to fresh air and monitor breathing. Consult a physician.

Section 4: FIRST AID MEASURES (continued)

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| Skin contact: | Wash skin immediately with soap and copious amounts of water. Remove contaminated clothing and shoes and wash before wearing. Consult a physician. |
| Eye contact: | Flush eyes immediately with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating eyelids with fingers. Consult a physician. |
| Ingestion: | If the person is conscious, wash out mouth with water. Consult a physician. |
| First aider: | Wear suitable protective clothing, such as chemical resistant gloves and chemical safety goggles. Use a NIOSH/MSHA approved respirator. Handle in laboratory with adequate ventilation. |
| Most important symptoms and effects: | May be harmful by inhalation, ingestion or skin absorption. May cause irritation. Prolonged or repeated contact may cause allergic or autoimmune reactions in certain sensitive individuals. Toxicological properties have not been thoroughly investigated. |

Section 5: FIREFIGHTING MEASURES

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| Extinguishing media: | Use extinguishing media appropriate to surrounding fire conditions (dry chemical powder, carbon dioxide or water spray recommended). |
| Hazardous Combustion or Decomposition Products: | Nature of decomposition products not known. |
| Advice for firefighters: | Wear self-contained breathing apparatus and full protective clothing to prevent contact with skin and eyes. |

Section 6: ACCIDENTAL RELEASE MEASURES

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| For non-emergency personnel: | Evacuate area. Wear suitable protective clothing, such as chemical resistant gloves and chemical safety goggles. Use a NIOSH/MSHA approved respirator. Handle in laboratory with adequate ventilation. |
| For emergency responders: | Wear suitable protective clothing, such as chemical resistant gloves and chemical safety goggles. Use a NIOSH/MSHA approved respirator. Handle in laboratory with adequate ventilation. |
| Environmental precautions: | Do not let product enter drains. |
| Containment: | Place in a suitable, closed bag/container. Avoid raising dust. Hold for appropriate waste disposal. |
| Cleaning up: | Sweep up, avoid raising dust. Ventilate area and wash spill site after material pickup is complete. |

Section 7: HANDLING AND STORAGE

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| Handling: | Avoid contact and inhalation. Keep container closed and open only as necessary. Wear protective equipment and follow general precautionary procedures applying to working in a laboratory/industrial environment (e.g. wash hands after handling). Follow general rules/regulations of laboratory waste disposal. |
| Storage: | Store at or below -70°C. |

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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| Engineering controls: | Handle in laboratory with adequate ventilation. |
| Personal protection equipment | |
| Eye and face protection: | Wear chemical safety goggles according to appropriate standards such as EN 166 (EU) NIOSH or (US). |
| Skin protection: | Wear chemical resistant gloves, which meet the specifications of directive 89/686/EEC. Wear suitable protective clothing according to the planned work and specific work-place. |
| Respiratory protection: | Use a CEN (EU) or NIOSH/MSHA (US) approved respirator. |
| Environmental exposure controls: | Do not let product enter drains. |

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

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| Appearance: | Clear solution |
| Physical State: | Liquid |

Section 10: STABILITY AND REACTIVITY

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| Chemical stability: | Stable under recommended storage conditions. |
| Hazardous decomposition products: | Nature of decomposition products not known. |
| Hazardous polymerization: | Mixture will not form hazardous polymers. |

Section 11: TOXICOLOGICAL INFORMATION

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| General information: | Only those hazardous and carcinogenic ingredients of the mixture are listed, which are present in a concentration of at least 1% and 0.1%, respectively. Test data are only available for individual ingredients. The physical, chemical and toxicological characteristics of the mixture have not been thoroughly investigated. |
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Section 11: TOXICOLOGICAL INFORMATION (continued)

Glycerol

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| Acute toxicity: | LD50 oral (rat) 12600 mg/kg LD50 dermal (rabbit) > 10000 mg/kg |
| Skin corrosion/irritation: | Mild skin irritation – 24h (skin, rabbit) |
| Eye damage/irritation: | Mild eye irritation – 24h (eyes, rabbit) |
| Carcinogenicity: | No component or substance of this product at levels greater or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. |
| Chronic exposure: | Extensive exposure may cause headache, nausea and vomiting. |
| Target organ(s): | May cause kidney irregularities. |

Sodium Chloride

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| Acute toxicity: | LD50 oral (rat) 3000 mg/kg LD50 dermal (rabbit) > 10000 mg/kg |
| Skin corrosion/irritation: | Skin irritation on prolonged or repeated contact (skin, rabbits). |
| Eye damage/irritation: | Mild eye irritation (eyes, rabbits). |
| Carcinogenicity: | No component or substance of this product at levels greater or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. |
| Chronic exposure: | No data available. |
| Target organ(s): | Not classified as specific target organ toxicant. |
| Additional information: | May cause nausea or vomiting after swallowing. |

Mixture

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| Chronic exposure: | Prolonged or repeated exposure to the mixture may cause allergic or autoimmune reactions in certain sensitive individuals. |
| Carcinogenicity: | No component or substance of this product at levels greater or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. |

Section 12: ECOLOGICAL INFORMATION

Sodium Chloride

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| Aquatic toxicity: | LC50 7650 mg/l – 96h (<i>Pimephales promelas</i>) EC50 1000 mg/l – 48h (<i>Daphnia magna</i>) |
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Section 13: DISPOSAL CONSIDERATIONS

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| Product/package disposal: | Due to the biological nature of this product and as good laboratory practice, we recommend that its disposal includes a biological inactivation step (e.g. by autoclaving, incineration, etc.), even though the biohazard properties of the product do not make such a step mandatory. |
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Section 13: DISPOSAL CONSIDERATIONS (continued)

Sewage disposal-relevant information:

Waste should not be disposed of by release to sewer.

Other disposal recommendations:

Country, federal, state and local regulations concerning disposal vary and change frequently. It remains the responsibility of the waste treatment operator to comply with these regulations. For this reason, we recommend that you contact your authorities for information on the disposal of this product and observe any applicable regulations. Alternatively, arrange for disposal by a licensed disposal company.

Section 14: TRANSPORT INFORMATION

This product is not hazardous and no precautionary steps according to ADR/RID, IMDG, and IATA are necessary.

Section 15: REGULATORY INFORMATION

General information:

This safety datasheet was generated according to Regulations (EC) No 1907/2006 and 1272/2008.

Safety, health and environmental regulations/legislation specific for the substance or mixture:

Not known.

Chemical safety assessment:

Not carried out.

Section 16: Other information

Caution:

Product has not been fully tested. Based on general health and good laboratory practice considerations, the observation of the following hazard and precautionary statements is recommended:

Hazard Statements:

H302 Harmful if swallowed
H312 Harmful in contact with skin
H332 Harmful if inhaled

Precautionary Statements:

P262 Do not get in eyes, on skin, or on clothing
P280 Wear protective gloves/protective clothing/eye protection/face protection
P281 Use personal protective equipment as required

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| Section 16: Other information (continued) |
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Disclaimer:

Material should only be handled by qualified, experienced professionals. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide for experienced personnel. This product is intended for research use or manufacturing only. DIARECT AG shall not be held liable for any damage resulting from the handling or from contact with the above product.

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