Medical Grade Silicone Rubber Solvent-Free Eco-Friendly Mold Release Agent ISO 10993 Compliant

Our Product Introduction

Basic Information

- Place of Origin: Guangdong, China
- Brand Name: Lubekote
- Certification: ISO 9001:2015, ISO 10993, LFGB, USP Class VI
- Model Number: LK-9800-MG
- Minimum Order Quantity: 10 Liters
- Price: USD 25-40 / Liter
- Packaging Details: 10L and 20L HDPE drum, 200L steel drum, cleanroom-grade packaging available
- Delivery Time: 5-7 working days for stock, 15-20 days for production
- Payment Terms: T/T,L/C,PayPal,Western Union
- Supply Ability: 15000 Liters per Month

Product Specification

- Product Type: Solvent-Free Water-Based Mold Release Agent
- Target Rubber: Medical Grade Silicone (Platinum-Cured)
- Application: Medical Devices, Pharmaceutical Components, Food Contact
- Dilution Ratio: 1:15 To 1:25
- Biocompatibility: ISO 10993-5, ISO 10993-10
- Appearance: Clear To Slightly Hazy Liquid
- PH Value: 6.5-7.5
- VOC Content: <10 G/L
- Shelf Life: 12 Months
- Highlight: **medical grade silicone mold release agent**, **solvent-free rubber mold release**, **eco-friendly ISO 10993 compliant release agent**

Our Product Introduction

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Product Description

Solvent-Free Eco-Friendly Mold Release Agent for Medical Grade Silicone

Product Introduction

Lubekote LK-9800-MG represents the pinnacle of clean, biocompatible mold release technology for medical grade silicone rubber applications. As the medical device industry increasingly demands higher purity standards and comprehensive biocompatibility documentation, traditional solvent-based or silicone oil-containing release agents are no longer acceptable. LK-9800-MG is formulated with a proprietary solvent-free, water-based polymer system that eliminates all organic solvents, silicone oils, and potentially cytotoxic extractables. The product has been independently tested and validated against ISO 10993-5 (cytotoxicity) and ISO 10993-10 (skin irritation and sensitization) standards, providing the biocompatibility assurance required for Class I, II, and III medical device manufacturing. Additionally, it meets LFGB (German Food and Feed Code) and USP Class VI requirements for pharmaceutical and food contact applications.

Key Features & Benefits

ISO 10993 Biocompatibility Compliant: Independently tested per ISO 10993-5 (cytotoxicity, MEM elution method) and ISO 10993-10 (irritation and delayed-type hypersensitivity), providing documented biocompatibility for medical device regulatory submissions.

100% Solvent-Free Formulation: Contains zero organic solvents, eliminating concerns about residual solvent extractables that could compromise medical device biocompatibility or pharmaceutical product stability.

Zero Silicone Oil Content: Unlike conventional silicone-based release agents that can leave silicone oil residues, LK-9800-MG is completely silicone-free, preventing cross-contamination that could affect subsequent bonding, coating, or sterilization processes.

Platinum Cure Compatible: Formulated without catalyst poisons (sulfur, amines, tin compounds) that can inhibit platinum-catalyzed addition cure systems commonly used for medical grade silicone.

Ultra-Low Extractables Profile: The cured release film has been validated to produce minimal extractable substances, with total organic carbon (TOC) levels well below USP <643> limits for pharmaceutical water systems.

Cleanroom-Ready: Filtered to 0.2 micron and filled under ISO Class 7 cleanroom conditions, suitable for direct use in ISO Class 7 and 8 medical device manufacturing environments.

Why Choose Us

Our 12-year legacy in rubber processing auxiliaries has evolved to meet the exacting standards of the medical device industry. We operate a dedicated medical-grade production line within our ISO 9001:2015 certified facility, with enhanced quality protocols including endotoxin testing (LAL assay per USP <85>), bioburden monitoring, and full traceability from raw material to finished batch. Our regulatory affairs team maintains comprehensive technical documentation including Master File (DMF) type III and Medical Device Master File (MAF) support for customer regulatory submissions. We provide change notification guarantees as required by ISO 13485 supply chain management. Each batch ships with a Certificate of Analysis (CoA) including biocompatibility lot verification. Our application scientists offer cleanroom process validation support and can customize formulations for specific medical silicone grades and molding parameters.

Technical Parameters

Parameter	Specification
Product Type	Solvent-Free Water-Based Mold Release Agent
Target Rubber	Medical Grade Silicone (Platinum-Cured)
Biocompatibility	ISO 10993-5, ISO 10993-10, USP Class VI
Dilution Ratio	1:15 to 1:25
Release Cycles per Application	4-6 Cycles
Appearance	Clear to Slightly Hazy Liquid
VOC Content	<10 g/L
Shelf Life	12 Months (Unopened)

Application Instructions

Mold Preparation: Clean mold with medical-grade isopropyl alcohol (IPA 70%) or validated alkaline cleaner. Rinse thoroughly with WFI (Water for Injection) or purified water. Dry completely in cleanroom environment.

Dilution: Using aseptic technique, dilute concentrate with sterile purified water or WFI at 1:15 to 1:25 ratio. Prepare only the volume needed for the production shift. Filter diluted solution through 0.2-micron filter if required by process validation.

Application: Apply using a validated clean spray system in a controlled environment. Use 2-3 light coats with 30-second intervals. Verify complete coverage under appropriate lighting.

Frequently Asked Questions (FAQ)

Q: What biocompatibility documentation is provided?

A: We provide a comprehensive Biocompatibility Summary Document including ISO 10993-5 cytotoxicity test report (MEM elution, L929 cells), ISO 10993-10 irritation and sensitization test reports, USP Class VI systemic toxicity test data, and a material characterization summary including GC-MS extractables profile.

Q: Is it suitable for implantable medical devices?

A: LK-9800-MG is validated for short-term (<24 hours) and prolonged (24 hours to 30 days) patient contact applications. For permanent implant applications (>30 days), please contact our regulatory team for specific guidance and additional testing data.

Q: Can it withstand EtO and gamma sterilization?

A: The release film is stable through standard EtO sterilization cycles (55°C, 60-80% RH) and gamma irradiation up to 50 kGy. Post-sterilization release performance has been validated through functional testing.

Q: What is the minimum order for medical grade evaluation?

A: We offer 1-liter medical grade evaluation kits including CoA, biocompatibility summary, and application protocol. A Quality Agreement and Supply Agreement are required for production supply.

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