

PolyMast™ suspension for intramammary infusion

Version 1.0 Revision Date: 02/03/2023 SDS Number: 000000041514 Date of last issue: -
Date of first issue: 02/03/2023

SECTION 1. IDENTIFICATION

Product name : PolyMast™ suspension for intramammary infusion

Synonyms : Hetacin-K® suspension for intramammary infusion
with active ingredient: hetacillin potassium

Manufacturer or supplier's details

Company name of supplier : Boehringer Ing. Pharma GmbH & Co.KG

Address : Binger Straße 173
Ingelheim 55216
Germany

Telephone : +498007790900

Emergency telephone number : Int. Emergency Telephone number: +1 703-527-3887
German Emergency Telephone number: +49800 1817059

Prepared by : EHS-Services@Boehringer-Ingelheim.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Safety Data Sheet only for the professional user., For veterinary use only, Refer to the product insert for complete instructions on usage

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Respiratory sensitisation : Category 1

Skin sensitisation : Category 1

GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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Precautionary statements : **Prevention:**
 P261 Avoid breathing mist or vapours.
 P272 Contaminated work clothing must not be allowed out of the workplace.
 P280 Wear protective gloves.
 P285 In case of inadequate ventilation wear respiratory protection.

Response:
 P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
 P304 + P341 IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
 P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
 P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.
 P363 Wash contaminated clothing before reuse.

Disposal:
 P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

This drug is not subject to the labelling requirements under the Globally Harmonized System (GHS)
 The pharmacological effect of the medicament has to be considered (see package leaflet).

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture
 Chemical nature : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Peanut oil	8002-03-7	>= 90 - <= 100
Hetacillin Potassium	5321-32-4	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
 (show the package insert where possible).
 First Aid responders should pay attention to self-protection and use the recommended protective clothing
 Remove from exposure, lie down.
 Take off immediately all contaminated clothing.
 Victim to lie down in the recovery position, cover and keep him warm.

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If inhaled	:	Move to fresh air.
In case of skin contact	:	Wash off immediately with plenty of water.
In case of eye contact	:	Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing.
If swallowed	:	Rinse mouth. Drink plenty of water.
Most important symptoms and effects, both acute and delayed	:	May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Notes to physician	:	Observe the summary of product characteristics of proprietary medicinal products Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Water Dry chemical Foam Carbon dioxide (CO ₂)
Unsuitable extinguishing media	:	None known.
Specific hazards during fire-fighting	:	In case of fire and/or explosion do not breathe fumes.
Hazardous combustion products	:	Carbon oxides
Further information	:	Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Complete suit protecting against chemicals

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Wear personal protective equipment. Ensure adequate ventilation. High risk of slipping due to leakage/spillage of product.
Environmental precautions	:	Do not flush into surface water or sanitary sewer system.

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Methods and materials for containment and cleaning up : Pick up and transfer to properly labelled containers. Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders).

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : No special protective measures against fire required.

Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms.

Conditions for safe storage : Refer to the product insert for instructions on storage.

Materials to avoid : Keep away from food, drink and animal feedingstuffs. Observe joint storage prohibition.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	Basis	Category	Values	Remarks
Hetacillin Potassium 5321-32-4	BIEL	3A	20 µg/m ³	
	BIPC	1b		
Abbreviations: BIEL = Boehringer Ingelheim Exposure Limit (internal value) BI-STEL = Boehringer Ingelheim Short-Term Exposure Limit (Excursion limit) BIPC = Boehringer Ingelheim Pregnancy Category BIPC 1b: No risk of harm to the unborn is to be expected, when the exposure does not exceed the BIEL value. There is evidence in animals and/or humans that this material has the potential to cause harm to the unborn at exposure levels exceeding the BIEL value.				

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Peanut oil	8002-03-7	TWA (mist - total)	10 mg/m ³	NIOSH REL
		TWA (mist - respirable)	5 mg/m ³	NIOSH REL

Engineering measures : Local exhaust
Emergency sprinkling nozzle

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazard-

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ous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection Material	:	Nitrile rubber
Remarks	:	The break through time depends amongst other things on the material, the thickness and the type of glove and therefore has to be measured for each case.
Eye protection	:	Safety glasses with side-shields (Not necessary when using full face mask)
Skin and body protection	:	Laboratory: laboratory coat; Factory: disposable Overall.
Protective measures	:	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.
Hygiene measures	:	General industrial hygiene practice. Wash hands and face before breaks and immediately after handling the product. Keep working clothes separately.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	suspension
Colour	:	off-white
Odour	:	No data available
pH	:	No data available
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	541 °F / 283 °C
Flammability (solid, gas)	:	Not applicable

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Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Bulk density	:	Not applicable
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	Not tested
Oxidizing properties	:	No data available
Particle size	:	Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	No decomposition if stored and applied as directed.
Possibility of hazardous reactions	:	No dangerous reaction known under conditions of normal use.
Conditions to avoid	:	No data available
Incompatible materials	:	No data available

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Hazardous decomposition products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified based on available information.

Product:

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:**Hetacillin Potassium:**

Acute oral toxicity : LD50 (Mouse): > 15,000 mg/kg
LD50 (Rat): > 10,000 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : LD50 (Mouse): 650 mg/kg
Application Route: intravenous

LD50 (Rat): > 1,400 mg/kg
Application Route: intravenous

Skin corrosion/irritation

Not classified based on available information.

Components:**Hetacillin Potassium:**

Remarks : No data available

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Hetacillin Potassium:**

Remarks : No data available

Respiratory or skin sensitisation**Skin sensitisation**

May cause an allergic skin reaction.

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Respiratory sensitisation

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components:**Hetacillin Potassium:**

Result : May cause sensitisation by skin contact.
Test substance : Analogous: Assessment derived from products with similar chemical character.

Result : May cause sensitisation by inhalation.
Test substance : Analogous: Assessment derived from products with similar chemical character.

Germ cell mutagenicity

Not classified based on available information.

Components:**Hetacillin Potassium:**

Genotoxicity in vitro : Test Type: Ames test
Result: negative
Remarks: In vitro tests did not show mutagenic effects
The value is given in analogy to the following substances:
Ampicillin

Genotoxicity in vivo : Remarks: No data available

Carcinogenicity

Not classified based on available information.

Components:**Hetacillin Potassium:**

Species : Mouse
Application Route : Oral
Exposure time : 103 weeks
Dose : <3000 mg/kg
Result : negative
The value is given in analogy to the following substances: Ampicillin trihydrate

Species : Rat, female
Application Route : Oral
Exposure time : 103 weeks
Dose : 750, 1500 mg/kg
Result : negative
The value is given in analogy to the following substances: Ampicillin trihydrate

Species : Rat, male
Application Route : Oral
Exposure time : 103 weeks
Dose : 750, 1500 mg/kg
Result : equivocal

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The value is given in analogy to the following substances: Ampicillin trihydrate

IARC No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

Components:
Hetacillin Potassium:

Effects on fertility : Species: Rat, male
Application Route: Oral
Dose: 40 mg/kg/day
Symptoms: Effects on fertility
The value is given in analogy to the following substances:
Ampicillin

Effects on foetal development : Test Type: Embryo-foetal development
Species: Mouse
Application Route: Oral
Dose: 400, 1300 mg/kg bw/day
Symptoms: Abnormalities of the musculoskeletal system
The value is given in analogy to the following substances:
Ampicillin trihydrate

Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Dose: 4000 mg/kg bw/day
Symptoms: Abnormalities of the musculoskeletal system
The value is given in analogy to the following substances:
Ampicillin trihydrate

Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Dose: 250 mg/kg bw/day
Symptoms: Reduced foetal weight

STOT - single exposure

Not classified based on available information.

Components:
Hetacillin Potassium:

Remarks : No data available

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STOT - repeated exposure

Not classified based on available information.

Components:**Hetacillin Potassium:**

Remarks : No data available

Repeated dose toxicity**Components:****Hetacillin Potassium:**

Species : Rat
Application Route : Oral
Exposure time : 26 weeks
Dose : 200, 500, 1000 mg/kg/day

Aspiration toxicity

Not classified based on available information.

Components:**Hetacillin Potassium:**

No data available

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Hetacillin Potassium:**

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae/aquatic plants : Remarks: No data available

Toxicity to fish (Chronic toxicity) : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: No data available

Toxicity to microorganisms : Remarks: No data available

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Ecotoxicology Assessment

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

Persistence and degradability**Components:****Peanut oil:**

Biodegradability : Result: Readily biodegradable.

Hetacillin Potassium:

Biodegradability : Result: No data available

Bioaccumulative potential**Components:****Peanut oil:**

Partition coefficient: n-octanol/water : Remarks: No data available

Hetacillin Potassium:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : Remarks: No data available

Mobility in soil**Components:****Hetacillin Potassium:**

Distribution among environmental compartments : Remarks: No data available

Other adverse effects**Product:**

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Components:**Hetacillin Potassium:**

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Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents.
Uncontaminated packaging can be recycled.

SECTION 14. TRANSPORT INFORMATION

International Regulations

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

49 CFR

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Respiratory or skin sensitisation

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

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Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

Peanut oil 8002-03-7

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California Permissible Exposure Limits for Chemical Contaminants

Peanut oil 8002-03-7

The components of this product are reported in the following inventories:

TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.
AIC	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. Hetacillin Potassium
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory

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KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

NZIoC : Not in compliance with the inventory

TECI : Not in compliance with the inventory

TSCA list

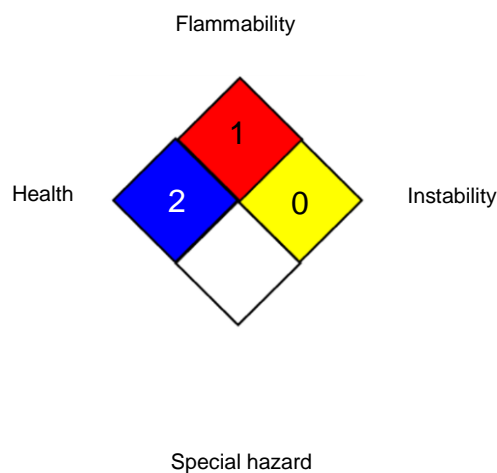
No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:

HEALTH	*	2
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

NIOSH REL : USA. NIOSH Recommended Exposure Limits

NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek

AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency

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Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Safety Data Sheet : The specifications are based on own tests and/or literature data.

Revision Date : 02/03/2023

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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