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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Poulvac Myco F

Trade Name: POULVAC®
Compound Number: 1751.01
Synonyms: F-VAX MAG
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary Vaccine

Details of the Supplier of the Safety Data Sheet

Zoetis Inc. 100 Campus Drive, P.O. Box 651 Florham Park, New Jersey 07932 (USA)

Rocky Mountain Poison Control Center Phone: 1-866-531-8896

Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem Belgium

Emergency telephone number: Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: VMIPSrecords@zoetis.com

International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Appearance: Brown White Liquid

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

EU Classification:

EU Indication of danger: Not classified

Label Elements

Signal Word: Not Classified

Other Hazards

Short Term: Contains trace quantities of penicillin which can cause allergic reactions in susceptible

individuals. Toxicity following ingestion is not expected. However, ingestion should be avoided. In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate

therapy instituted. May cause eye, skin and respiratory tract irritation Repeated exposure to dust or mist may produce allergic reactions.

Australian Hazard Classification

Long Term:

(NOHSC):

Non-Hazardous Substance. Non-Dangerous Goods.

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Note: This document has been prepared in accordance with standards for workplace safety, which

require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases.

Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU	EU Classification	GHS	%
		EINECS/ELINCS		Classification	
		List			
Penicillin	1406-05-9	215-794-6	Not Listed	Not Listed	<1.0
Potassium hydroxide	1310-58-3	215-181-3	Xn; R22	Acute Tox. 4	<1.0
			C; R35	(H302)	
				Skin Corr. 1A	
				(H314)	

Ingredient	CAS Number	EU	EU Classification	GHS	%
		EINECS/ELINCS List		Classification	
CASEIN ACID HYDROLYSATE	91079-40-2	293-428-4	Not Listed	Not Listed	*
Dibasic Potassium Phosphate	7758-11-4	231-834-5	Not Listed	Not Listed	*
Glutamic acid	56-86-0	200-293-7	Not Listed	Not Listed	*
Lactose NF, monohydrate	64044-51-5	Not Listed	Not Listed	Not Listed	*
Mycoplasma Gallisepticum	Not Assigned	Not Listed	Not Listed	Not Listed	*
Potassium phosphate	7778-77-0	231-913-4	Not Listed	Not Listed	*
Povidone	9003-39-8	Not Listed	Not Listed	Not Listed	*
Water	7732-18-5	231-791-2	Not Listed	Not Listed	*

Additional Information: * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace

safety.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention

immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek

medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not

induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of

O1

For information on potential signs and symptoms of exposure, See Section 2 - Hazards

Identification and/or Section 11 - Toxicological Information.

Medical Conditions

Exposure:

Aggravated by Exposure:

Allergy to penicillins

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Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: Skin effects may indicate an allergic reaction. Ocular symptoms may indicate an allergic

reaction. Pulmonary symptoms may indicate allergic reaction or asthma. For combustion products, refer to section number 5. Medical treatment in cases of overexposure should be treated as an overdosage of penicillin antibiotic. Refer to current prescribing information or to

local poison control information centers.

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Formation of toxic gases is possible during heating or fire.

Products:

Fine / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill

Collecting: area thoroughly.

Additional Consideration for

Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Avoid accidental injection. Minimize generating airborne mists and vapors. Avoid breathing mist or aerosols. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Incompatible Materials: This material can be denatured or inactivated by a variety of organic solvents, salts or heavy

metals.

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Glutamic acid

Latvia OEL - TWA 10 mg/m³

Penicillin

Bulgaria OEL - TWASweden OEL - TWAs

0.1 mg/m³

0.1 mg/m³

Potassium hydroxide

ACGIH Ceiling Threshold Limit: 2 mg/m^3 2 mg/m³ **Australia PEAK** 2 mg/m³ **Austria OEL - MAKs** 2.0 mg/m³ **Bulgaria OEL - TWA** 1 mg/m^3 Czech Republic OEL - TWA 2 mg/m³ Estonia OEL - TWA 2 mg/m³ **Greece OEL - TWA** 2 mg/m³ **Hungary OEL - TWA** 2 ma/m3 Japan - OELs - Ceilings **Poland OEL - TWA** 0.5 mg/m³ 1 mg/m^3 Sweden OEL - TWAs **Switzerland OEL -TWAs** 2 mg/m³

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Refer to applicable national standards and regulations in the selection and use of personal

Equipment: protective equipment (PPE).

Hands: Wear impervious gloves if skin contact is possible. **Eyes:** Wear safety glasses or goggles if eye contact is possible.

Skin: Individuals with known sensitivity to penicillin should wear long sleeves to avoid skin contact.

Wash hands and arms thoroughly after handling this material.

Respiratory protection: None required under normal conditions of use. If the applicable Occupational Exposure Limit

(OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control

exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:LiquidColor:White/BrownOdor:No data available.Odor Threshold:No data available.

Molecular Formula: Mixture Molecular Weight: Mixture

Solvent Solubility:
Water Solubility:
Solubility:
Solubility:
Soluble: Water
Water
No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

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Vapor Pressure (kPa):No data availableVapor Density (g/ml):No data availableRelative Density:No data availableViscosity:No data available

Flammablity:

Autoignition Temperature (Solid) (°C):

Flammability (Solids):

Flash Point (Liquid) (°C):

Upper Explosive Limits (Liquid) (% by Vol.):

Lower Explosive Limits (Liquid) (% by Vol.):

Polymerization:

No data available
No data available
Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do

not freeze.

Incompatible Materials: This material can be denatured or inactivated by a variety of organic solvents, salts or heavy

metals.

Hazardous Decomposition

Products:

No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:

Toxicological properties of the formulation have not been investigated. The information included in this section describes the potential hazards of the individual ingredients. The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms.

Acute Toxicity: (Species, Route, End Point, Dose)

Potassium hydroxide

Rat Oral LD50 273 mg/kg

Povidone

Rat Oral LD50 100 g/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Potassium hydroxide

Skin Irritation Rabbit Severe
Skin Irritation Guinea Pig Severe
Eye Irritation Rabbit Moderate

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Povidone

IARC: Group 3 (Not Classifiable)

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11. TOXICOLOGICAL INFORMATION

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. Releases to

the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State

specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental

releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

WHMIS hazard class:

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

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15. REGULATORY INFORMATION

CASEIN ACID HYDROLYSATE

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed
293-428-4

Dibasic Potassium Phosphate

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not Listed

Not Listed

Not Listed

Not Listed

Not Eisted

Not

Glutamic acid

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not Listed

Not Listed

Not Listed

Not Listed

Not Listed

Not Eisted

Not Listed

Not

Lactose NF, monohydrate

CERCLA/SARA 313 Emission reporting

California Proposition 65

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not Listed

Mycoplasma Gallisepticum

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed

Not Listed

Penicillin

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed
215-794-6

Potassium hydroxide

CERCLA/SARA 313 Emission reporting Not Listed **CERCLA/SARA Hazardous Substances** 1000 lb and their Reportable Quantities: 454 kg Not Listed **California Proposition 65** Inventory - United States TSCA - Sect. 8(b) Present Australia (AICS): Present Standard for the Uniform Scheduling Schedule 5 Schedule 6 for Drugs and Poisons: **EU EINECS/ELINCS List** 215-181-3

Potassium phosphate

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Not Listed

Not Listed

Not Listed

Present

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15. REGULATORY INFORMATION

EU EINECS/ELINCS List 231-913-4

Povidone

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not Listed

Water

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

REACH - Annex IV - Exemptions from the

Not Listed
Present
Present

obligations of Register:
EU EINECS/ELINCS List 231-791-2

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.2; H302 - Harmful if swallowed Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage

Xn - Harmful C - Corrosive

R22 - Harmful if swallowed. R35 - Causes severe burns.

Data Sources:The data contained in this MSDS may have been gathered from confidential internal sources,

raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

Prepared by: Toxicology and Hazard Communication Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet
