



MATERIAL SAFETY DATA SHEET

Revision date: 06-Jun-2006

Version: 1.0

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

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CHEMTREC (24 hours): 1-800-262-8200

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ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Porphyromonas Denticanis-Gulae-Salivosa Bacterin

Trade Name: Not determined
Chemical Family: Mixture
Intended Use: Veterinary Vaccine

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Formaldehyde	50-00-0	200-001-8	0.1 - 1.0%
Quil-A saponin	66594-14-7	Not listed	##

Ingredient	CAS Number	EU EINECS List	%
Porphyromonas denticanis	Not assigned	Not listed	*
Porphyromonas gulae	Not assigned	Not listed	*
Porphyromonas salivosa	Not assigned	Not listed	*
Water, purified	7732-18-5	231-791-2	>90%
Cholesterol	57-88-5	200-353-2	##

Additional Information: * Proprietary
Trace
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Cloudy, white liquid
Signal Word: WARNING

Statement of Hazard: Contains formaldehyde: potential cancer hazard; May cause sensitization of the skin and respiratory system; May cause eye, skin and respiratory tract irritation

Eye Contact: May cause eye irritation.
Skin Contact: May cause skin irritation. May cause allergic reaction.
Inhalation: An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8). See 'Known clinical effects' and 'Other potential health effects', below.
Ingestion: None known

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Potential Health Effects: 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. Saponins have little toxicity for humans when ingested but have hemolytic effects when injected intravenously.

EU Indication of danger: Irritant

EU Hazard Symbols:

Xi



R43 - May cause sensitization by skin contact.

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.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Wash skin with soap and water. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media: As for primary cause of fire.

Hazardous Combustion Products: Not known

Fire Fighting Procedures: Dike and collect water used to fight fire.

Fire / Explosion Hazards: Not flammable.

Additional Information: This product is a nonflammable aqueous solution. This material is not expected to support combustion.

6. ACCIDENTAL RELEASE MEASURES

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

Measures for Cleaning / Collecting: Contain the source of the spill or leak. Use non-combustible absorbent material to wipe up spill and place in a sealed container for disposal. Clean spill area thoroughly. Prevent discharge to drains.

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Measures for Environmental Protections:

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

Additional Consideration for Large Spills:

Dike, pump, or use non-combustible material to absorb spill; then place in a labeled container for disposal. Close container and move it to a secure holding area. Prevent discharge to drains.

7. HANDLING AND STORAGE

General Handling:

Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment.

Storage Conditions:

Store under refrigeration in closed container.

Storage Temperature:

2-7°C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Formaldehyde

OSHA - Specifically Regulated Chemicals

0.5 ppm-Action Level

0.75 ppm-TWA

2 ppm-STEL

ACGIH Ceiling Threshold Limit:

0.3 ppm

ACGIH - Sensitizer Designation

Listed

See exposure limits for component (s) listed above.

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Exposure monitoring may be necessary to determine requirements.

Personal Protective Equipment:

Hands:

Wear impervious gloves if skin contact is possible.

Eyes:

Safety glasses or goggles

Skin:

Wear protective clothing when working with large quantities. Wash hands and arms thoroughly after handling this material.

Respiratory protection:

In the event of a spill where the applicable Occupational Exposure Limit (OEL) may be exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:

Liquid

Color:

Cloudy white

Molecular Formula:

Mixture

Molecular Weight:

Mixture

Solubility:

Soluble: Water (based on components)

pH:

7.0 +/- 1.5

Flash Point (°C):

Non-flammable

Boiling Point (°C):

>100

Specific Gravity:

1.0 +/- 0.2

Vapor Pressure (kPa):

Expected to be negligible

10. STABILITY AND REACTIVITY

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Stability: Stable
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: None expected under normal conditions.
Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

General Information: The bacterial cells included in this product have been inactivated and are no longer infectious. The primary hazards are due to the formaldehyde content.

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

Formaldehyde

Rat Oral LD50 800 mg/kg

Cholesterol

Rat Subcutaneous LC 50 > 2000 ug/kg

Rat Subcutaneous LC 50 2000 g/kg

Quil-A saponin

Rat IV LD50 670 ug/kg

Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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

Formaldehyde

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Moderate Severe

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Formaldehyde

90 Day(s) Dog Inhalation Not Specified Lungs

90 Day(s) Rat Inhalation Not Specified Lungs

90 Day(s) Monkey Inhalation Not Specified Lungs

9 Day(s) Rat Inhalation 15 ppm LOAEL Respiratory system

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Formaldehyde

Embryo / Fetal Development Mouse Oral 185 mg/kg/day Not teratogenic, Maternal toxicity

Embryo / Fetal Development Rat Inhalation 40 ppm Not Teratogenic, Maternal Toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Formaldehyde

In Vitro Bacterial Mutagenicity (Ames) Bacteria Positive

In Vitro Chromosome Aberration Rodent Positive

In Vitro Sister Chromatid Exchange Rodent Positive

In Vivo Chromosome Aberration Not specified Positive

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Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Formaldehyde

2 Year(s) Rat Inhalation 6 ppm LOAEL Tumors
2 Year(s) Mouse Inhalation 15 ppm LOAEL Tumors

Carcinogen Status: Contains formaldehyde: potential cancer hazard.

Formaldehyde

IARC: Group 1
NTP: Listed
OSHA: Present

Cholesterol

IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Observe all local and national regulations when disposing of this material. This product may qualify as a RCRA Hazardous Waste. Status should be confirmed by testing for RCRA hazardous characteristics (i.e. corrosivity, toxicity, reactivity, or ignitability).

Formaldehyde

RCRA - K Series Wastes Listed
RCRA - U Series Wastes Listed

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: Xi
EU Indication of danger: Irritant

EU Risk Phrases: R43 - May cause sensitization by skin contact.

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EU Safety Phrases:

S24 - Avoid contact with skin.
S37 - Wear suitable gloves.

OSHA Label:

WARNING

Contains formaldehyde: potential cancer hazard; May cause sensitization of the skin and respiratory system; May cause eye, skin and respiratory tract irritation

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A

Formaldehyde

CERCLA/SARA 313 Emission reporting
CERCLA/SARA Hazardous Substances
and their Reportable Quantities:

0.1% de minimis concentration
10 lb final RQ
100 lb final RQ
4.54 kg final RQ
4.54 kg final RQ
4.54 kg final RQ
4.54 kg final RQ
45.4 kg final RQ
500 lb TPQ

CERCLA/SARA - Section 302 Extremely Hazardous
TPQs

CERCLA/SARA - Section 302 Extremely Hazardous
Substances EPCRA RQs

California Proposition 65

EU EINECS List

OSHA - Specifically Regulated Chemicals

100 lb
carcinogen, initial date 1/1/88 (gas)
200-001-8
0.5 ppm-Action Level
0.75 ppm-TWA
2 ppm-STEL

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

Listed

Water, purified

EU EINECS List

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

231-791-2
Listed

Cholesterol

EU EINECS List

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

200-353-2
Listed

16. OTHER INFORMATION

Prepared by:

Corporate Occupational Toxicology & Hazard Assessment

Pfizer 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 a warranty of any kind, expressed or implied.

End of Safety Data Sheet