

SAFETY DATA SHEET



1. Identification

Product identifier	RESPISURE-ONE®/ER BAC PLUS®
Other means of identification	
Synonyms	RespiSure-ONE/ER Bac Plus * Erysipelothrix Rhusiopathiae-Mycoplasma Hypopneumoniae Bacterin
Recommended use	Veterinary vaccine
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Company Name (USA)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-800-366-5288
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (CA)	Zoetis Canada Inc. 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	productsupport@zoetis.com
Product Support	1-800-461-0917
	All Safety Data Sheets are available via our Zoetis Canada website at https://www.zoetis.ca/sds/sds.aspx
Supplier	Not available.
2. Hazard(s) identification	
Physical hazards	Not classified.
Health hazards	Not classified.
Environmental hazards	Not classified.
Label elements	
Hazard symbol	None.
Signal word	None.
Hazard statement	The mixture does not meet the criteria for classification.
Precautionary statement	
Prevention	Observe good industrial hygiene practices.
Response	Wash hands after handling.
Storage	Store away from incompatible materials.
Disposal	Dispose of waste and residues in accordance with local authority requirements.
Other hazards	None known.
Supplemental information	Direct contact with eyes may cause temporary irritation. In the event of accidental injection, an allergic reaction may occur. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Amphigen base (mineral oil + soy lecithin)		8042-47-5	1
Formaldehyde		50-00-0	<0.1
Erysipelothrix rhusiopathiae		Not assigned	*
Mycoplasma Hyopneumoniae		Not assigned	*
Sodium O-(ethylmercurithio)benzoate		54-64-8	##
Water, purified		7732-18-5	

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Composition comments ## Trace
* Non-hazardous Ingredients

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	In the case of skin contact, immediately wash the skin with plenty of soap and water. In the event of accidental self injection or needle stick injury, wash the injury thoroughly with clean running water. Get medical attention immediately.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do.
Ingestion	Rinse mouth. Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients.
Indication of immediate medical attention and special treatment needed	Treat symptomatically. Where parenteral oil-adjuvanted vaccine exposure has occurred, the patient should be promptly evaluated for the development of vasospasm and/or compartment syndrome.
General information	For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.
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Methods and materials for containment and cleaning up

Large Spills: Stop the flow of material, if this is without risk. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid discharge into drains, water courses or onto the ground.

Environmental precautions**7. Handling and storage****Precautions for safe handling**

Avoid contact with eyes, skin, and clothing. Avoid breathing mist or vapour. Avoid accidental injection. Wash thoroughly after handling. When using, do not eat, drink or smoke. Wear personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Store out of direct sunlight in dark, dry conditions. @ 2 - 7°C (36 - 45°F). Do not freeze. Store in original tightly closed container. Keep away from heat, sparks and open flame. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection**Occupational exposure limits****US. ACGIH Threshold Limit Values**

Components	Type	Value	Form
Amphigen base (mineral oil + soy lecithin) (CAS 8042-47-5)	TWA	5 mg/m ³	Inhalable fraction.
Formaldehyde (CAS 50-00-0)	Ceiling	0.3 ppm	
Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8)	STEL	0.03 mg/m ³	
	TWA	0.01 mg/m ³	

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Type	Value	Form
Amphigen base (mineral oil + soy lecithin) (CAS 8042-47-5)	STEL	10 mg/m ³	Mist.
	TWA	5 mg/m ³	Mist.
Formaldehyde (CAS 50-00-0)	Ceiling	1.3 mg/m ³	
	TWA	1 ppm 0.9 mg/m ³	
Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8)	STEL	0.75 ppm 0.03 mg/m ³	
	TWA	0.01 mg/m ³	

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value	Form
Amphigen base (mineral oil + soy lecithin) (CAS 8042-47-5)	TWA	1 mg/m ³	Mist.
Formaldehyde (CAS 50-00-0)	Ceiling	1 ppm	
	TWA	0.3 ppm	
Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8)	STEL	0.03 mg/m ³	
	TWA	0.01 mg/m ³	

Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act)

Components	Type	Value	Form
Amphigen base (mineral oil + soy lecithin) (CAS 8042-47-5)	TWA	5 mg/m3	Inhalable fraction.
Formaldehyde (CAS 50-00-0)	Ceiling	0.3 ppm	
Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8)	STEL	0.03 mg/m3	
	TWA	0.01 mg/m3	

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Type	Value	
Formaldehyde (CAS 50-00-0)	Ceiling	1.5 ppm	
	STEL	1 ppm	
Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8)	STEL	0.03 mg/m3	
	TWA	0.01 mg/m3	

Canada. Quebec OELs. (Ministry of Labour - Regulation Respecting the Quality of the Work Environment)

Components	Type	Value	Form
Amphigen base (mineral oil + soy lecithin) (CAS 8042-47-5)	STEL	10 mg/m3	Mist.
	TWA	5 mg/m3	Mist.
Formaldehyde (CAS 50-00-0)	Ceiling	3 mg/m3	
		2 ppm	
Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8)	STEL	0.03 mg/m3	
	TWA	0.01 mg/m3	

Canada. Saskatchewan OELs (Occupational Health and Safety Regulations, 1996, Table 21)

Components	Type	Value	
Formaldehyde (CAS 50-00-0)	Ceiling	0.3 ppm	

Biological limit values No biological exposure limits noted for the ingredient(s).

Exposure guidelines**Canada - Alberta OELs: Skin designation**

Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8) Can be absorbed through the skin.

Canada - British Columbia OELs: Skin designation

Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8) Can be absorbed through the skin.

Canada - Manitoba OELs: Skin designation

Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8) Can be absorbed through the skin.

Canada - Ontario OELs: Skin designation

Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8) Can be absorbed through the skin.

Canada - Quebec OELs: Skin designation

Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8) Can be absorbed through the skin.

Canada - Saskatchewan OELs: Skin designation

Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8) Can be absorbed through the skin.

US ACGIH Threshold Limit Values: Skin designation

Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8) Can be absorbed through the skin.

Control banding approach

Not available.

Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection	If contact is likely, safety glasses with side shields are recommended.
Skin protection	
Hand protection	Wear protective gloves. Wear impervious gloves if skin contact is possible.
Other	Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Respiratory protection	No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn.
Thermal hazards	Not applicable.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Physical state	Liquid.
Form	Liquid.
Colour	Not available.

Odour Not available.

Odour threshold Not available.

pH 6 - 8

Melting point/freezing point Not available.

Initial boiling point and boiling range > 100 °C (> 212 °F)

Flash point Non-flammable

Evaporation rate Not available.

Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit – upper (%) Not available.

Vapour pressure Not available.

Vapour density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Soluble

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Explosive properties Not explosive.

Oxidising properties Not oxidising.

Specific gravity 0.8 - 1.2

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Sunlight. Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.
Incompatible materials	Strong oxidising agents. This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	No adverse effects due to inhalation are expected.
Skin contact	Prolonged skin contact may cause temporary irritation.
Formaldehyde	Species: Rabbit Severity: Moderate Severe
Amphigen base (mineral oil + soy lecithin)	Species: Rabbit Severity: Slight
Eye contact	Direct contact with eyes may cause temporary irritation.
Sodium O-(ethylmercurithio)benzoate	Species: Rabbit Severity: Mild
Formaldehyde	Species: Rabbit Severity: Severe
Amphigen base (mineral oil + soy lecithin)	Species: Rabbit Severity: Slight

Ingestion Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients.

Information on toxicological effects

Acute toxicity

Components	Species	Test results
Amphigen base (mineral oil + soy lecithin) (CAS 8042-47-5)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg
Formaldehyde (CAS 50-00-0)		
Acute		
Oral		
LD50	Rat	800 mg/kg
Chronic		
Inhalation		
LOAEL	Mouse	15 ppm, 2 years Tumours
	Rat	15 ppm, 9 days Respiratory system
		6 ppm, 2 years Tumours

Components	Species	Test results
Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8)		
Acute		
Oral		
LD50	Rat	75 mg/kg
Subcutaneous		
LD50	Rat	98 mg/kg
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
Corrosivity		
Amphigen base (mineral oil + soy lecithin)	Species: Rabbit Severity: Slight	
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.	
Eye contact		
Sodium O-(ethylmercurithio)benzoate	Species: Rabbit Severity: Mild	
Formaldehyde	Species: Rabbit Severity: Severe	
Amphigen base (mineral oil + soy lecithin)	Species: Rabbit Severity: Slight	
Respiratory or skin sensitisation		
ACGIH sensitisation		
FORMALDEHYDE (CAS 50-00-0)	Dermal sensitization Respiratory sensitisation	
Canada - British Columbia OELs: Respiratory or skin sensitiser		
Formaldehyde (CAS 50-00-0)	Capable of causing respiratory, dermal or conjunctival sensitization.	
Canada - Manitoba OELs Hazard: Dermal sensitization		
Formaldehyde (CAS 50-00-0)	Dermal sensitization	
Canada - Manitoba OELs Hazard: Respiratory sensitization		
Formaldehyde (CAS 50-00-0)	Respiratory sensitisation	
Canada - Saskatchewan OELs Hazard Data: Sensitiser		
Formaldehyde (CAS 50-00-0)	Sensitiser.	
Respiratory sensitisation	Not a respiratory sensitizer.	
Skin sensitisation	Based on available data, the classification criteria are not met. This product contains formaldehyde and merthiolate which are considered to be skin sensitizers. This product is not expected to cause skin sensitisation.	
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Mutagenicity		
Formaldehyde	In Vitro Bacterial Mutagenicity (Ames) Result: positive Species: Bacteria	
	In Vitro Chromosome Aberration Result: positive Species: Rodent	
	In Vitro Sister Chromatid Exchange Result: positive Species: Rodent	
	In Vivo Chromosome Aberration Result: positive Species: Not specified	

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. No known carcinogens are present at greater than 0.1%.

ACGIH Carcinogens

Amphigen base (mineral oil + soy lecithin) (CAS 8042-47-5) A4 Not classifiable as a human carcinogen.
 Formaldehyde (CAS 50-00-0) A2 Suspected human carcinogen.

Canada - Alberta OELs: Carcinogen category

Formaldehyde (CAS 50-00-0) Suspected human carcinogen.

Canada - Manitoba OELs: carcinogenicity

Amphigen base (mineral oil + soy lecithin) (CAS 8042-47-5) Not classifiable as a human carcinogen.
 Formaldehyde (CAS 50-00-0) Suspected human carcinogen.

Canada - Quebec OELs: Carcinogen category

Formaldehyde (CAS 50-00-0) Suspected carcinogenic effect in humans.

IARC Monographs. Overall Evaluation of Carcinogenicity

Amphigen base (mineral oil + soy lecithin) (CAS 8042-47-5) 3 Not classifiable as to carcinogenicity to humans.
 Formaldehyde (CAS 50-00-0) 1 Carcinogenic to humans.

US. National Toxicology Program (NTP) Report on Carcinogens

Formaldehyde (CAS 50-00-0) Known To Be Human Carcinogen.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Developmental effects

Formaldehyde 185 mg/kg/day Embryo / Fetal Development, Not teratogenic
 Maternal toxicity
 Species: Mouse
 Organ: Oral

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

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Not an aspiration hazard.

Further information The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Components	Species	Test results
Formaldehyde (CAS 50-00-0)		
Aquatic		
Crustacea	EC50 Water flea (Daphnia pulex)	4.3 - 7.8 mg/l, 48 hours
Fish	LC50 Striped bass (Morone saxatilis)	10.302 - 16.743 mg/l, 96 hours

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions	Avoid release to the environment. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. 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. Dispose of contents/container in accordance with local/regional/national/international regulations.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company. This product contains trace quantities of mercury, releases to the environment should be avoided.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

TDG	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
IMDG	Not regulated as dangerous goods.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not established.

15. Regulatory information

Canadian regulations	This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.	
Controlled Drugs and Substances Act	Not regulated.	
Export Control List (CEPA 1999, Schedule 3)	Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8)	Substance subject to notification or consent.
Greenhouse Gases	Not listed.	
Ontario. Toxic Substances. Toxic Reduction Act, 2009. Regulation 455/09 (July 1, 2011)	Formaldehyde (CAS 50-00-0) Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8)	
Precursor Control Regulations	Not regulated.	
International regulations		
Stockholm Convention	Not applicable.	
Rotterdam Convention	Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8)	Pesticide
Kyoto protocol	Not applicable.	
Montreal Protocol	Not applicable.	
Basel Convention	Not applicable.	

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information

Issue date 08-May-2017

Version No. 01

Disclaimer Zoetis Inc. believes that the information contained in this 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. The information in the sheet was written based on the best knowledge and experience currently available.

Revision information Product and Company Identification: Synonyms
Composition / Information on Ingredients: Ingredients