

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Trade name or designation of the mixture	Vanguard R/Versiguard Rabies
Registration number	-
Synonyms	VANGUARD R * Versiguard Rabies * Inactivated Rabies Vaccine
Issue date	06-September-2016
Version number	01

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses	Veterinary vaccine
Uses advised against	ENRESOU006 - Not for human use

1.3. Details of the supplier of the safety data sheet

Company Name (US)	Zoetis Inc. 100 Campus Drive, P.O. Box 651 Florham Park, New Jersey 07932 (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
Contact E-Mail	VMIPRecords@zoetis.com
Company Name (EU)	Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem Belgium
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	VMIPRecords@zoetis.com

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture**

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Regulation (EC) No 1272/2008 as amended

This mixture does not meet the criteria for classification according to Regulation (EC) 1272/2008 as amended.

Hazard summary	Not classified for health hazards. However, occupational exposure to the mixture or substance(s) may cause adverse health effects.
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2.2. Label elements**Label according to Regulation (EC) No. 1272/2008 as amended**

Contains:	Aluminium hydroxide, Inactivated Rabies Virus, strain SAD VNUKOVO-32, Thimerosal
Hazard pictograms	None.
Signal word	None.
Hazard statements	The mixture does not meet the criteria for classification.

Precautionary statements

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.

Supplemental label information	None.
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2.3. Other hazards

Direct contact with eyes may cause temporary irritation. Allergic reactions are possible. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
Thimerosal	0,01	54-64-8 200-210-4	-	080-004-00-7	
Classification:	Acute Tox. 2;H300, Acute Tox. 1;H310, Acute Tox. 2;H330, STOT RE 2;H373, Aquatic Acute 1;H400, Aquatic Chronic 1;H410				1,A
Aluminium hydroxide	*	21645-51-2 244-492-7	-	-	
Classification:	-				
Inactivated Rabies Virus, strain SAD VNUKOVO-32	*	Not assigned -	-	-	
Classification:	-				

List of abbreviations and symbols that may be used above

The full text for all H-statements is displayed in section 16.

Composition comments

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

SECTION 4: First aid measures

General information

IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

4.1. Description of first aid measures

Inhalation	If inhaled, remove to fresh air. If breathing is difficult, trained personnel should give oxygen. If symptoms persist, get medical attention.
Skin contact	Wash off immediately with soap and plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if irritation develops and persists.
Eye contact	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention immediately.
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.

4.2. Most important symptoms and effects, both acute and delayed

Direct contact with eyes may cause temporary irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Allergic reactions are possible. 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. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

4.3. Indication of any immediate medical attention and special treatment needed

None known.

SECTION 5: Firefighting measures

General fire hazards

No unusual fire or explosion hazards noted.

5.1. Extinguishing media

Suitable extinguishing media	Water spray. Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	Do not use water jet.

5.2. Special hazards arising from the substance or mixture

During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters	Firefighters should wear full protective clothing including self contained breathing apparatus.
Special fire fighting procedures	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

For non-emergency personnel Keep unnecessary personnel away. For personal protection, see section 8.

For emergency responders Personnel must wear appropriate protective equipment (see Section 8).

6.2. Environmental precautions Use appropriate containment to avoid environmental contamination.

6.3. Methods and material for containment and cleaning up Clean up in accordance with all applicable regulations. Ensure adequate ventilation. Remove sources of ignition. Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly. Prevent release to the environment.

Never return spills to original containers for re-use. Should not be released into the environment.

6.4. Reference to other sections For personal protection, see section 8. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling When handling, use appropriate personal protective equipment (see Section 8). Avoid accidental injection. Avoid contact with eyes. Avoid contact with skin. Avoid breathing mist or vapour. Observe good industrial hygiene practices. Wash thoroughly after handling. Handle and open container with care. Avoid release to the environment.

7.2. Conditions for safe storage, including any incompatibilities Store in a cool, dry place out of direct sunlight. Store at 2-8°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze. Store away from incompatible materials (see Section 10 of the SDS).

7.3. Specific end use(s) Not available.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters****Occupational exposure limits****Austria. MAK List, OEL Ordinance (GwV), BGBl. II, no. 184/2001**

Components	Type	Value	Form
Aluminium hydroxide (CAS 21645-51-2)	MAK	5 mg/m3	Respirable fraction.
		10 mg/m3	Inhalable fraction.
	STEL	20 mg/m3	Inhalable fraction.
		10 mg/m3	Respirable fraction.
Thimerosal (CAS 54-64-8)	MAK	0,01 mg/m3	Inhalable fraction.
	STEL	0,1 mg/m3	Inhalable fraction.

Belgium. Exposure Limit Values.

Components	Type	Value
Thimerosal (CAS 54-64-8)	STEL	0,03 mg/m3
	TWA	0,01 mg/m3

Croatia. Dangerous Substance Exposure Limit Values in the Workplace (ELVs), Annexes 1 and 2, Narodne Novine, 13/09

Components	Type	Value
Thimerosal (CAS 54-64-8)	MAC	0,01 mg/m3

Cyprus. OELs. Control of factory atmosphere and dangerous substances in factories regulation, PI 311/73, as amended.

Components	Type	Value
Thimerosal (CAS 54-64-8)	TWA	0,01 mg/m3
		0,001 ppm

Czech Republic. OELs. Government Decree 361

Components	Type	Value
Thimerosal (CAS 54-64-8)	Ceiling	0,03 mg/m3
	TWA	0,01 mg/m3

Finland. Workplace Exposure Limits

Components	Type	Value
Thimerosal (CAS 54-64-8)	TWA	0,01 mg/m3

France. Threshold Limit Values (VLEP) for Occupational Exposure to Chemicals in France, INRS ED 984

Components	Type	Value
Thimerosal (CAS 54-64-8)	VME	0,01 mg/m3

Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)

Components	Type	Value	Form
Aluminium hydroxide (CAS 21645-51-2)	TWA	4 mg/m3	Inhalable fraction.
		1,5 mg/m3	Respirable fraction.

Germany. TRGS 900, Limit Values in the Ambient Air at the Workplace

Components	Type	Value	Form
Aluminium hydroxide (CAS 21645-51-2)	AGW	10 mg/m3	Inhalable fraction.
		1,25 mg/m3	Respirable fraction.

Greece. OELs (Decree No. 90/1999, as amended)

Components	Type	Value
Thimerosal (CAS 54-64-8)	STEL	0,03 mg/m3
	TWA	0,01 mg/m3

Hungary. OELs. Joint Decree on Chemical Safety of Workplaces

Components	Type	Value
Thimerosal (CAS 54-64-8)	STEL	0,04 mg/m3
	TWA	0,01 mg/m3

Ireland. Occupational Exposure Limits

Components	Type	Value
Thimerosal (CAS 54-64-8)	STEL	0,03 mg/m3
	TWA	0,01 mg/m3

Italy. Occupational Exposure Limits

Components	Type	Value	Form
Aluminium hydroxide (CAS 21645-51-2)	TWA	1 mg/m3	Respirable fraction.
Thimerosal (CAS 54-64-8)	STEL	0,03 mg/m3	
	TWA	0,01 mg/m3	

Latvia. OELs. Occupational exposure limit values of chemical substances in work environment

Components	Type	Value
Aluminium hydroxide (CAS 21645-51-2)	TWA	6 mg/m3

Lithuania. OELs. Limit Values for Chemical Substances, General Requirements

Components	Type	Value
Aluminium hydroxide (CAS 21645-51-2)	TWA	6 mg/m3
Thimerosal (CAS 54-64-8)	TWA	0,01 mg/m3

Norway. Administrative Norms for Contaminants in the Workplace

Components	Type	Value
Thimerosal (CAS 54-64-8)	TLV	0,01 mg/m3

Poland. MACs. Regulation regarding maximum permissible concentrations and intensities of harmful factors in the work environment, Annex 1

Components	Type	Value	Form
Aluminium hydroxide (CAS 21645-51-2)	TWA	2,5 mg/m3	Inhalable fraction.
		1,2 mg/m3	Respirable fraction.

Portugal. VLEs. Norm on occupational exposure to chemical agents (NP 1796)

Components	Type	Value
Thimerosal (CAS 54-64-8)	STEL	0,03 mg/m3
	TWA	0,01 mg/m3

Romania. OELs. Protection of workers from exposure to chemical agents at the workplace

Components	Type	Value
Thimerosal (CAS 54-64-8)	STEL	0,01 mg/m3

Slovakia. OELs. Regulation No. 300/2007 concerning protection of health in work with chemical agents

Components	Type	Value	Form
Aluminium hydroxide (CAS 21645-51-2)	TWA	4 mg/m3	Inhalable fraction.
Thimerosal (CAS 54-64-8)	TWA	1,5 mg/m3 0,01 mg/m3	Respirable fraction.

Spain. Occupational Exposure Limits

Components	Type	Value
Thimerosal (CAS 54-64-8)	STEL TWA	0,03 mg/m3 0,01 mg/m3

Sweden. Occupational Exposure Limit Values

Components	Type	Value
Thimerosal (CAS 54-64-8)	TWA	0,01 mg/m3

Switzerland. SUVA Grenzwerte am Arbeitsplatz

Components	Type	Value	Form
Aluminium hydroxide (CAS 21645-51-2)	TWA	3 mg/m3	Respirable dust.
Thimerosal (CAS 54-64-8)	TWA	0,01 mg/m3	Inhalable dust.

Biological limit values
Czech Republic. Limit Values for Indicators of Biological Exposure Tests in Urine and Blood, Annex 2, Tables 1 and 2, Government Decree 432/2003 Sb.

Components	Value	Determinant	Specimen	Sampling time
Thimerosal (CAS 54-64-8)	0,056 µmol/mmol	Mercury	Creatinine in urine	*
	0,1 mg/g	Mercury	Creatinine in urine	*

* - For sampling details, please see the source document.

Hungary. Chemical Safety at Workplace Ordinance Joint Decree No. 25/2000 (Annex 2): Permissible limit values of biological exposure (effect) indices

Components	Value	Determinant	Specimen	Sampling time
Thimerosal (CAS 54-64-8)	0,05 mg/g	Mercury	Creatinine in urine	*
	0,028 µmol/mmol	Mercury	Creatinine in urine	*

* - For sampling details, please see the source document.

UK. EH40 Biological Monitoring Guidance Values (BMGVs)

Components	Value	Determinant	Specimen	Sampling time
Thimerosal (CAS 54-64-8)	20 µmol/mol	Mercury	Creatinine in urine	*

* - For sampling details, please see the source document.

Recommended monitoring procedures Follow standard monitoring procedures.

Derived no-effect level (DNEL) Not available.

Predicted no effect concentrations (PNECs) Not available.

8.2. Exposure controls

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

General information Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Eye/face protection Wear safety glasses or goggles if eye contact is possible.

Skin protection

- Hand protection Wear impervious gloves if skin contact is possible.

- Other 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.
Hygiene measures	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.
Environmental exposure controls	Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid.
Physical state	Liquid.
Form	Not available.
Colour	Not available.
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Solubility (other)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidising properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Direct sources of heat. Contact with incompatible materials. Protect from freezing. Avoid exposure to light, sunlight and elevated temperatures.
10.5. Incompatible materials	As a precautionary measure, keep away from strong oxidizers.
10.6. Hazardous decomposition products	No hazardous decomposition products are known.

SECTION 11: Toxicological information

General information Not classified in accordance with international standards for workplace safety. |par

Information on likely routes of exposure

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact Prolonged skin contact may cause temporary irritation.

Eye contact Direct contact with eyes may cause temporary irritation.

Thimerosal Species: Rabbit
Severity: Mild

Ingestion Expected to be a low ingestion hazard.

Symptoms Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Allergic reactions are possible. 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.

11.1. Information on toxicological effects

Components	Species	Test results
Aluminium hydroxide (CAS 21645-51-2)		
<u>Acute</u>		
Oral		
LD50	Rat	> 5000 mg/kg
Thimerosal (CAS 54-64-8)		
<u>Acute</u>		
Oral		
LD50	Mouse	91 mg/kg
	Rat	75 mg/kg
Subcutaneous		
LD50	Rat	98 mg/kg
Skin corrosion/irritation	Due to partial or complete lack of data the classification is not possible.	
Serious eye damage/eye irritation	Due to partial or complete lack of data the classification is not possible.	
Eye contact		
Thimerosal	Species: Rabbit Severity: Mild	
Respiratory sensitisation	Due to partial or complete lack of data the classification is not possible.	
Skin sensitisation	Due to partial or complete lack of data the classification is not possible.	
Germ cell mutagenicity	Due to partial or complete lack of data the classification is not possible.	
Carcinogenicity	Due to partial or complete lack of data the classification is not possible.	
Reproductive toxicity	Due to partial or complete lack of data the classification is not possible.	
Specific target organ toxicity - single exposure	Due to partial or complete lack of data the classification is not possible.	
Specific target organ toxicity - repeated exposure	Due to partial or complete lack of data the classification is not possible.	
Aspiration hazard	Due to partial or complete lack of data the classification is not possible.	
Mixture versus substance information	No information available	
Other information	The antigens included in this product are non-infectious. All have been prepared from attenuated preparations of microorganisms.	

SECTION 12: Ecological information

12.1. Toxicity 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. Releases to the environment should be avoided.

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

12.3. Bioaccumulative potential no data available.

Partition coefficient n-octanol/water (log Kow)	Not available.
Bioconcentration factor (BCF)	Not available.
12.4. Mobility in soil	no data available.
12.5. Results of PBT and vPvB assessment	Not available.
12.6. 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.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste	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. Empty containers should be taken to an approved waste handling site for recycling or disposal
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	Avoid release to the environment. Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

RID

Not regulated as dangerous goods.

ADN

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended

Thimerosal (CAS 54-64-8)

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended

Thimerosal (CAS 54-64-8)

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Not listed.

Authorisations

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, as amended

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding, as amended

Thimerosal (CAS 54-64-8)

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances

Thimerosal (CAS 54-64-8)

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, as amended

Thimerosal (CAS 54-64-8)

Directive 94/33/EC on the protection of young people at work, as amended

Thimerosal (CAS 54-64-8)

Other regulations

The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006, as amended.

National regulations

Follow national regulation for work with chemical agents.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

Not available.

References

Not available.

Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

Full text of any H-statements not written out in full under Sections 2 to 15

H300 Fatal if swallowed.
H310 Fatal in contact with skin.
H330 Fatal if inhaled.
H373 May cause damage to organs through prolonged or repeated exposure.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

Revision information

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

Training information

Follow training instructions when handling this material.

Disclaimer

ENDISCL004 - 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.