

SAFETY DATA SHEET



Revision date: 16-Sep-2014

Version: 2.2

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

Product Identifier

Material Name: Nolvadent®

Trade Name: NOLVADENT®
Chemical Family: Mixture

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

Intended Use: Veterinary product
Restrictions on Use: Not for human use

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

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

2. HAZARDS IDENTIFICATION

Appearance: Clear pink liquid

Classification of the Substance or Mixture

GHS - Classification

Acute Toxicity - Dusts and Mists: Category 4
Acute aquatic toxicity: Category 2
Chronic aquatic toxicity: Category 2
Flammable liquids- Category 3

EU Classification:

EU Indication of danger: T - Toxic
N - Dangerous for the environment

EU Risk Phrases:

R23 - Toxic by inhalation.
R10 - Flammable.
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Label Elements

Signal Word: Warning

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2. HAZARDS IDENTIFICATION

Hazard Statements:	H332 - Harmful if inhaled H226 - Flammable liquid and vapor H411 - Toxic to aquatic life with long lasting effects
Precautionary Statements:	P271 - Use only outdoors or in a well-ventilated area P261 - Avoid breathing dust/fume/gas/mist/vapors/spray P280 - Wear protective gloves/protective clothing/eye protection/face protection P264 - Wash hands thoroughly after handling P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking P240 - Ground/Bond container and receiving equipment P243 - Take precautionary measures against static discharge P241 - Use explosion-proof electrical/ventilating/lighting/equipment P242 - Use only non-sparking tools P233 - Keep container tightly closed P403 + P235 - Store in a well-ventilated place. Keep cool P273 - Avoid release to the environment P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P337 + P313 - If eye irritation persists: Get medical advice/attention P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower P312 - Call a POISON CENTRE/doctor/physician if you feel unwell P391 - Collect spillage P501 - Dispose of contents/container in accordance with all local and national regulations



Other Hazards

Short Term:

Vapors may cause drowsiness and dizziness. May cause respiratory tract irritation. May cause eye irritation. May cause slight skin irritation. May be harmful if swallowed. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. May cause liver and kidney effects

Australian Hazard Classification (NOHSC):

Hazardous Substance. Dangerous Goods.

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Chlorhexidine acetate	56-95-1	200-302-4	Xn;R22 Xi;R36 T+;R26 N;R50	Acute Tox. 4 (H302) Acute Tox.2(H330) Eye Irrit.2A (H319) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	2
Ethyl alcohol (ethanol)	64-17-5	200-578-6	F; R11	Flam. Liq. 2 (H225)	6

Additional Information: 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 Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
- Medical Conditions Aggravated by Exposure:** None known

Indication of the Immediate Medical Attention and Special Treatment Needed

- Notes to Physician:** None

5. FIRE-FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture

- Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire. May include oxides of carbon nitrogen and products of chlorine
- Fire / Explosion Hazards:** Vapors will form flammable or explosive mixtures with air at room temperature. Fine particles (such as dust and mists) may fuel fires/explosions. Flammable liquid and vapor

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus. Use spark-proof tools and explosion-proof equipment

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6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Ensure adequate ventilation. Eliminate all sources of ignition and ventilate area using explosion-proof equipment. 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 / Collecting:

Contain the source of the spill if it is safe to do so. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity). Use non-combustible absorbent material to wipe up spill and place in a sealed container for disposal. Clean contaminated surface thoroughly.

Additional Consideration for Large Spills:

Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Contain the source of the spill or leak if it is safe to do so. Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal. Clean spill area thoroughly. 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

Flammable liquid and vapor- keep away from ignition sources and clean up spills promptly. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin, and clothing. Use appropriate personal protective equipment. Wash thoroughly after handling. Use with adequate ventilation. Avoid breathing vapor or mist. 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:

Keep in a cool, well-ventilated place. Keep away from heat, sparks, flame, and other sources of ignition.

Incompatible Materials:

Acids, bases, and oxidizers

Specific end use(s):

No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Ethyl alcohol (ethanol)

ACGIH Threshold Limit Value (STEL)	1000 ppm
Australia TWA	1000 ppm
	1880 mg/m ³
Austria OEL - MAKs	1000 ppm
	1900 mg/m ³
Belgium OEL - TWA	1000 ppm
	1907 mg/m ³
Bulgaria OEL - TWA	1000.0 mg/m ³
Czech Republic OEL - TWA	1000 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Denmark OEL - TWA	1000 ppm 1900 mg/m ³
Estonia OEL - TWA	500 ppm 1000 mg/m ³
Finland OEL - TWA	1000 ppm 1900 mg/m ³
France OEL - TWA	1000 ppm 1900 mg/m ³
Germany - TRGS 900 - TWAs	500 ppm 960 mg/m ³
Germany (DFG) - MAK	500 ppm 960 mg/m ³
Greece OEL - TWA	1000 ppm 1900 mg/m ³
Hungary OEL - TWA	1900 mg/m ³
Latvia OEL - TWA	1000 mg/m ³
Lithuania OEL - TWA	500 ppm 1000 mg/m ³
Netherlands OEL - TWA	260 mg/m ³
Vietnam OEL - TWAs	1000 mg/m ³
OSHA - Final PELs - TWAs:	1000 ppm 1900 mg/m ³
Poland OEL - TWA	1900 mg/m ³
Portugal OEL - TWA	1000 ppm
Romania OEL - TWA	1000 ppm 1900 mg/m ³
Slovakia OEL - TWA	500 ppm 960 mg/m ³
Slovenia OEL - TWA	1000 ppm 1900 mg/m ³
Spain OEL - TWA	1000 ppm 1910 mg/m ³
Sweden OEL - TWAs	500 ppm 1000 mg/m ³
Switzerland OEL -TWAs	500 ppm 960 mg/m ³

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Chlorhexidine acetate

Zoetis OEB

OEB 4 (control exposure to the range of 1ug/m³ to <10ug/m³)

Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Eyes: Wear safety glasses or goggles if eye contact is possible.
Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection: If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. 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:	Liquid	Color:	Pink
Odor:	Medicinal	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Solvent Solubility:	No data available
Water Solubility:	Soluble
pH:	No data available.
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	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
Vapor Pressure (kPa):	No data available
Vapor Density (g/ml):	No data available
Relative Density:	No data available
Viscosity:	No data available

Flammability:	
Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	53.3°C / 128°F
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

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:	Extremes of temperature and direct sunlight. Fine particles (such as mists) may fuel fires/explosions. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electrostatic discharge).
Incompatible Materials:	Acids, bases, and oxidizers
Hazardous Decomposition Products:	Toxic or corrosive oxides of carbon and nitrogen.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

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11. TOXICOLOGICAL INFORMATION

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.

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

Chlorhexidine acetate

Mouse Oral LD 50 2000 mg/kg
Rat Oral LD 50 (F) 1180 / (M) 1710 mg/kg
Rat Inhalation LC 50 0.10 - 0.46 mg/L
Rabbit Dermal LD 50 > 2000 mg/kg

Ethyl alcohol (ethanol)

Mouse Oral LD50 3450 mg/kg
Rat Oral LD50 7060mg/kg
Rat Inhalation LC50 10h 20,000ppm

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)

Chlorhexidine acetate

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Severe
Skin Sensitization - GPMT Guinea Pig Negative

Ethyl alcohol (ethanol)

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

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

Chlorhexidine acetate

13 Week(s) Rabbit Dermal 500 mg/kg/day LOAEL Liver, Skin

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Chlorhexidine acetate

Embryo / Fetal Development Rat Oral 31.25 mg/kg/day LOEL Maternal toxicity
Embryo / Fetal Development Rat Oral 62.5 mg/kg/day NOEL No effects at maximum dose

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

Chlorhexidine acetate

Mammalian Cell Mutagenicity Mouse Lymphoma Negative
In Vitro Cytogenetics Chinese Hamster Ovary (CHO) cells Negative
In Vivo Micronucleus Rat Hepatocyte Negative

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11. TOXICOLOGICAL INFORMATION

Carcinogen Status: Ethanol has been shown to be carcinogenic in long-term studies only when consumed as alcoholic beverage. None of the other components of this mixture are listed as a carcinogen by IARC, NTP or OSHA.

Ethyl alcohol (ethanol)

IARC: Group 1 (Carcinogenic to Humans)
OSHA: Listed

Product Level Toxicity Data

Inhalation ATE (Acute Toxicity Estimate), calculated 5 mg/l (dusts/mists)

12. ECOLOGICAL INFORMATION

Environmental Overview: Releases to the environment should be avoided. The environmental characteristics of this mixture have not been fully evaluated. The following information is available for the individual ingredients.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Chlorhexidine acetate

<i>Oncorhynchus mykiss</i> (Rainbow Trout)	NA	LC50	96 Hours	1.9 ppm
<i>Lepomis macrochirus</i> (Bluegill Sunfish)	N/A	LC50	96 Hours	0.6 ppm
<i>Daphnia Magna</i> (Water Flea)	N/A	EC50	N/A	0.06 mg/L

Ethyl alcohol (ethanol)

Oncorhynchus mykiss (Rainbow Trout) LC50/96h 12,900-15,300 mg/L

Terrestrial Toxicity: (Species, Method, End Point, Duration, Result)

Chlorhexidine acetate

Colinus virginianus (Bobwhite Quail) N/A LD50 N/A 2013 mg/kg

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Waste of 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). 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.

Domestically-non-restricted (alcohol content L/T 25%)
Transport according to the requirements of the appropriate regulatory body.

UN number: UN 1993
UN proper shipping name: Flammable Liquid, n.o.s. (contains ethanol)
Transport hazard class(es): 3
Packing group: III
Environmental Hazard(s): Marine Pollutant
Flash Point (°C): 53.3°C / 128°F

IATA / ICAO

IATA UN / ID No: UN 1993
IATA Proper shipping name: Flammable Liquid, n.o.s. (contains ethanol)
IATA Hazard Class: 3
IATA Packing Group: III

IMDG IMDG

IMDG UN / ID No: UN 1993
IMDG Proper shipping name: Flammable Liquid, n.o.s. (contains ethanol)
IMDG Hazard Class: 3
IMDG Packing Group: III
Flash Point (°C): 53.3°C / 128°F
Environmental Hazard(s): Marine Pollutant

ADR/RID

ADR / RID UN / ID No: UN 1993
ADR/RID Proper shipping name: Flammable Liquid, n.o.s. (contains ethanol)
ADR / RID Hazard Class: 3
ADR / RID Packing Group: III
ADR / RID Item Number: UN 1993
Environmental Hazard(s): Marine Pollutant

DOT

DOT Proper shipping name: Not regulated

15. REGULATORY INFORMATION

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

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15. REGULATORY INFORMATION

Canada - WHMIS: Classifications

WHMIS hazard class:

Class B, Division 3

Class D, Division 2, and Subdivision B.

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



Chlorhexidine acetate

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

Not Listed

Australia (AICS):

Present

EU EINECS/ELINCS List

200-302-4

Ethyl alcohol (ethanol)

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

carcinogen initial date 4/29/11 in alcoholic beverages
developmental toxicity initial date 10/1/87 in alcoholic beverages

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

Present

Australia (AICS):

Present

EU EINECS/ELINCS List

200-578-6

16. OTHER INFORMATION

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

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Acute toxicity, inhalation-Cat.2; H330 - Fatal if inhaled

Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation

Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life

Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects

Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor

Xn - Harmful

Xi - Irritant

T+ - Very toxic

N - Dangerous for the environment

F - Highly flammable

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R22 - Harmful if swallowed.
R36 - Irritating to eyes.
R26 - Very toxic by inhalation.
R50 - Very toxic to aquatic organisms.
R11 - Highly flammable.

Data Sources: The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

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.

End of Safety Data Sheet