



MATERIAL SAFETY DATA SHEET

Revision date: 25-May-2010

Version: 3.0

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

Pfizer Animal Health
Pfizer Inc
235 East 42nd Street
New York, NY 10017
Poison Control Center Phone: 1-866-531-8896
Technical Services Phone: 1-800-366-5288
Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd,
Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

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

Material Name: Roccal D Plus

Trade Name:	Roccal-D Plus
Chemical Family:	Mixture
Intended Use:	Veterinary product used as disinfectant

2. HAZARDS IDENTIFICATION

Appearance: Green liquid
Signal Word: DANGER

Statement of Hazard: Harmful in contact with skin.
Harmful if swallowed.
Causes severe skin burns and eye damage.
May cause damage to endocrine system through prolonged or repeated exposure.

Additional Hazard Information:
Short Term: May be harmful if absorbed through the skin. (based on components) .
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on endocrine system (based on components) .
EU Indication of danger: Corrosive
T - Toxic
N - Dangerous for the environment

EU Hazard Symbols:



EU Risk Phrases:

R34 - Causes burns.
R21 - Harmful in contact with skin.
R22 - Harmful if swallowed.
R48/23/25 - Toxic: danger of serious damage to health by prolonged exposure through inhalation and if swallowed.
R51/53 - Toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.

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2. HAZARDS IDENTIFICATION

Australian Hazard Classification (NOHSC): Hazardous Substance. Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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 EINECS/ELINCS List	EU Classification	%
Alkyl Dimethyl Benzyl Ammonium Chloride	68424-85-1	270-325-2	Xn;R22 C;R34 N;R50	4.6
Didecyldimethylammonium chloride	7173-51-5	230-525-2	C;R34 Xn;R22	9.2
Quaternary ammonium compounds, benzylcoco alkyl dimethyl, chlorides	61789-71-7	263-080-8	Not Listed	9.2
Citric acid	77-92-9	201-069-1	Xi; R36	*
Sodium hydroxide	1310-73-2	215-185-5	C;R35	*
Propylene glycol	57-55-6	200-338-0	Not Listed	*
Tetrasodium EDTA	64-02-8	200-573-9	Not Listed	*
Tributyltin Oxide	56-35-9	200-268-0	T;R25 T;R48/23/25 Xn;R21 Xi;R36/38 N;R50-53	1

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Fragrance	NOT ASSIGNED	Not Listed	Not Listed	*
C.I. Acid Blue 25	6408-78-2	229-068-1	Not Listed	*
FD & C Yellow No. 5	1934-21-0	217-699-5	Not Listed	*
Water	7732-18-5	231-791-2	Not Listed	*
9-10 Mole Nonionic Surfactant	Not assigned	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 mentioned in this Section, see Section 16

4. FIRST AID MEASURES

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

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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. If not breathing, give artificial respiration. Get medical attention.
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.

5. FIRE FIGHTING MEASURES

Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products:	Formation of toxic gases is possible during heating or fire.
Fire Fighting Procedures:	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Fire / Explosion Hazards:	Fine particles (such as dust and mists) may fuel fires/explosions.

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 spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
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:	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

General Handling:	Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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.
Storage Conditions:	Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Didecyldimethylammonium chloride
ACGIH Threshold Limit Value (TWA) 0.1 mg/m³

Sodium hydroxide

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

ACGIH Ceiling Threshold Limit:	2 mg/m ³
Australia PEAK	2 mg/m ³
Austria OEL - MAKs	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed
France OEL - TWA	Listed
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Japan - OELs - Ceilings	2 mg/m ³
Latvia OEL - TWA	Listed
OSHA - Final PELs - TWAs:	2 mg/m ³
Poland OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Sweden OEL - TWAs	Listed

Propylene glycol

Australia TWA	10 mg/m ³ 150 ppm 474 mg/m ³
Ireland OEL - TWAs	Listed
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed

Tributyltin Oxide

Austria OEL - MAKs	Listed
Bulgaria OEL - TWA	Listed
Germany - TRGS 900 - TWAs	0.0021 ppm 0.05 mg/m ³
Germany (DFG) - MAK	0.004 ppm MAK 0.02 mg/m ³ MAK
Slovenia OEL - TWA	Listed

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental Exposure Controls:

Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment:

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

Hands:

Wear impervious gloves if skin contact is possible.

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 the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	Color:	Green
Odor:	Floral	Molecular Formula:	Mixture
Molecular Weight:	Mixture		
Water solubility:	100%		
pH:	8-10		
Boiling Point (°C):	>100		
Specific Gravity:	1.015		
Flash Point (Liquid) (°C):	61	Closed cup	
Polymerization:		Will not occur	

10. STABILITY AND REACTIVITY

Chemical Stability:	Stable at normal conditions
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	Soaps, anionic materials, oxidizers, and chlorine

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Citric acid

Rat Oral LD50 3000 mg/kg

Propylene glycol

Mouse Oral LD50 22,000 mg/kg

Rat Oral LD50 20,000 mg/kg

Rabbit Dermal LD50 20,800 mg/kg

Tetrasodium EDTA

Mouse Oral LD50 30 mg/kg

Rat Oral LD50 > 2000 mg/kg

Didecyldimethylammonium chloride

Rat Oral LD 50 84 mg/kg

Rat Sub-tenon injection (eye) LD 50 45 mg/kg

Alkyl Dimethyl Benzyl Ammonium Chloride

Rat Oral LD50 426 mg/kg

Rat Sub-tenon injection (eye) LD50 100 mg/kg

Rat Dermal LD50 930 mg/kg

Rat Inhalation 0.054-0.51 mg/L

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11. TOXICOLOGICAL INFORMATION

Tributyltin Oxide

Rat Oral LD50 87 mg/kg
Rat Dermal LD50 605 mg/kg
Rat Inhalation LC50 4h 0.065 mg/L

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)

Sodium hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Citric acid

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Propylene glycol

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Tetrasodium EDTA

Skin Irritation Rabbit Moderate
Eye Irritation Rabbit Moderate

Didecyldimethylammonium chloride

Skin Irritation Rabbit Corrosive

Alkyl Dimethyl Benzyl Ammonium Chloride

Skin Irritation Rabbit Corrosive
Skin Irritation Guinea Pig Negative

Quaternary ammonium compounds, benzylcoco alkyldimethyl, chlorides

Skin Irritation Rabbit Corrosive

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

Tributyltin Oxide

4 Week(s) Rat Oral 80 mg/kg/day LOAEL Endocrine system, Blood
4 Week(s) Rat Oral 50 mg/kg LOAEL Thymus

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

Didecyldimethylammonium chloride

Embryo / Fetal Development Rabbit Oral 10 mg/kg/day NOAEL Not teratogenic
Embryo / Fetal Development Rabbit Oral 10 mg/kg/day LOAEL Fetotoxicity, Maternal Toxicity
Embryo / Fetal Development Rat Oral 20 mg/kg/day NOAEL Not Teratogenic, Fetotoxicity
2 Generation Reproductive Toxicity Rat Oral 1500 ppm NOAEL Reproductive toxicity

Tributyltin Oxide

Embryo / Fetal Development Mouse Oral 11.7 - 35 mg/kg LOAEL Maternal toxicity, Teratogenic
Embryo / Fetal Development Mouse Oral 40 mg/kg/day LOAEL Maternal Toxicity, Embryotoxicity

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11. TOXICOLOGICAL INFORMATION

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

Alkyl Dimethyl Benzyl Ammonium Chloride

Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Positive
In Vivo Micronucleus Mouse Bone Marrow Positive
In Vitro Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Negative

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

Tributyltin Oxide

106 Week(s) Rat Oral 50 mg/kg/day LOAEL Benign tumors, Endocrine system

Carcinogen Status:

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

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been thoroughly investigated. Harmful effects to aquatic organisms could occur.

Mobility, Persistence and Degradability: This substance is water soluble and is expected to remain primarily in water

Bioaccumulation and Toxicity: High acute toxicity to aquatic organisms could occur. See aquatic toxicity data, below.

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

Alkyl Dimethyl Benzyl Ammonium Chloride

Pimephales promelas (Fathead Minnow) EPA LC50 96 Hours 0.28 mg/L
Lepomis macrochirus (Bluegill Sunfish) EPA LC50 96 Hours 0.515 mg/L
Oncorhynchus mykiss (Rainbow Trout) EPA LC50 96 Hours 0.923 mg/L
Cyprinodon variegatus (Sheepshead Minnow) LC50 96 Hours 0.86 mg/L
Daphnia magna (Water Flea) EPA EC-50 48 Hours 0.0059 mg/L
Pimephales promelas (Fathead Minnow) EPA NOEC 34 Days 0.032 mg/L

Tributyltin Oxide

Daphnia magna (Water Flea) EPA EC50 48 Hours 0.004 mg/L
Oncorhynchus mykiss (Rainbow Trout) ASTM LC50 96 Hours 0.003 mg/L
Cyprinodon variegatus (Sheepshead Minnow) EPA LC50 96 Hours 0.005 mg/L

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.

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14. TRANSPORT INFORMATION

Not regulated for ground transport in non-bulk (< 119 gal) packages within the U.S.:
For all Air and Water shipments, the following applies:

UN proper shipping name: Environmentally hazardous substances, liquid, n.o.s. (Tributyltin compounds), Marine Pollutant
UN number: UN 3082
Transport hazard class(es): 9
Packing group: III

15. REGULATORY INFORMATION

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

EU Risk Phrases:
R34 - Causes burns.
R21 - Harmful in contact with skin.
R22 - Harmful if swallowed.
R48/23/25 - Toxic: danger of serious damage to health by prolonged exposure through inhalation and if swallowed.
R51/53 - Toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.

EU Safety Phrases:
S23 - Do not breathe fumes/vapour/spray.
S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.
S57 - Use appropriate containment to avoid environmental contamination.

OSHA Label:
DANGER
Harmful in contact with skin.
Harmful if swallowed.
Causes severe skin burns and eye damage.
May cause damage to endocrine system through prolonged or repeated exposure.

Canada - WHMIS: Classifications

WHMIS hazard class:
E corrosive material



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15. REGULATORY INFORMATION

Alkyl Dimethyl Benzyl Ammonium Chloride

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	270-325-2

Didecyldimethylammonium chloride

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 6
EU EINECS/ELINCS List	230-525-2

Quaternary ammonium compounds, benzylcoco alkyldimethyl, chlorides

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	263-080-8

Citric acid

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	201-069-1

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb final RQ 454 kg final RQ
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5

Propylene glycol

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	200-338-0

C.I. Acid Blue 25

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	229-068-1

FD & C Yellow No. 5

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	217-699-5

Water

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed

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15. REGULATORY INFORMATION

REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2
Tetrasodium EDTA	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	200-573-9
Tributyltin Oxide	
CERCLA/SARA 313 Emission reporting	1.0% de minimis concentration
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	200-268-0

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R21 - Harmful in contact with skin.
R22 - Harmful if swallowed.
R25 - Toxic if swallowed.
R34 - Causes burns.
R35 - Causes severe burns.
R36 - Irritating to eyes.
R50 - Very toxic to aquatic organisms.
R36/38 - Irritating to eyes and skin.
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R48/23/25 - Toxic: danger of serious damage to health by prolonged exposure through inhalation and if swallowed.

Data Sources: Safety data sheets for individual ingredients. Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 15 - Regulatory Information. Updated Section 12 - Ecological Information.

Prepared by: Product Stewardship Hazard Communications
Pfizer Global Environment, Health, and Safety Operations

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 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