1.0 Identification

Product identifier	**Dermcare OTOFLUSH®**
Other means of identification	APVMA approval number: 60080 Active constituents: 2.0g/L Poly(hexamethylene) biguanide hydrochloride, 1.2g/L Disodium edetate
Recommended use & restrictions on use	**This SDS applies to handling and storage of this substance in workplace environments.** Other use, including consumer use, will have different requirements not addressed herein. VETERINARY APPLICATION: A neutral buffered ear flush solution to clean and reduce microbial numbers in ears of dogs and as a pre-treatment to improve the penetration of and increase bacterial susceptibility to antimicrobial preparations used to treat Canine Otitis Externa.
Details of manufacturer / importer	**DERMCARE-VET PTY LTD** 7 Centenary Road, Slacks Creek, QLD, 4127, AUSTRALIA Phone: (07) 3387 9700 Email: dermcare@dermcare.com.au Website: http://www.dermcare.com.au
Emergency phone number	(07) 3387 9700 (Monday – Friday, 9:00am – 5:00pm AEST) After Hours Poisons Information 13 11 26

2.0 GHS Hazard Identification

Classification of the hazardous chemical	Sensitisation, skin Category 1 Serious eye damage/eye irritation Category 2B
Signal word	**WARNING**
Hazard statement	H317 May cause an allergic skin reaction H320 Causes eye irritation
Precautionary statements	P261 Avoid breathing vapours. P264 Wash hands thoroughly after handling. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves and eye protection.
GHS pictograms	

3.0 Ingredients / Composition %w/w

Ingredient Name / Nature	0<1	1<10	>10	>20	>30	>40	>50	>60	>70	>80	>90
Water & ingredients deemed not to be hazardous at that concentration											
Poly(hexamethylene) Biguanide Hydrochloride CAS 27083-27-8											

4.0 First Aid Measures

First aid instructions	Consider your own safety first.
Swallowed	IF SWALLOWED: Rinse mouth with water and spit, do not induce vomiting this may cause aspiration into the lungs. Drink a glass of water, seek medical advice as merited by the symptoms
Eye	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists get medical advice/attention.
Skin	IF ON SKIN: Rinse thoroughly clean under running water, seek medical advice if symptoms merit. If skin irritation or rash occurs get medical advice/attention.
Inhaled	IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms call a POISON CENTER or doctor/physician. Call a POISON CENTER or doctor/physician if you feel unwell.
Symptoms caused by exposure	Eyes: Potential eye irritation, itch, redness.
Medical attention / special treatment	Treat symptomatically; note the potential for anaphylactic response.

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5.0 Fire Fighting Measures

Extinguishing media	This is a water based product, and does not support combustion.
Specific hazards arising from the chemical	No data.
Special protective equipment & precautions for fire fighters HAZCHEM	No data.

6.0 Accidental Release Measures

Personal precautions, protective equipment & emergency procedures	Do not panic. Avoid standing in or dispersing this material, hard surfaces may become slippery especially when wet.
Environmental precautions	Avoid unnecessary discharge.
Methods & materials for containment & cleaning up	Routine amounts can be collected into absorbent paper towel and disposed as routine waste.

7.0 Storage & Handling

Precautions for safe handling	Avoid unnecessary skin contact. Wear gloves and protective eyewear, wash hands thoroughly after use. Development and implement safe workplace practices appropriate to your circumstances and intended use/handling of this product. Limit unnecessary exposure.
Safe storage practice	Keep out of reach of children. Maintain tightly closed in original container.
- Avoid	Unnecessary skin contact.
- Control	No data.
- Maintain	In clean and hygienic manner.
- Other	No data.

8.0 Exposure Controls / Personal Protection

National exposure standards	NICNAS has reviewed Poly(hexamethylene) Biguanide Hydrochloride (PHMB), CAS 27083-27-8, contained in this product at 0.2% and has indicated that control measures to minimise the risk from oral, inhalation, dermal and ocular exposure to the chemicals should be implemented in accordance with the hierarchy of controls. The conclusion of this evaluation was that polihexanide is a possible skin sensitiser in humans in product formulations at 0.5%, with a potential for causing sensitisation at 0.2% in sensitive individuals.				
Biological monitoring	No data.				
Control banding	Band Zero – Household or Consumer Use	Band 1 – good industrial hygiene practice	Band 2 – use local exhaust ventilation	Band 3 – enclose the process	Other
Engineering controls	None specified.				
PPE	Refer to Australian/New Zealand Standard AS/NZS 2161.1: 2000 for guidance on selection and use of protective gloves.				

9.0 Physical & Chemical Properties

Appearance	Clear, colourless liquid.	**Partition co-efficient: n-octonol/water**	As for water.
Odour	Unremarkable.	**Solubility**	As for water.
pH	6.5 – 7.5	**Vapour Pressure**	As for water.
Melting / freezing point	~0^{o}C.	**Vapour density**	As for water.
Boiling point	~100^{o}C.	**Relative density**	~1.0g/mL.
Flash point	As for water.	**Auto-ignition temperature**	As for water.
Evaporation rate	As for water.	**Decomposition temperature**	As for water.
Flammability	As for water.	**Viscosity**	As for water.
Explosive limits	As for water.	**Other**	No data.

10.0 Stability & Reactivity

Reactivity	No data.
Chemical stability	Essentially chemically stable.
Possibility of hazardous reactions	No data.
Conditions to avoid	Store below 30^{o}C, out of reach of children.
Incompatible materials	No data.
Hazardous Decomposition Products	Nitrosamines may form in solution.

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11.0 Toxicological Information

Ingredient name / type	Poly(hexamethylene) Biguanide Hydrochloride (PHMB), CAS 27083-27-8, contained at 0.2%.
Acute toxicity	A median lethal dose (LD_{50}) of 1,049mg/kg bw.
Skin corrosion / irritation	Based on the treatment-related effects reported in repeated dose toxicity studies, repeated dermal exposure to polihexanide is not considered to cause serious damage to health. Polihexanide was applied to the clipped dorsal skin at doses of 0, 20, 60 or 200mg/kg bw/day (as Vantocil P containing 20.2% polihexanide) for 30 days under occlusive conditions for a total of 21 six-hour applications in rats (n=5; Wistar-derived Alpk:APfSD). The study was conducted in accordance with test guidelines similar to OECD TG 410. Local irritation (scabbing and erythema) at the site of application was observed. No overt signs of treatment-related systemic toxicity were reported in this study (ECHA, 2011; SCCS, 2014). In a repeat dose dermal study (21 days), no signs of systemic toxicity or skin irritation were reported in female albino rabbits (strain not specified). In this study, 1mL of solution containing 1,200ppm (equivalent to approximately 36mg/kg bw/day) was applied daily to the clipped dorsal skin of rabbits for 23 hours. The exposed skin was washed with soap and water after 23 hours, then the solution was re-applied an hour after washing (SCCS, 2014).
Serious eye damage / irritation	Polihexanide was found to be **highly irritating,** based on the results from eye irritation studies in rabbits. (SCCS, 2014). Effects were not reversible within the observation periods. In an OECD TG 405-compliant study, 0.1mL of solid polihexanide was instilled into the conjuctival sac of one eye of a male NZW rabbit. The other eye was used as a control. The treatment-related effects on the cornea, iris, and conjunctivae were evaluated at the following timepoints: 1, 24, 48, 72 hours; and 7, 14, 21 days. This single treatment resulted in corneal opacity (opalescent), iridial inflammation and severe conjunctival irritation. In addition, other treatment-related effects such as vascularisation and pale appearance of the nictating membrane were also observed. These changes were not reversible by day 21. In humans a study of six clinical case reports showed that a 0.02% aqueous polihexanide solution was well-tolerated by human corneal and conjunctival epithelium when used for the treatment of *Acanthamoeba* keratitis (Duguid et al., 1996).
Respiratory or skin sensitisation	RESPIRATORY: Conflicting information exists. PHMB can be considered irritating to the respiratory tract leading to 50% reduction of respiratory rate at 264mg/m^3. Based on the data from a mouse study (non-guideline compliant), polihexanide is not expected to cause respiratory irritation. However, polihexanide was reported to cause respiratory irritation in a repeat dose inhalation toxicity study in rats. In a mouse study, a group of five female Alpk:APfCD-1 mice were exposed (nose-only inhalation) to spa water containing Bacquacil (20% polihexanide). The analysed concentrations tested in this non-guideline study were reported to be 11.7, 62.9 and 208mg/m^3 polihexanide. Compared with the control, there was no significant respiratory depression in treated animals (SCCS, 2014). SKIN: Polihexanide is considered to be a **moderate skin sensitiser** based on the positive results seen in guinea pig maximisation tests (GPMT). The skin sensitisation potential of polihexanide was investigated in an OECD TG 406-compliant maximisation study in Alpk:Dunkin Hartley guinea pigs. A dose-ranging study was conducted to determine the concentrations to be used in the main test. The study was undertaken using 20 female guinea pigs and 10 control animals. Intradermal induction used 0.06% polihexanide (with or without Freund's complete adjuvant (FCA)) under occlusive conditions for 48 hours. Topical induction was with 20.2% polihexanide solution. The challenge concentrations used were 20.2 and 6% polihexanide under occlusive condition for 24 hours. The ensuing skin reactions were observed and scored 24 or 48 hours following patch removal. In the guinea pigs challenged with 20.2% polihexanide, scattered mild redness or moderate diffuse redness were observed in 18/20 & 16/20 animals 24 & 48 hours after patch removal, respectively. The average scores for redness were 1.4 at 24 hours and 1.2 at 48 hours. Similar effects were observed in some animals challenged with 6% polihexanide: 5/20 after 24 hours; and 2/20 48 hours after patch removal. The average scores were 0.3 at 24 hours and 0.1 at 48 hours. Under these tests conditions, polihexanide is considered to be a moderate sensitiser. However, the SCCS has noted that, at 20.2%, polihexanide 'should be considered a strong sensitiser according to Regulation (EC) No 1272/2008 (CLP regulation)' (ECHA, 2011; SCCS, 2014). Polihexanide and its related compound, chlorhexidine gluconate were examined for their cross-reactivity potential in accordance with the Magnusson and Kligman method. The study was undertaken using 20 female Dunkin Hartley guinea pigs and 8 control animals. Intradermal induction used 0.25% polihexanide in water with and without FCA. Topical induction was with 20% polihexanide. Challenge concentrations used 20% polihexanide or 0.05, 0.5 and 4% chlorhexidine gluconate. No cross-reactivity with chlorhexidine gluconate was observed. Positive skin reactions were noted in 8/20 animals of the treated group and 3/8 animals of the control group following challenge with 20% polihexanide. When rechallenged with 20% polihexanide, 3/20 animals from the treated group showed skin reactions. Polihexanide was considered a mild sensitiser by the authors of the study.
Germ cell mutagenicity	Based on the limited publicly available data, polihexanide is not considered genotoxic *in vivo* or *in vitro.*

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Carcinogenicity	The potential carcinogenic effects of polihexanide have been studied in laboratory animals. Induction of **vascular tumours was reported following long-term oral exposure of rats and mice to high doses of polihexanide**. According to the report published by the APVMA in 2011, whilst the cancer-related effects of polihexanide may be relevant to human health, the tumours in rodents were only observed in high doses, above the maximum tolerated dose.
Reproductive toxicity	Based on the data available from several animal studies, there is no evidence of reproductive toxicity. Polihexanide does not show specific developmental toxicity. The developmental effects observed in studies are secondary to maternal toxicity.
Specific Target Organ Toxicity (STOT) – single exposure	Dietary administration of PHMB led to a treatment-related reduction in body weight at ≥2,000ppm accompanied by clinical-chemical indication of poor nutritional state. From 2,000ppm there were findings in some haematological parameters, notably increased haemoglobin and haematocrit in males. The kidney was identified as a target organ.
Specific Target Organ Toxicity (STOT) – repeated exposure	Based on the treatment-related effects reported in repeated dose toxicity studies, repeated **inhalation exposure** polihexanide is considered to **cause serious damage to health**. In a 28-day repeated dose inhalation toxicity study in male and female Wistar-derived [Alpk:APfSD] rats, the no observed adverse effect concentration (NOAEC) for polihexanide was nominally reported to be 0.0239mg/m^3. In this OECD TG 412-compliant study, rats were exposed nose-only to 0.025, 0.25, and 2.5mg/m^3 polihexanide for six hours a day, five days a week for 28 days. Measured concentrations were 0.0239mg/m^3 (particle size range 0.32 – 1.30µm); 0.257mg/m^3 (particle size range 0.48 – 5.06µm); and 2.47mg/m^3 (particle size range 0.67 – 1.67µm). The treated animals were allowed to recover for 13 weeks. Changes in bodyweight and food consumption were observed in males exposed to 0.25 or 2.5mg/m^3 polihexanide. No deaths occurred in any of the treatment groups. Histopathological analysis showed transient changes in the larynx and trachea in animals from 0.25 and 2.5mg/m^3 groups. In these groups, increased liver, lung and thymus weights (males only) were reported. Irreversible pneumonitis (severity reduced at the end of the recovery period) and bronchitis were seen in the lungs of animals treated with 2.5mg/m^3 polihexanide (ECHA, 2011; SCCS, 2014).
Aspiration hazard	No data identified.
Skin - acute	A median lethal dose (LD_{50}) of 1,049mg/kg bw was reported following a single oral exposure of Sprague Dawley (SD) rats to polihexanide.
Inhaled - acute	It is not possible to establish an LC_{50} for PHMB, but it could be estimated to be higher than 0.36mg/L for PHMB.
Swallowed - acute	PHMB can be considered of moderate acute oral toxicity; classification as Acute toxicity 4 H302 (harmful if swallowed) is justified.
Eye - acute	Severe eye irritant.
Early onset symptoms	No data identified.
Delayed health effects from exposure	Polihexanide is considered to be a moderate skin sensitiser based on the positive results seen in guinea pig maximisation tests (GPMT).
Exposure level & health effects	Polihexanide is a possible skin sensitiser in humans in product formulations at 0.5%, with a potential for causing sensitisation at 0.2% in sensitive individuals.
Interactive effects	No data identified.
Other	Two cases of severe anaphylaxis were reported following contact with a surgical wound treated with hospital disinfectant containing 0.2% polihexanide (Olivieri et al., 1998). Additionally, an 81-year old female patient experienced symptoms of a grade III anaphylaxis with palmar pruritus, flush, swelling of lips, swallowing difficulties, hypotension and loss of consciousness while using a new brand of wet toilet paper containing polihexanide as a disinfectant (Kautz et al., 2010). The patient had no previously known allergies or atopic diseases. Based on the detailed allergy history, the patient had experienced episodes of grade II anaphylaxis during wound care of an existing leg ulcer: once when using a new wound dressing Suprasorb; and twice after wound cleansing with two different disinfectants, Lavanid 1 and Prontosan.

12.0 Ecological Information

Ecotoxicity	(Ingredient) PHMB is very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Avoid release to the environment.
Persistence & biodegradability	No data.
Bioaccumulative potential	No data.
Mobility in soil	No data.
Other adverse effects	No data.

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13.0 Disposal Considerations

Disposal containers & methods	Wrap in paper, dispose as routine waste. DO NOT re-use or refill container.
Physical/chemical properties that may affect disposal options	No data.
Effects of sewage disposal	No data.
Special precautions for incineration or land fill	No data.

14.0 Transport Information

UN number	**Proper shipping name / technical name**	**Transport hazard class**	**Packing Group**
None allocated.	None allocated.	None allocated.	None allocated.
Environmental hazards for transport purposes		**Special precautions for user**	
None allocated.		None allocated.	

15.0 Regulatory Information

Montreal Protocol	**Stockholm Convention**	**Rotterdam Convention**	**Basel Convention**	**MARPOL**
Not applicable.	Not included.	Not included.	Not included.	Not included.
SUSMP	Not classified under SUSMP.			
Prohibitions / licensing restrictions	For use only by or under direction of a veterinary surgeon.			
APVMA	APVMA approval number: 60080			
NICNAS	Control measures to minimise the risk from oral, inhalation, dermal and ocular exposure to the chemicals should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate, or minimise risk arising from storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemicals are used. Examples of control measures which could minimise the risk include, but are not limited to: - air monitoring to ensure control measures in place are working effectively and continue to do so; - health monitoring for any worker who is at risk of exposure to the chemicals, if valid techniques are available to monitor the effect on the worker's health; - minimising manual processes and work tasks through automating processes; - work procedures that minimise splashes and spills; - regularly cleaning equipment and work areas; and - using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemicals. Guidance on managing risks from hazardous chemicals are provided in the *Managing risks of hazardous chemicals in the workplace—Code of practice* available on the Safe Work Australia website. Personal protective equipment should not solely be relied upon to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selecting personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.			

16.0 Other Information

16.1 Consumer & General Usage Information

Directions for use	Read label.
Directions for removal	Rinse thoroughly clean under running water.
Nano materials	None identified.
Animal derived ingredients	None identified.

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16.2 SDS Preparation

Date prepared	20 December 2016.
Changes made	Transition to GHS, full review.
Reference standards	Preparation of Safety Data Sheets for Hazardous Chemicals Code of Practice February 2016. ISBN 978-0-642-33311-7. GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS) Fourth revised edition.
Resources relied upon include	Hazardous Substances Data Bank (HSDB) https://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB Suppliers' SDS; RTECS Toxicity Database; IRAC; CDC NIOSH, HSIS, Safe Work Australia GHS Hazardous Chemical Information List. National Industrial Chemicals Notification and Assessment Scheme INVENTORY MULTI-TIERED ASSESSMENT AND PRIORITISATION (IMAP) HUMAN HEALTH TIER II ASSESSMENT FOR Polihexanide. Scientific Committee on Consumer Safety SCCS OPINION ON the safety of poly(hexamethylene) biguanide hydrochloride (PHMB). The SCCS adopted this opinion at its 6th plenary meeting on 18 June 2014.
Disclaimer: This SDS provides safety data only for the product and circumstances of use nominated. The SDS summarises our best knowledge of the specific, well known and equivocally demonstrated health and safety hazard information pertaining to workplace use of the nominated substance(s) however the author expressly disclaims that the SDS is complete, is a representation or is a guarantee. Published and other resources have been relied upon, and in some cases conflicting information has been identified. Each user should read the SDS and consider the information in the context of their specific conditions and circumstances, and in conjunction with other products.	
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16.3 Key Abbreviations or Acronyms Used

%	percent (parts per hundred)
***C or ^{o}C**	degrees Celsius
<	less than
>	greater than
ACCC	Australian Competition and Consumer Commission
ADG	Australian Dangerous Goods
AICS	Australian Inventory of Chemical Substances
APVMA	Australian Pesticides and Veterinary Medicines Authority
AS	Australian Standard
ASCC	Australian Society of Cosmetic Chemists
BOD	Biochemical Oxygen Demand
CAS	Chemical Abstracts Service (Registry Number)
cc	cubic centimetres (equivalent to mL)
COD	Chemical Oxygen Demand
COSING	The European Commission database with information on Cosmetic Ingredients & Substances Dangerous Goods
DGBE	Diethylene Glycol Monobutyl Ether
ECHA	European Chemical Agency
EINECS	European Inventory of Existing Commercial Chemical Substances (Identifying Number)
EU	Europe / European
FSANZ	Food Standards Australia New Zealand
g	gram
GHS	Globally Harmonised System (safety symbols and labelling)
GMO	Genetically Modified Organism
h or hr	hour
HAZCHEM	Emergency action code of numbers and letters that provide information to emergency services especially fire fighters
HSIS	The Safe Work Australia Hazardous Substances Information System
IATA	The International Air Transport Association
ICAO	The International Civil Aviation Organization
IFA	The International Fragrance Association
INCI	The International Nomenclature of Cosmetic Ingredients
kg	kilogram
L	litre
LC_{50}	LC_{50} is the average concentration of a material (by a defined route) that causes the death of 50% (one half) of a group of (defined) test animals. Normally quoted in mg/kg body weight.
LD_{50}	LD_{50} is the average dose of a material, given all at once, which causes the death of 50% of a group of (defined) test animals. Normally quoted in mg/kg body weight. Products with a LD_{50} of less than 5,000mg/kg are scheduled poisons in Australia (see SUSMP).

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LD_{LO}	Lethal Dose Low is the minimum amount of a material shown to be lethal to a specified type of animal. Typically quoted in mg/kg body weight.
m or min	minute
m^3	cubic metre
Max or max	maximum
mg	milligram
Min or min	minimum
mL	millilitre
mm	millimetre
mm Hg	millimetre of Mercury
MOS	Margin of Safety
MRL	Maximum Residue Limit
MSDS	Material Safety Data Sheet (see also SDS)
Nano	Nano(sized) material / Nano Technology; …industrial materials (including a cosmetic ingredient) comprising 10% or more by composition that has been intentionally produced, manufactured or engineered to have either an internal or external property that is a size range typically between 1nm and 100nm.
ng	nanogram
NICNAS	The National Industrial Chemicals Notification and Assessment Scheme (AUSTRALIA)
NIOSH	The National Institute for Occupational Safety and Health (USA)
NOAEL	No Observed Adverse Effects Limit
NOHSC	National Occupational Health and Safety Commission (AUSTRALIA)
NOS	Not Otherwise Specified
NZS	New Zealand Standard
OECD	Organization for Economic Co-operation and Development (Test Method number)
OSHA	The Occupational Safety and Health Administration (USA)
PEL	Permissible Exposure Limit
pH	(pH) A measure of acidic (less than 7) or alkalinity (above 7); extreme values represent extreme acidic or alkaline conditions. Typically products with a pH less than three or greater than 11 are scheduled poisons (SUSMP).
ppb	parts per billion
PPE	Personal Protective Equipment
ppm	parts per million
RTECS	The Registry of Toxic Effects of Chemical Substances
SCCP	Scientific Committee on Cosmetic Products and Non-Food Products (EUROPE)
SCCS	Scientific Committee on Consumer Safety (EUROPE)
SDS	Safety Data Sheet, (previously called MSDS) now SDS under GHS
STEL	Short Term Exposure Limit
SUSMP	Standard for the Uniform Scheduling of Medicine & Poisons (AUSTRALIA) also Poisons Standard
TGA	Therapeutic Goods Administration (AUSTRALIA)
TLV	Threshold Limit Value
TWA	Time Weighted Average
ug	microgram
uL	microlitre
UN	United Nations (number)
US or USA	The United States of America

End of SDS