Australian Government

Australian Pesticides and Veterinary Medicines Authority

Polihexanide: Regulatory Decisions

The reconsideration of products containing polihexanide and approvals of their associated labels

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Comments and enquiries regarding copyright:

Director Public Affairs and Communication
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604 Australia

Telephone: +61 2 6210 4988

Email: communications@apvma.gov.au.

This publication is available from the APVMA website: www.apvma.gov.au.

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FOREWORD

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority with responsibility for the regulation of agricultural and veterinary chemicals in Australia. Its statutory powers are provided in the Agvet Codes scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994.*

The APVMA has legislated powers to reconsider the approval of an active constituent, registration of a chemical product or approval of a label at any time after it has been registered. The reconsideration process is outlined in Part 2, Division 4 of the Agvet Codes.

A reconsideration may be initiated when new research or evidence has raised concerns about the use or safety of a particular chemical, a product containing that chemical, or its label. The scope of each reconsideration can cover a range of areas including human health (toxicology, public health, occupational health and safety), the environment (environmental fate and ecotoxicology), residues and trade, chemistry, efficacy or target crop or animal safety. However, the scope of each reconsideration is determined on a case- by-case basis reflecting the specific issues raised by the new research or evidence.

The reconsideration process includes a call for data from a variety of sources, a scientific evaluation of that data and, following public consultation, a regulatory decision about the ongoing use of the chemical or product. The data required by the APVMA must be generated according to scientific principles. The APVMA conducts science and evidence-based risk analysis with respect to the matters of concern, analysing all relevant information and data available.

In undertaking reconsiderations, the APVMA works in close cooperation with other regulators- the Department of the Environment and Energy, Food Standards Australia New Zealand (FSANZ), state departments of agriculture, as well as other expert advisers as appropriate.

This document, *Polihexanide: Regulatory Decisions*, sets out the APVMA's regulatory decisions relating to products containing polihexanide. The review findings and regulatory decisions are based on information collected from a variety of sources and comments received from public consultation.

This document, and the previously published proposed regulatory decisions report and supporting scientific assessments are available from the following APVMA website links.

- Polihexanide: Regulatory Decisions (published May 2018)
- Polihexanide Proposed Regulatory Decisions (published January 2018)
- Human Health Risk Assessment of Polihexanide (published January 2018).
- Polihexanide Carcinogenicity Hazard Assessment Report (published June 2011)

EXECUTIVE SUMMARY

Introduction

Polihexanide is a polymer of chlorhexidine. The chemical is used to control microorganisms in swimming pools and spas. It is also used to disinfect surfaces, equipment and air spaces in veterinary practices and animal houses. Further, it is also used as an antimicrobial skin treatment for dogs, cats and horses to prevent re-infestation; or to clean and reduce microorganisms in ears of dogs.

The APVMA reconsideration of registrations of products containing polihexanide and associated label approvals began in July 2005 due to concerns about the carcinogenicity potential of polihexanide.

Review findings

The APVMA, in collaboration with the then Office of Chemical Safety (OCS) within the Department of Health, assessed the potential of polihexanide for carcinogenicity. The assessment identified polihexanide as a potential carcinogen in whole-life studies in rodents via the oral route, but only at high exposure levels. Such high levels are unlikely to be encountered when polihexanide products are used according to label instructions in occupational or public settings. Further, polihexanide did not appear to be genotoxic and clear NOAELS (no observed adverse effect levels) were demonstrated in animal carcinogenicity studies. Hence, the carcinogenicity findings in rodents are not regarded as a barrier to continuing registration of products containing polihexanide.

The APVMA also assessed the risk to workers and the public exposed to polihexanide when using pool chemcals, veterinary disinfectants and skin treatment products used to treat dogs, cats and horses. This assessment included post-application exposure for the public bathing in pools/spas treated with polihexanide products. Both qualitative and quantitative risk assessments were undertaken.

Based on the consideration of the hazards associated with the products, and the estimated exposure and risks associated with use of the products, the APVMA determined that all product registrations can continue after strengthening the first aid instructions and safety directions on the product labels.

Regulatory decisions

After consideration of all data and assessments, and all submissions to the proposed regulatory decisions report, the APVMA has made the following regulatory decisions:

Vary relevant particulars of registration and label approvals of selected products (as described in Appendix 1) to include appropriate safety directions and first aid instructions that are consistent with the hazards associated with each product.

Note that where a product has multiple label approvals, the variations are made only to the most recently approved label (Column 4, Table 2). The older label approvals (Column 6, Table 2) are cancelled (see below), as the older labels no longer meet the labelling criteria of the Agvet Codes.

Affirm these product registrations once the necessary particulars and conditions have been varied.

Cancel all previous product label approvals, except for the varied labels as described above, as those labels no longer meet the labelling criteria of the Agvet Codes.

The review of polihexanide is concluded

The APVMA has taken the necessary administrative and regulatory steps to give effect to the above decisions. These actions conclude the review of polihexanide product registrations and associated label approvals.

Phase-out periods

The APVMA has determined that the maximum legislative one-year phase-out period is appropriate for the continued supply and use of registered products bearing (i) the pre-variation version of the previously approved labels (Column 4 of Table 2); and (ii) cancelled labels (Column 6 of Table 2). During this period, products may continue to be used according to the earlier approved label instructions.

1 INTRODUCTION

1.1 Polihexanide

Polihexanide or poly(hexamethylene) biguanide hydrochloride or PHMB is a polymer of chlorhexidine and a member of the guanidine family. Two CAS numbers (27083-27-8 and 32289-58-0) are in use for polihexanide, both relating to the hydrochloride salt, the former relating to the technical material and the latter to the pure polymer (minus monomers). Polihexanide is a cationic biocide and binds to the negatively charged phosphate head groups of phospholipids on the bacterial cell wall, resulting in a disruption of the membrane culminating in cell death.

Polihexanide is widely used in Agricultural and Veterinary (Agvet) products as a biocide for control of micro-organisms, and algae in swimming pools and spas, as a disinfectant for veterinary hospitals and animal accommodations, and as an antiseptic in veterinary products (Table 1). These products are regulated by the APVMA.

Polihexanide is also used in non-agricultural/veterinary situations such as a biocide (disinfectant) in medical equipment, medical procedures, contact lens cleansers, food preparation surfaces, and industrial uses. In these situations the Therapeutic Goods Administration (TGA) and the National Industrial Chemical (Notification and Assessment) Scheme (NICNAS) within the Department of Health and Ageing are responsible for regulation and not the APVMA.

Table 1: Uses of polihexanide products registered in Australia (includes only those products regulated by the APVMA)

Situation	Polihexanide content	Other active constituents
Swimming pools and spas sanitisers	20 – 200 g/L	None
Veterinary products used as surface, equipment, air space and animal housing disinfectants	4 g/L 1 g/L	Benzalkonium chloride Benzalkonium chloride Didecyl dimethyl ammonium chloride
Veterinary products – germicidal products for topical application	0.3 g/L 2 g/L	Benzalkonium chloride Disodium edetate

1.2 APVMA reconsideration of polihexanide

The APVMA initiated a reconsideration of the registrations of polihexanide products and their label approvals due to concerns that polihexanide may be a potential carcinogen.

Details of the product registrations and associated label approvals are outlined in Table 2 below.

Table 2: Details of polihexanide products label approvals.

APVMA Product Registration number (1)	Product Name (2)	Registration Holder (3)	Previously approved labels, now varied as an outcome of the review (4)	New label approval number (5)	Previously approved labels, now cancelled as an outcome of the review (6)
48356	HTL Bio-Blu Swimming Pool and Spa Water Treatment and Sanitiser	HTL Pty Ltd	48356/107402	48356/RV0518A	48356/01
49284	King Neptune's Ozone Clear Pool Sanitiser	Isaac Technologies Pty Ltd	49284/1098	49284/ RV0518B	
57606	Aquafresh by Lo-Chlor Pool Sanitiser	M I International Pty Ltd T/A Lo-Chlor Chemicals	57606/56365	57606/ RV0518C	57606/0603
59949	Aquaspa By Lo-Chlor Spa Sanitiser	M I International Pty Ltd T/A Lo-Chlor Chemicals	59949/0509	59949/ RV0518D	59949/0408
61106	Clark Rubber Filtrite Sanit-Eezy for Family Pools Eezy Sanitiser .	Clark Rubber Franchising pty Ltd	61106/59508	61106/ RV0518E	61106/0606
64278	Nature Spa Spa Water Treatment & Sanitiser	Enviro Spa & Pool Pty Ltd	64278/0909	64278/ RV0518F	
64823	Clark Rubber Filtrite Sanit-Eezy Eezy Sanitiser	Clark Rubber Franchising pty Ltd	64823/50208	64823/ RV0518G	
66624	Crystal Waters Spa Sanitiser	M I International Pty Ltd T/A Lo-Chlor Chemicals	66624/56198	66624/ RV0518H	66624/54048
66943	Crystal Waters Pool Sanitiser	M I International Pty Ltd T/A Lo-Chlor Chemicals	66943/57122	66943/ RV0518I	66943/54752
68964	Filtrite Sanit-Eezy Eezy Sanitiser for Spas Spa Sanitiser	Clark Rubber Franchising pty Ltd	68964/59507	68964/ RV0518J	

APVMA Product Registration number (1)	Product Name (2)	Registration Holder (3)	Previously approved labels, now varied as an outcome of the review (4)	New label approval number (5)	Previously approved labels, now cancelled as an outcome of the review (6)
82162	Spa Soft Spa Sanitiser	M I International Pty Ltd T/A Lo-Chlor Chemicals	82162/105117	82162/ RV0518K	
54149	F10SC Veterinary Disinfectant	Health & Hygiene Pty Ltd	54149/0502	54149/ RV0518L	
59720	F10SCXD Veterinary Disinfectant Cleanser	Health & Hygiene Pty Ltd	59720/1105	59720/ RV0518M	
59998	Trigene II Virucidal Disinfectant Concentrate	Ceva Animal Health Pty Ltd (formerly Delvet Pty Ltd)	59998/0906	59998/ RV0518N	
62103	Microtech 7000 General Purpose Disinfectant	Chemetall (Australasia) Pty Ltd	62103/0508	62103/ RV0518O	
70073	Safe4 Disinfectant Cleaner Concentrate	Safe4 All (Aust) Pty Ltd	70073/106951	70073/ RV0518P	70073/62442
58543	F10 Germicidal Treatment Shampoo	Health & Hygiene Pty Ltd	58543/0207	58543/ RV0518Q	58543/0904
58544	F10 Germicidal Barrier Ointment	Health & Hygiene Pty Ltd	58544/1105	58544/ RV0518R	58544/0904
60080	Dermcare Otoflush	Dermcare-Vet Pty Ltd	60080/0407	60080/ RV0518S	

The basis for a reconsideration of the approvals and registrations of a chemical is whether the APVMA remains satisfied that the safety, efficacy and trade criteria listed in sections 5A, 5B and 5C of the Agvet Codes for continued registration and approval are being met. The requirements that were relevant to the scope of this reconsideration (toxicology and human health) were that the use of the product in accordance with instructions approved, or to be approved, by the APVMA for the product or contained in an established standard.

2 SUMMARY OF ASSESSMENTS AND FINDINGS

As part of the review, the OCS, completed scientific risk assessments for polihexanide. A summary of the assessments is given in the following paragraphs. For detailed scientific assessments and review findings, see the reports available on the APVMA website.

The toxicological assessment identified polihexanide as a potential carcinogen in whole-of life studies in rodents via the oral route, but only at high exposure levels which are unlikely to be encountered in occupational or public settings. Since polihexanide did not appear to be genotoxic and clear NOAELs were demonstrated in animal carcinogenicity studies, the OCS advised the APVMA that carcinogenicity findings in rodents are not a barrier to continuing registration of products containing polihexanide.

The OCS also assessed risk to human health from pool and spa products as well as veterinary products. This assessment included risk from occupational exposure and risk from post-application exposure (e.g. from bathing or swimming in pools treated with polihexanide). In summary, the human health risk assessment showed that products containing polihexanide can be used safely provided that appropriate signal headings and first aid instructions and safety directions are included onto labels.

There have been no impurity or stability concerns raised with respect to polihexanide active constituent or products containing this active constituent. On that basis, the APVMA determined that it can continue to be satisfied that the active constituent and products containing this active constituent would meet the safety criteria.

As there are no direct food uses for polihexanide, and very limited potential for inadvertent contamination of food based on current Australian use patterns, there are no grounds for establishing an Acute Reference Dose (ARfD) or Acceptable Daily Intake (ADI) for polihexanide. The residues risk is therefore acceptable.

Polihexanide is currently in Schedule 6 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) and preparations containing 5% or less of polihexanide are exempt from scheduling. Many products included in this review contain other active constituents – benzalkonium chloride, disodium edetate or didecyl dimethyl ammonium chloride (DDAC). Benzalkonium chloride and DDAC are also included in SUSMP. The review considered the toxicity of all these constituents and their respective concentrations in each product in assessing hazard and risk; and in formulating signal headings and first aid instructions and safety directions.

3 STAKEHOLDER CONSULTATION ON PROPOSED REVIEW FINDINGS

After consideration of the hazards, estimated exposure and likely risks associated with use of the products, the APVMA published the Proposed Review Decisions report (PRD) and invited stakeholder comments. The PRD is available on the APVMA website.

In the PRD, the APVMA proposed that all product registrations could be affirmed once variations to product labels have been made to include appropriate signal headings and first aid instruction and safety directions.

3.1 Summary of submissions received and the APVMA response

The APVMA received only one submission on the proposed review decisions. The submission was from registration holder Health & Hygiene Pty Ltd. The comments made in the submission and the APVMA consideration are as follows.

Health & Hygiene Pty Ltd comments with respect to F10 Germicidal Treatment Shampoo (58543) and F10 Germicidal Barrier Ointment (58544)

- The proposed safety directions – "Harmful if swallowed. May irritate the eyes. Avoid contact with eyes. Repeated exposure may cause allergic disorder. Wash hands after use" - are not consistent with the hazards associated with the products as polihexanide concentration in the products is only 0.03%.
- The proposed statement "Repeated exposure may cause allergic disorders" is unnecessary as the products are slight eye irritants but are not skin irritants or sensitisers. Further, repeat exposure is unlikely as the products are used for a relatively short course of treatment.

APVMA consideration

F10 Germicidal Treatment Shampoo has acute oral toxicity and although low, is at a level which necessitates the statement "Harmful if swallowed". Further it is a slight eye irritant. Hence the statements "May irritate the eyes. Avoid contact with eyes. Wash hands after use" are necessary.

The APVMA agrees that the statement "Repeated exposure may cause allergic disorders" is not required, on the basis that the product is not a skin sensitiser.

Accordingly, the APVMA has modified the safety directions for F10 Germicidal Treatment Shampoo (58543) as shown below.

	Instruction
Safety directions	Previously proposed: Harmful if swallowed. May irritate the eyes. Avoid contact with eyes. Repeated exposure may cause allergic disorders. Wash hands after use. Now amended to: Harmful if swallowed. May irritate the eyes. Avoid contact with eyes. Wash hands after use.

F10 Germicidal Barrier Ointment has low acute oral toxicity, but not at a level that requires a hazard statement. It has low acute dermal and inhalational toxicity, but does not cause eye irritation, skin irritation or skin sensitisation. On that basis, the APVMA has determined that safety direction "Wash hands after use" is sufficient.

Accordingly, the APVMA has modified the safety directions for F10 Germicidal Barrier Ointment (58544) as shown below.

	Instruction
Safety directions	Previously proposed: Harmful if swallowed. May irritate the eyes. Avoid contact with eyes. Repeated exposure may cause allergic disorders. Wash hands after use. Now amended to: Wash hands after use

Health & Hygiene Pty Ltd comments with respect to F10SC Veterinary Disinfectant (54140) and F10SCXD Veterinary Disinfectant Cleanser (59720)

- The proposed safety directions "May irritate the eyes and skin. Repeated exposure may cause allergic disorders" are not appropriate. As the safety direction are relevant only to the accidental splashing of the concentrate, a note to the effect that safety directions apply to handling of the concentrate before dilution to the recommended working solution should suffice.
- The proposed statement "May irritate the eyes and skin" is unnecessary when the statement "Avoid contact with eyes and skin" is already included.
- The statement "Repeated exposure may cause allergic disorders" is inappropriate as the incidence of repeated exposure to the concentrate will be infrequent, if at all. Further, the concentration of polihexanide in the working solution level is no more than 0.03%.

APVMA consideration

The products are of moderate acute oral toxicity, low dermal and inhalational toxicity and are slight skin and eye irritants. They are considered potential sensitisers.

The only proposed PPE are gloves and the safety directions instruct the user to use these when opening the container and preparing the product for use. It is agreed that PPE are not required with applying the diluted product, but the hazard statements relating to the concentrated product remain applicable. Both the hazard statement "May irritate eyes and skin" and the precautionary statement "Avoid contact with eyes" are warranted as the products are slight eye irritants.

"Repeat exposure may cause allergic responses" is a standard statement which is warranted by the formulation of the products (active and non-active constituents).

Accordingly, the APVMA has finalised the safety direction for these products as proposed in the PRD.

4 REVIEW DECISIONS

Based on the toxicology and human health risk assessments, and consideration of stakeholder submissions, the APVMA has made following decisions with respect to the registration of polihexanide products and their associated label approvals.

4.1 Relevant particulars of product registrations and label approvals varied

The APVMA determined that it was not satisfied that the products listed in Table 2 meet the safety criteria as defined in section 5A of the Agvet Code when they were used according to the instructions for use on the previously approved labels listed in Column 4 of Table 2.

However, the APVMA has determined that the relevant particulars of product registrations and label approvals (specifically, the label instructions for use of the products) could be varied in such a way as described in Appendix 1, and then the APVMA can be satisfied that the products listed in Table 2 meet the safety criteria as defined in section 5A of the Agvet Code when they are used according to the instructions for use on the varied labels.

Accordingly, the APVMA has varied the relevant particulars of product registrations and label approvals as described in Appendix 1.

Note that where a product had multiple label approvals, the variations were made only to the most recently approved label (Column 4, Table 2) with a new approval number allotted (shown in Column 5 of Table 2) to uniquely identify the labels varied resulting from this review. All the other label approvals have been cancelled (see Section 4.3 below), thus leaving only one approved label for each of the products as listed in Column 5 of Table 2.

4.2 Product registrations affirmed

After varying the relevant particulars of product registrations and label approvals as described in Section 4.1 above, the APVMA has affirmed the product registrations (Column 1 of Table 2) in accordance with s.34A of the Agvet Code.

4.3 Older label approvals cancelled

The older label approvals (Column 6, Table 2) have been cancelled in accordance with s.41(2) of the Agvet Code, as these labels no longer meet the labelling criteria [s.5D(1)(i) of the Agvet Code], Now, each product in Table 2 has only one set of relevant label particulars approved.

4.4 Phase-out periods for earlier approved labels and cancelled labels

The APVMA has determined under s 81(3)(b) of the Agvet Code that one-year phase-out period shall apply for the continued supply and use of registered products bearing the earlier approved labels (Column 4 of Table 2). During

this time, products may continue to be used according to the earlier approved label instructions. After that period all product that is supplied should bear the varied approved label (Column 5 of Table 2).

The APVMA has determined under s 45A and s 45B of the Agvet Code that one-year phase-out period shall apply for possessing, having custody of or using products listed in Table 2 bearing cancelled labels shown in Column 6 of Table 2. During this time, product may continue to be used according to the earlier approved label instructions.

Appendix

LABEL VARIATIONS

Pool and spa products

Pool and spa products 48356, 49284, 57606, 61106, 64278, 64823 and 66943 contain 200 g/L polihexanide and are in Schedule 6 of Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). They cause slight skin irritation, severe eye irritation and skin sensitisation. Previously approved labels (Column 4 of Table 2) of these products do not contain signal headings, first aid instructions and safety directions relevant to the hazards and potential risks.

The relevant particulars of the label approvals of these pool and spa products (48356, 49284, 57606, 61106, 64278, 64823 and 66943) have been varied to include the following signal headings, first aid instructions and safety directions. The varied labels have been given new approval numbers (Column 5 of Table 2). The new relevant label particulars contain appropriate signal headings, first aid instructions and safety directions to address the hazards and risks associated with the products.

	Inclusions
Signal Headings	POISON KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING
First Aid Instructions	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126; New Zealand 0800 764 766. If in eyes, hold eyes open, flood with water for at least 15 minutes and see a doctor.
Safety Directions	May irritate the skin. Will damage the eyes. Repeated exposure may cause allergic disorders. Avoid contact with eyes and skin. When opening the container and using the product, wear rubber gloves. Wash hands after use. After each day's use wash gloves.

Spa sanitising products

Spa sanitising products 59949, 66624, 68964 and 82162 contain 20 g/L polihexanide. They are not scheduled in SUSMP. They do not cause skin or eye irritation and are non-skin-sensitisers. Previously approved labels (Column 4 of Table 2) of these products do not contain signal headings, first aid instructions and safety directions relevant to the hazards and potential risks.

The relevant particulars of the label approvals of these spa sanitising products (59949, 66624, 68964 and 82162) have been varied to delete the current Signal Headings and add the following Signal Heading, First Aid Instructions and Safety Direction. The varied labels have been given new approval numbers (Column 5 of Table 2). The new relevant label particulars contain appropriate signal headings, first aid instructions and safety direction to address the hazards and risks associated with the products.

	Instruction
Signal Heading	READ SAFETY DIRECTIONS BEFORE OPENING OR USING
First Aid Instructions	First aid is not generally required. If in doubt, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor.
Safety Direction	Wash hands after use.

Veterinary disinfectants

Veterinary disinfectants 54149, 59720, 62103 and 70073 contain benzalkonium chloride at concentrations that place them in Schedule 5 of SUSMP. They cause slight skin and eye irritation and are skin sensitisers. They cause moderate acute oral toxicity, low dermal and inhalational toxicity. While the signal headings on the previously approved labels of these products are appropriate, the first aid instructions and safety directions are not relevant to the hazards and potential risks.

The relevant particulars of the label approvals of these veterinary disinfectants used for surface, equipment, air space and animal housing disinfection (54149, 59720, 62103 and 70073) have been varied to include the following statements. The varied labels have been given new approval numbers (Column 5 of Table 2). The new relevant label particulars contain appropriate signal headings, first aid instructions and safety direction to address the hazards and risks associated with the products.

	Instruction
First Aid Instructions	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126; New Zealand 0800 764 766. If swallowed, do NOT induce vomiting. Give a glass of water.
Safety Directions	Harmful if swallowed. May irritate the eyes and skin. Repeated exposure may cause allergic disorders. Avoid contact with eyes and skin. When opening the container and preparing the product for use, wear elbow length chemical resistant gloves. Wash hands after use. After each day's use wash gloves.

Veterinary disinfectant Trigene II Virucidal Disinfectant Concentrate

The veterinary disinfectant Trigene II Virucidal Disinfectant Concentrate (59998) contains didecyldimethylammonium chloride and is in Schedule 6 of SUSMP. The product has moderate oral toxicity and is a moderate skin irritant, severe eye irritant and a skin sensitiser. The signal headings on the previously approved labels meet the requirements of those for Schedule 6 products, but the first aid instructions and safety directions are not appropriate for the hazard and risk associated with the chemical.

The relevant particulars of the label approvals of the veterinary disinfectant product have been varied to delete current First Aid Instructions and Safety Directions and to include the following First Aid Instructions and Safety Directions. The varied label has been given a new approval number (Column 5 of Table 2). The new relevant label particulars contain appropriate signal headings, first aid instructions and safety direction to address the hazards and risks associated with the product.

	Instruction
First Aid Instructions	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126; New Zealand 0800 764 766.If swallowed, do NOT induce vomiting. Give a glass of water. If skin contact occurs, remove contaminated clothing and wash skin thoroughly. . If in eyes, hold eyes open, flood with water for at least 15 minutes and see a doctor.
Safety Directions	Harmful if swallowed. Will damage eyes. Will irritate the skin. Repeated exposure may cause allergic disorders. Avoid contact with eyes and skin. When opening the container and preparing solution, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow-length chemical resistant gloves and face shield or goggles. Wash hands after use. After each day's use, wash gloves, face shield or goggles and contaminated clothing.

Germicidal products for topical application

F10 Germicidal Treatment Shampoo (product registration number 58543)

The germicidal products for topical application, 58543 has low acute oral, acute dermal and inhalational toxicity. It is slight eye irritant but is not skin irritant or sensitiser. The products contains polihexanide and benzalkonium chloride at low concentrations and is not scheduled in SUSMP. Previously approved labels (Column 4 of Table 2) of the product does not contain appropriate signal headings, first aid instructions and safety directions that are consistent with the hazard and risk associated with the products.

In product 58543, benzalkonium chloride is present at less than the scheduling cut-off, and therefore additional first aid instructions are not required. The relevant particulars of the label approvals of this product have been varied to include the following signal headings, first aid instructions and safety directions. The varied label has been given a new approval number (Column 5 of Table 2). The new relevant label particulars contain appropriate signal headings, first aid instructions and safety direction to address the hazards and risks associated with the product.

	Instruction
Signal Headings	READ SAFETY DIRECTIONS BEFORE OPENING OR USING FOR ANIMAL TREATMENT ONLY
First Aid Instructions	First aid is not generally required. If in doubt, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor.
Safety Directions	Harmful if swallowed. May irritate the eyes. Avoid contact with eyes. Wash hands after use.

F10 Germicidal Barrier Ointment (product registration number 58544)

This product has low acute oral, acute dermal and inhalational toxicity. It is not an eye irritant, skin irritant or skin sensitiser. The product contains polihexanide and benzalkonium chloride at low concentrations and is not scheduled in SUSMP. Previously approved labels do not contain appropriate signal headings, first aid instructions and safety directions that are consistent with the hazard and risk associated with the product.

In this product, benzalkonium chloride is present at less than the scheduling cut-off, and therefore it does not require additional first aid instructions. The relevant particulars of the label approvals of this product

have been varied to include the following signal headings, first aid instructions and safety directions. The varied label has been given a new approval number (Column 5 of Table 2). The new relevant label particulars contain appropriate signal headings, first aid instructions and safety direction to address the hazards and risks associated with the product.

	Instruction
Signal Headings	READ SAFETY DIRECTIONS BEFORE OPENING OR USING FOR ANIMAL TREATMENT ONLY
First Aid Instructions	First aid is not generally required. If in doubt, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor.
Safety Direction	Wash hands after use.

Veterinary ear cleaning product Dermacare Otoflush

The veterinary ear cleaning product 60080 contains disodium edetate as an active constituent in addition to polihexanide. The product is not scheduled in SUSMP. Although the signal heading and first aid instructions on the previously approved label is appropriate, the safety directions are not consistent with the hazard and risk associated with the product.

The relevant particulars of the label approvals of the product have been varied to include the following safety directions. The varied label has been given a new approval number (Column 5 of Table 2). The new relevant label particulars contain appropriate signal headings, first aid instructions and safety direction to address the hazards and risks associated with the product.

	Instruction
First Aid Instructions	First aid is not generally required. If in doubt, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor.
Safety Direction	Wash hands after use.