

Dairy Sanitiser Model requirements

Purpose of the model

The purpose of this model is to:

1. Provide guidance to applicants as to products that are eligible for simplified registration.
2. Enable applicants to supply information in a format that enables APVMA to rapidly confirm eligibility for registration and to then register the relevant products.
3. Enable APVMA to confirm eligibility for registration without evaluation of data.

The model applies to dairy cleansers and sanitisers for on-farm use.

Section 14 of the *Agricultural and Veterinary Chemicals Code Act 1994* states that APVMA must grant an application for registration unless APVMA is not satisfied that:

1. The product will not pose an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues;
2. The product would not be likely to have an effect that is harmful to human beings;
3. The product would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment;
4. The use of the product would not unduly prejudice trade or commerce between Australia and places outside Australia;
5. The product will be effective when the product is used in accordance with directions contained in the product labelling.

An agricultural chemical product conforming with this model entitles a person to apply to the Australian Pesticides and Veterinary Medicines Authority (APVMA) to register the product.

The model enables information to be provided to confirm to APVMA that, when used according to label directions, the product will not pose undue harm to people, will not have an effect that is harmful to human beings, will not have an unintended effect that is harmful to animals, plants or things or to the environment, will not prejudice trade and will be effective.

Applications must be submitted under Category 10 using the application form available on the APVMA website. The fee for an application is the statutory fee and timeframe are those for modules 1 (Screening) and 11.4 (Finalisation). No data assessment is required.

Eligibility for Registration under the Model

The model applies to products that are classified as low risk entitling them to processing with reduced regulatory consideration.

The model applies only to products:

1. In which all ingredients have been considered for Scheduling and have been determined to be Unscheduled (i.e. listed in Appendix B of the Poisons Standard) or are listed in Schedule 5 or Schedule 6 of the Poisons Standard, and
2. That when used according to label directions do not leave residues in or on milking plant and equipment.
3. Have a history of use in other situations that demonstrates the products do not pose an undue risk to:
 - a. People handling the product, and
 - b. The environment.

Definitions

Dairy cleansers and sanitisers

Products used for cleaning and/or sanitising on-farm milking plant equipment and facilities. Dairy cleansers and sanitisers do not include products applied directly to animals or for treatment of animals.

Dairy cleaners and sanitisers are used for prevention and control of physical and microbial contamination, residues and odour of milk plant equipment.

Harm

Harm is damage or adverse effect.

Hazard

Qualitative description of adverse effect posed by a substance without regard to dose or exposure.

Poisons Standard

The current edition of the Standard for the Uniform Scheduling of Medicines and Poisons as published by the Australian Government.

Risk

Risk is the probability of harm. It is a combination of the harm that can occur and the potential for that harm to occur. Risk can be reduced (mitigated) by implementation of procedures to limit the probability of harm, e.g. limiting exposure to harmful substances reduces the risk posed by those substances.

Proposed Use and Situation

Proposed Use

For prevention and control of:

- Physical contaminants in milk plant equipment.
- Microbial contaminants in milk plant equipment.
- Residues of substances, including milk and other substances in milk plant equipment.
- Odour.

Situation

On-farm milking plant and equipment including dairy sheds and associated equipment, milk vats and equipment used to transfer or store milk.

Active Constituent

To be considered under the scheme the active constituent(s) must:

1. Be included one of the lists of acceptable active constituents, or
2. Be available for use and to be used for similar purposes in other situations (e.g. milk processing plants) in Australia or overseas, or
3. Be used at similar concentrations or lower in similar situations in Australia or overseas, and
4. Be Scheduled in Schedule 5 or 6 or listed as an ingredient not requiring control by Scheduling, i.e. Appendix B of the Poisons Standard.

Where the active constituent is not currently used for the same purpose in the same situation as that proposed, justification will need to be provided for use of the substance in Australia.

Lists of acceptable active constituents include:

- Active constituents approved for use by APVMA.
- Food Standards Code
- APVMA list of Active Constituents Excluded from the Requirements for Approval.
- Actives reserved from registration.
- NZFSA Manual 15
- NZFSA Dairy Maintenance Compounds
- 9 CFR 71.10
- 21 CFR 178,1010

It is not necessary for the active constituent to be approved in Australia as an active constituent but must have been considered by other relevant authorities and found to be acceptable for use in comparable situations.

Demonstrating Applicability to the Model

Minimal potential to pose an undue hazard to the safety of people exposed to the product

1. All products must have been considered for Scheduling. Only products that have been determined to not require Scheduling (listed in Appendix B of the Poisons Standard) or are listed in Schedules 5 or 6 are eligible.
2. Only products with simple Safety Directions and First Aid statements are eligible for consideration under the model.
3. The supporting documentation provides full formulation details with:
 - a. Name of the product.
 - b. Name of the product as listed in the Poisons Standard.
 - c. Content of the substance in the formulation.
 - d. Schedule in the Poisons Standard. If not Scheduled explanation as to why Scheduling is not applicable, e.g. reference to common uses or listing in other permitted uses.
 - e. Safety Directions for the product.
 - f. First Aid Directions for the product.
4. Confirmation the product is available for other uses that do not require registration by APVMA, e.g. a product that is also supplied as a cleaner/disinfectant for industrial and institutional use.

Minimal potential to pose an undue hazard to the safety of people exposed to residues of the product

1. Only products that do not leave residues are eligible.
2. The product label must provide instructions to ensure the substance is removed before milk comes into contact with treated surfaces.

Absence of an effect that is harmful to human beings

1. All products must have been considered for Scheduling. Only products that have been determined to not require Scheduling (listed in Appendix B of the Poisons Standard) or are listed in Schedules 5 or 6 of the Poisons Standard are eligible.
2. Only products with simple Safety Directions and First Aid statements are eligible for consideration under the model.
3. The supporting documentation provides full formulation details with:
 - a. Name of the product.
 - b. Name of the product as listed in the Poisons Standard.
 - c. Content of the substance in the formulation.
 - d. Schedule in the Poisons Standard. If not Scheduled explanation as to why Scheduling is not applicable, e.g. reference to common uses or listing in other permitted uses.
 - e. Safety Directions for the product.
 - f. First Aid Directions for the product.
4. Confirmation the product is available for other uses that do not require registration by APVMA, e.g. a product that is also supplied as a cleaner/disinfectant for industrial and institutional use.

Unintended effects that are harmful to animals not likely

1. Products intended for application onto animals or animal feed are not eligible for registration under the model.
2. Equipment treated with products registered under the model must be rinsed prior to any animal contact to ensure residues do not remain on the equipment.

Unintended effects that are harmful to plants or things not likely

1. Product labels recommending use on plants are not eligible for registration under the model.
2. The application must provide reference to situations in which the product or a closely similar product is used without causing harm to equipment, surfaces or things.
3. If there is a potential for harm to specific surfaces or materials, the label must state the hazard and provide information as to methods for avoiding damage.

Unintended effects that are harmful to the environment not likely

1. Products eligible for registration under this model are not applied in a wide or dispersive manner.
2. Environmental effects must be demonstrated by reference to the same product or a similar product being available for use in other situations, e.g. to clean milk tankers, for use in institutional or industrial situations.

The product will be effective when used in accordance with directions contained in the product labelling.

1. Information must be provided to demonstrate the product will be effective/efficacious when used in accordance with label directions.
2. Suitable evidence of efficacy includes:
 - a. History of use for similar purposes in other situations, e.g. use in milk processing plants.
 - b. History of use of other products with same active constituents to achieve the required results.
 - c. Approvals from other countries, comparable to Australia, for similar uses.
 - d. Testing results following standardised protocols, e.g. TGO 54, AOAC, ASTM or European standard methods.

Intellectual Property Rights/Data Protection

Products not previously registered in Australia for use as dairy cleansers or sanitisers may need to reference data submitted by others in support of registrations in Australia or overseas. Where data are subject to data protection in Australia or overseas, such reference is not permitted without the authorisation of the data owner.

All applications must be accompanied by a declaration and/or letter of authorisation:

1. If no protected data are being referenced, a declaration that the application does not rely on reference to any protected data with verification, e.g. reference to a broad range of products that have been registered for > 15 years.
2. If the product references another product (in Australia or overseas) that may have protected data, a letter of access from the data owner must be provided, e.g. registrant of reference product.

Data/Label Requirements

Label

Signal Heading

The signal heading must be justified by use of the following table:

Ingredient	Content (% w/w or %w/v)	Schedule	Safety Directions required (Yes/No)

Products containing ingredients that have not been Scheduled in Australia are not eligible for registration under the scheme.

Products containing ingredients at higher concentrations than have been Scheduled are not eligible for registration under the scheme.

Only products that are Unscheduled or are included in Schedules 5 or 6 of the Poisons Standard are eligible for inclusion in the scheme.

Product Name

Name must be unique.

Active Constituent

To be considered under the scheme the active constituent(s) must:

5. Be included on the list of acceptable active constituents, or
6. Be available for use and to be used for similar purposes in other situations (e.g. milk processing plants) in Australia or overseas,
7. Be used at similar concentrations or lower in similar situations in Australia or overseas, and
8. Be Scheduled in Schedules 5 or 6 or listed as an ingredient not requiring control by Scheduling, i.e. Appendix B of the Poisons Standard.

Where the active constituent is not currently used for the same purpose in the same situation as that proposed, justification will need to be provided for use of the substance in Australia.

Lists of acceptable active constituents include:

- Active Constituents approved for use by APVMA.
- Food Standards Code
- APVMA list of Active Constituents Excluded from the Requirements for Approval
- Actives reserved from registration.
- NZFSA Manual 15
- NZFSA Dairy Maintenance Compounds
- 9 CFR 71.10
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Statement of Claims

A brief statement of claims needs to be provided. The statement should describe the intended use of the product. The statement should not be deceptive or misleading to potential users of the product.

Contents

A contents statement as either:

Contents: g/L (liquid).

New Contents: g/kg (solid).

Contact details

Australian contact details must be stated, including:

1. Name of company.
2. Physical address for company, i.e. address where a person can visit the company.
3. Australian telephone number.

Company web address or other details can be provided.

Directions for Use

Directions for Use must include:

1. If relevant, restrictions on use of product including situations in which product should not be used.
2. Situation in which product can be used.
3. Rate of use. Describe the concentration required to achieve the desired result.
4. Critical Comments. Describe any special information relevant to effective use of product, e.g. water to be used for mixing, how product is applied, whether product is left on treated surfaces for any required time.

Supporting documentation must demonstrate that use of the product in accordance with the Directions for Use will achieve the desired result. Supporting material can include:

1. Reference to similar products, their rate and method of use and claims. Reference products can include products used for similar purposes in other situations, e.g. in milk processing plants.
2. Efficacy data generated using an acceptable protocol. Acceptable protocols include TGO 54, AOAC, ASTM or European standard methods. Evidence of applicability of the protocol to the target situation must be demonstrated.

NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION statement

Re-entry

Mandatory if a re-entry interval is specified for the active constituent on similar products

Re-entry interval must be justified if used, e.g. by reference to similar products.

Products claiming no re-entry interval when similar products have a re-entry interval are not eligible for consideration under the scheme.

General Instructions

General statement about the product.

Mixing

Specific mixing instructions if they have not been provided in the Directions for Use.

Application

Specific application instructions if they have not been provided in the Directions for Use.

Protection of Wildlife, Fish, Crustacea and Environment

Mandatory if product poses risk to environment if used inappropriately.

Justification for Protection statement or for excluding a Protection statement must be provided. Justification can include reference to similar products or use in other situations.

Standard statements can be obtained from the Ag Labelling Code.

Storage and Disposal

Instructions for storage and disposal of product. Standard statements can be obtained from the Ag Labelling Code. Justification for the proposed statement must be given.

Safety Directions

Mandatory if Safety Directions required by Scheduling of the product.

Appropriate Safety Directions to be used as specified for the Scheduled ingredients.

Only products with simple Safety Directions are eligible for consideration under the scheme.

First Aid

Manadatory if First Aid statements required by Scheduling of the product.

Appropriate First Aid statements to be used as specified for the Scheduled ingredients.

Only products with simple First Aid statements are eligible for consideration under the scheme.

MSDS

Statement referencing MSDS, e.g. Additional information is listed in the Material Safety Data Sheet which can be obtained from the supplier.

Batch Number

Date of Manufacture

If product has a shelf-life less than 2 years, replace Date of Manufacture with Expiry Date.

APVMA Approval Number

To be issued by APVMA