agriculture,
forestry & fisheries

Department:
Agriculture, Forestry and Fisheries
REPUBLIC OF SOUTH AFRICA

GUIDELINE ON LABELLING OF STOCK REMEDIES

This guideline is intended to provide labelling recommendations to applicants wishing to submit applications for the registration of Stock Remedies in South Africa in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

TABLE OF CONTENTS

1. DEFINITIONS AND TERMINOLOGY

applicant – the person in whose name an application for the registration of a Stock Remedy has been filed

Label – as defined in the stock remedies regulations

manufacture – as defined in the stock remedies regulations

Republic- Republic of South Africa

registered name – the name approved by the Registrar under which a Stock Remedy s registered and shall be sold

registration holder – the company to whom a certificate of registration in respect of a particular Stock Remedy has been issued.

the Act - Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, (Act No. 36 of 1947).

2. INTRODUCTION AND OBJECTIVE

This guideline is intended to outline procedures and specific labelling requirements for registration applications of Stock Remedies under the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, (Act No. 36 of 1947), (hereafter referred to as Act 36/1947) for use in all animals.

This guideline will include background information on the legal requirements, as well as the various registration criteria, including the data to be included in a registration dossier for Stock Remedies under Act 36/1947 as amended.

3. SCOPE

The scope of this guideline applies to the labelling of all Stock Remedies submitted for registration under Act 36/1947 as new registration submissions as well as to any proposed amendments to the labelling or mandatory wording as required by other legislation..

4. GENERAL INFORMATION

Section 7(1) of the Act requires that no person shall sell a Stock Remedy into the Republic unless the container in which it is sold complies with the prescribed requirements and is sealed and labelled in such manner as may be prescribed.

Regulation 10(3) of the Act stipulates that a Stock Remedy shall not be sold in a container or packaging which was not approved by the Registrar and if appropriate approved in terms of a provision of any other law

Regulation 11 of the Act states that:

- No person shall sell any Stock Remedy without an approved label.
- The Registrar may authorise a deviation from the prescribed format and contents of any label, and may authorise the inclusion on the label of a Stock Remedy of any information that is not required to be included by the Regulations. The Registrar may also prescribe additional requirements for the labelling of Stock Remedies.
- A Stock Remedy container shall not be labelled with any marks or signs other than the prescribed details in the labelling requirements, or in terms of a provision of any other law, or that which was approved by the Registrar.

- No words or marks may appear on the container in which a registered Stock Remedy is sold, or on a label and/or pamphlet affixed thereto without prior approval of the Registrar.

- Only recognised, chemical, analytical and pharmaceutical expressions or terms or those expressions or terms which, for reasons of clarity, have been approved by the Registrar may be marked or printed on the container in which a registered Stock Remedy is sold, or on a label affixed thereto, for the purpose of explaining the composition of such remedy.

- Approval of labelling by Act 36/1947 does not absolve the company from the obligations of complying with any other relevant legislation.

All wording shall be in at least two of the official languages, of which the main language shall be English. Translations into any of the other official languages shall correspond exactly with the English text. An affidavit must be submitted stating that the information on the label in another language is the same as on the approved label.

Draft labels for approval shall be submitted in Duplicate

The package insert is mandatory only where an abbreviated label is used, or where the container is too small for a full label.

The name and address of the Registration Holder (Applicant) shall appear on the label and be clearly legible.

Illustrations on labels may not be larger than 20% of the size of the label. These shall be in context of the remedy and submitted with the application. No pictures of children shall be allowed. Permission shall be requested from the Registrar for larger illustrations.

Intramammary preparations may be packed in a printed carton, a printed opaque plastic envelope or a translucent plastic envelope in which the syringe bears a printed label. A package insert shall be enclosed in each of these three packaging forms, or firmly attached thereto with an elastic band or adhesive tape.

Proposed labels in any of the other official languages shall be submitted in duplicate for approval, together with an affidavit stating that the translation is true and accurate.

One sample of the final printed artwork shall be submitted to the Registrar within 3 months of approval.

Registration numbers for other countries may be included on the packaging but shall appear below the South African registration number.

No colour bands or pictograms are required.

Injection of young piglets in the neck with oxytetracycline preparations is prohibited.

Labelling shall comply with ISO notation, e.g. “5 kg” – a space is left between the value and the unit of measurement. Millilitres shall be written as “ml”. Other base units shall be used as follows:
Length – metre (m); mass – kilogram (kg); time – second (s); temperature – degrees Celsius (°C); volume – litres (l).

Label statement s such as WARNINGS, NOTE TO PHYSICIANS, DIRECTIONS FOR USE, etc. shall be expressed in bold upper case type.

Vaccinations shall bear the statement, “NB: THIS PACK MUST BE SOLD AS A UNIT. DO NOT BREAK SEAL OR OPEN PRIOR TO SALE.” This may be omitted if a separate package insert is included for each vial in the pack.

Names of particular vaccine strains shall be typed in lower case, i.e. the full name shall appear in lower case only, and the abbreviation in upper case, e.g. “B V D.”

NOTE – this represents the minimum information required. Applicants may include additional information on approval of the Registrar.

5 SPECIFIC INFORMATION:

The Stock Remedy label shall be divided into main and side panels.

5.1 STOCK REMEDIES CONTAINING MORE THAN 500 ml OR 500 g:

The immediate container of every Stock Remedy intended for administration shall have a label attached on which only the following particulars pertaining to the contents of such package shall appear in clearly legible letters in at least two of the official languages in the following sequence, of which English is the main language:

5.1.1 Main Panel:

The main panel shall preferably not be larger than 40 % of the printed surface of the label. Where there are two main panels, each may not be larger than 20 % of the printed surface.

The following mandatory text should appear on the main panel:

(a) "For (external) animal use only"

The wording "For (external) animal use only must appear at the top of main panel of the Stock Remedy label, with the exception of pigeon remedies and disinfectants. No equivalent wording need appear on disinfectants, the words "For (external) pigeon use only" should appear at the top of the main panel for pigeon remedies. The statement should appear in clearly legible font.

(b) Restricted use in terms of the Veterinary and Para-Veterinary Professions Act

In the case of Stock Remedies that are approved with conditional use by, or under the supervision of persons, registered in terms of, or authorised in terms of section 23 (1) (c) of the Veterinary and Para-Veterinary Professions Act, 1982 (Act 19 of 1982), the following statement shall be included:

"Only for use by or under the supervision of persons registered in terms of, or authorised in terms of, Section 23 (1) (c) of the Veterinary and Para-Veterinary Professions Act, 1982 (Act 19 of 1982)"

(c) Name of Remedy (Trade name)

The name of the remedy must correspond *exactly* with the registered name of the product as it appears on the registration certificate. The print size of the trade name must be the largest on the label. Where the name is exceptionally long, the trade name may be printed in larger print than the rest of the registered name.

(d) Registration Number

Reg. No. … (Act 36 of 1947)
This must *always* appear directly below the registered trade name.

(e) Claims for Remedy
These shall correspond *exactly* with the claims submitted in the registration application dossier. Reference from the dossier/data submitted shall be linked to each claim made on the label.

(f) Toxicity Indications

The toxicity indication is classified according to the established LD_{50} for the product.

The toxicity indication should appear **in red,** in letters of print size not less than half the size of the largest letter in the name of the remedy.

GROUP	STANDARD TEXT	LD_{50}	
I	Skull and crossbones in red on contrasting colour background 'POISON – EXTREMELY TOXIC" in red print	Oral	< 50 mg/ kg
		Dermal	< 200 mg/kg
		Inhalation	< 2000 mg/l/h
II	'POISONOUS' in red on contrasting colour background	Oral	51 – 500 mg/kg
		Dermal	200 – 2 000 mg/kg
		Inhalation	2 001 – 20 000 mg/l/h
III	'CAUTION' in red on contrasting colour background	Oral	501 – 5 000 mg/kg
		Dermal	2 001 – 20 000 mg/kg
		Inhalation	20 001 – 200 000 mg/l/h
IV	No poison group indication on label	Oral	> 5 001 mg/kg
		Dermal	> 2 001 mg/kg
		Inhalation	> 200001 mg/l/h

(g) Storage Instructions

The storage temperature should appear in clearly legible print, for example, "Store between 2 - 8 °C in refrigerator".

The storage instructions should be based on the stability evaluation of the drug substance. Where applicable, specific storage requirements should be stated. These may include the relevant temperature range, particularly for drug substances that cannot tolerate freezing. The use of terms such as "ambient conditions" or "room temperature" is not acceptable.

(h) Composition

Only the active ingredient(s) need be stated.

The active ingredient(s) should appear in bold print. The quantity of pure active ingredient(s) shall be stated as g/kg or ml/litre.

(i) Contents, i.e. volume or quantity of product pack

The registered pack size(s) should appear on the main panel.

The applicant may decide where to place the pack size in the layout, however the pack size must appear below the composition, and be clearly legible.

The pack sizes shall correspond to those sizes detailed in the application form.

(j) Name and Address of Registration Holder (Applicant)

The name and address of the Registration Holder (Applicant) should be included without any preceding wording.

Space permitting, the Registration Holder may also provide other information such as the name of the manufacturer or distributor where this differs from that of the registration holder on the main panel, space permitting.

The Manufacturer's or Distributor's name should appear in a smaller print size than the Registration Holder below the Registration Holder's details.

5.1.2 Side Panel(s)

(a) Warning(s)

Warnings should appear at the top of the side panel.
All warnings should be **bulleted** (not numbered)

- Withdrawal periods. The withdrawal period(s) should be clearly indicated and should appear as the first warning statements.
- The following terminology must be used:

- Withdrawal period: Meat, eggs, milk: none or x days (according to data – MRL and ADI – withdrawal period determined/confirmed by DoH: Food Control)

- Meat: Not for use in animals intended for human consumption (e.g. horses, pigeons, fish)

- Eggs: Not for use in layers producing eggs for human consumption

- Milk: Not for use in animals (cattle, goats, sheep) producing milk for human consumption

- No withdrawal period (for products where there are no residue implications and no residue data is necessary i.e no MRL necessary such as vitamins)

- Symptoms of human poisoning, first aid treatment, and note to Veterinarian (compulsory for Groups 1a and 1b)

The following two standard statements should appear as the last two warnings:

- Keep out of reach of children, uninformed persons and animals.

- Although this remedy has been (extensively) tested (under a large variety of conditions), failure thereof may ensue as a result of a wide range of reasons. If this is suspected, seek veterinary advice; notify the registration holder and the Registrar. The words extensively and large variety of conditions must only be used for products that have been tested under those conditions.

The following standard warnings should be included for **vaccines:**

Warnings:

- **Withdrawal period for vaccines 21 days**
- Vaccinate healthy animals/chickens only
- Do not slaughter animals/ chickens for human consumption for at least 21 days after vaccination. Ensure that marketed animals do not have local reactions (swellings) at the site of vaccine administration, or elevated temperature reactions (fever) as this may result in the condemnation of the carcasses
- Do not mix this vaccine with any other vaccine or medication
- Do not use within 2 weeks of antimicrobial treatment.
- Do not store partially used containers for future use, and use the entire contents when opened (where applicable)
- Do not inject intravenously
- Vaccination of animals/chickens in production may lead to a slight decrease/drop in production (e.g. milk, eggs)
- Accidental self-injection could lead to a severe allergic reaction. Consult a physician and provide him/her with vaccine details

b) Precautions

Precautions appear underneath Warnings

All precautions should be **bulleted** (not numbered).

- Wear protective clothing, masks, gloves, boots, etc. according to hazard standards
- Avoid contact of the product with skin, eyes and mouth
- Do not eat, drink or smoke whilst handling the product
- Dispose of any containers, disposable equipment and any other waste after use in accordance with National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008)
- Do not store unused containers for future use
- Do not contaminate rivers, dams or any water sources with containers or waste

The following standard precautions should be included for **vaccines:**

- Observe aseptic precautions. Ensure that all vaccination equipment (containers, syringes and needles) are clean and sterile prior to and during use.
- Do not use disinfectants or antiseptics to sterilise any equipment or drinking water equipment.
- Use entire contents when container first opened and do not store unused containers for future use.
- Destroy any unused vaccine and dispose of all the vaccine containers and disposable equipment after use in accordance with National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008).
- Adhere to the vaccination programme to obtain optimum results.

Each statement should appear on a new line.

(b) Directions for Use

"Use only as directed" must be stated.

Where applicable, the directions for use should be specific to the species indicated.

Oxytetracycline preparations should include the statement "As with all oxytetracycline solutions, darkening may occur during use without affecting efficacy."

The following additional directions for use should be included for **vaccines:**

- For the vaccination of …….. (target species), age, etc. e.g. piglets, calves steers, replacement heifers, lambs, broilers, layers, replacement pullets, breeders, etc). Do not use the word fowls or poultry - they are too broad and not specific.
- Include any additional information, e.g. whether a primary vaccine with a live vaccine is recommended, etc. it may not be used in animals in full production, breeding or pregnant animals, etc.
- Allow the vaccine to gradually reach room temperature (20 – 25 °C) prior to use
- Shake well before use and at regular intervals during the vaccination process
- Remove the aluminium overseal just before the vaccine is ready for use
- Route of administration, e.g. subcutaneous, intramuscular, etc.
- Exact site of injection, e.g. breast muscle, thigh, etc. For intramuscular injection of breast muscle, the needle should be pointed in the direction of the head to prevent it entering the body cavity
- Ensure that all animals are vaccinated.
- Water treatment or spray – ensure clean potable non-chlorinated water is used. The water and equipment must have no traces of detergents or disinfectants

(d) Tables, if any, as in the case of efficacy tables for **anthelmintic products.**

(e) Lot number, Expiry Date and Date of Manufacturer as applicable.

The lot number, expiry date and date of manufacture should, where possible, appear at the bottom of the panel.

The lot number, expiry date and date of manufacture should be preceded by the words: “Lot No.”, “Expires” or “Exp.” and “Manuf” respectively.

5.1.3 Print size

The minimum permissible print size is 8 point and the print must be clearly legible.

5.1.4 Depictions/illustrations/pictures on labels may not exceed more than 20 % of the size of the panel on which they appear.

Where an applicant requires a larger picture on the label, a request for a larger picture size should be submitted to the Registrar. The application should be accompanied by the proposed label layout and the reasons for the request.

5.1.5 Pictures on labels should be in context with the remedy.

All picture(s), together with the subject matter thereof, should be indicated in the label application in order to ensure approval for their use on printed item(s).

5.2 STOCK REMEDIES CONTAINING 500 ml, 500 g OR LESS

5.2.1 It is permissible to apply for use of an abbreviated label for smaller containers (500 ml or 500 g and less); however, a package insert must be included with the packaging.

5.2.2 The following information is required on abbreviated labels / cartons containing 500 g, 500 mℓ or less:

a. For (external) animal use only
b. Name of remedy – identical to that appearing on the registration certificate
c. Registration Number, Reg. No. … (Act 36 of 1947)
d. Claim(s) for remedy
e. Toxicity indications according to poison classification – in red letters at least one half the size of the largest letter in the product name
f. Storage instructions
g. Composition – quantity of pure active ingredient(s) only
h. The statement, “For full particulars see enclosed package insert”
i. Name and address of Registration Holder
i. Batch Number, Expiry date and Manufactured date (at bottom of label)

5.3 LABELLING OF INTRAMAMMARY INFUSIONS

5.3.1 Syringe or Tube

The syringe or tube of an intramammary preparation should bear an abbreviated label or printing directly on the container. The text may differ according to the size of the syringe or tube. Any deviations must be approved by the Registrar of Act 36 of 1947.

5.3.2 Large Syringe or Tube (containing 10 ml, 10 g or more)

(a) Trade name of product
(b) Registration number (Act 36 of 1947)
(c) Pack size / contents (e.g. 10 g)
(d) Composition
(e) Name and address of Registration Holder
(f) The statement, “For full particulars, see enclosed package insert”

5.3.3 Small Syringe or Tube (containing less than 10 ml or 10 g)

(a) Trade name of product
(b) Registration number (Act 36 of 1947)
(c) Pack size / Contents (e.g. 5 g)
(d) The wording: “For full particulars, see enclosed package insert”

5.3.3.1 The intramammary syringe or tube may be packed as follows:

- In a printed carton
- In a printed opaque plastic envelope
- In a transparent plastic envelope (in which case there need be no printing thereon if the printed syringe or tube is clearly visible through the envelope)
- The syringe or tube need not be packed in one of the above if the package insert is firmly attached thereto
- The carton, opaque plastic envelope or transparent plastic envelope should be packed in an outer carton with a full label thereon.
- A package insert must be enclosed in each pack.

5.4 LABELLING OF VACCINES

(a) Restricted use in terms of the Veterinary and Para-Veterinary Professions Act

In the case of all small animal (dog and cat) vaccines, and other vaccines where appropriate, the following statement should appear at the top of the label below the “For Animal Use Only” statement:

“Only for use by or under the supervision of persons registered in terms of, or authorised in terms of, Section 23 (1) (c) of the Veterinary and Para-Veterinary Professions Act, 1982 (Act 19 of 1982)”

The statement shall also be used on other Stock Remedies if it can be substantiated that the product should be used by, or under the supervision of persons, registered in terms of, or authorised in terms of section 23 (1) (c) of the Veterinary and Para-Veterinary Professions Act, 1982 (Act 19 of 1982)

(b) Composition of vaccines

The composition of vaccine should include details on the contents of the vials, including the number of doses, strain, tissue culture origin, etc.

5.5 LABELLING ON STOCK REMEDIES USED FOR CONTROLLED DISEASES

The following statement should be included for all notifiable or controlled diseases that are controlled in terms of the Animal Diseases and Parasites Act, 1984 (Act 35 / 1984):

“Notifiable/ Controlled diseases – the State Veterinarian must be contacted”. Where appropriate, specific wording relating to the controlled disease may be required. Refer to the Animal Health Directorate within the Department of Agriculture.
As an example, the following wording must be used: Salmonella is a controlled disease in terms of to the Animal Diseases Act, Act 35/1984. Any occurrence or suspected occurrence of Salmonella must be reported immediately to the local state veterinarian.

Note Any other amendments, additions or waivers to the labelling requirements must be justified scientifically and an application for amendment to the label must be submitted for approval by the Registrar.

5.6 LABELLING OF ENDOPARASITICIDE AND ECTOPARASITICIDE PREPARATIONS

- Mention may only be made of specific identified local (RSA) parasite species on the labels and package inserts of endoparasiticide and ectoparasiticide preparations.
- The following wording shall appear on the label:

  "The list contains the parasite species tested. This remedy may also be effective against other species. For more information consult your veterinarian."

5.7 PACKAGE INSERTS

A package insert is only mandatory where an abbreviated label is used or where the full label is not used on the immediate container.
The package insert shall contain all the information as for a full label referred to in 1 (Main and side panels), in the following format:

(a) For (external) animal use only
(b) Trade name
(c) Registration number (Act 36/1947)
(d) Indications
(e) Toxicity statement
(f) Storage instructions
(g) Composition
(h) Warnings
(i) Precautions
(j) Directions for Use, including words "Use only as directed"
(k) Efficacy
(l) Presentation
(m) Name and Address of the Registration Holder

The Toxicity Statement relative to the Poison Classification does need not to appear in red in the package insert.

5.8 CARTONS

A full label information carton is only required in cases where the use of an abbreviated label is approved (Refer (6.2.2)).

5.9 UNIT SALES PACKING AND/OR DISPLAY CARTONS

These shall:

(a) Have an abbreviated label affixed to the outside as required in 6.2.2
(b) Be properly sealed
(c) Have at least one package insert enclosed in the carton
(d) Have the following wording printed in large bold print on the main panel(s) and flap where it is to be opened:

"This carton shall be sold as a unit. Do not break seal or open before sale"

6. OXPECKER CLAIMS

May only claim if scientific data has been submitted with an expert report (by a local expert in either field but not with vested interests in the company) submitted with the data.

May only claim oxpecker compatible.

Logos for oxpecker claims must be approved by the Registrar

1. ANNEXURES

6.1 Annexure 1:

EXAMPLE OF A FULL LABEL (For contents of more than 500 ml or 500 g)

MAIN PANEL

For (external) animal use only

TRADE NAME OF PRODUCT

(Identical to that given in the registration certificate)

Reg. No. G…..(Act 36/1947)

Claim/s for product

HAZARD WARNING STATEMENT

(In red print, in accordance with Poison Classification, Groups I – IV. See Annexure 1)

STORAGE

E.g. Store in a refrigerator between 2 - 8 °C

COMPOSITION

Contains (pure content of active ingredient/s), given in g/kg or ml/ℓ)

(In bold print)

Nett Mass or Volume e.g. 5 g

Name and address of Registration Holder

(No preceding words)

SIDE PANELS

1. Warning/s
2. Precaution/s
3. Directions for Use, including words “Use only as directed”
4. Table/s

   (In the case of application for anthelmintics, a separate efficacy table shall be attached to the application).
5. Batch No.: (Preferably at bottom of label)
6. Expiry date: (Preferably at bottom of label)
7. Date of manufacture: (Preferably at bottom of label) or abbreviated to :

   Lot No: Lot No:

   Exp. Manuf.

6.2 Annexure 2:

EXAMPLE: ABBREVIATED LABEL

(1 ℓ or 1 kg and smaller where a full outer carton is included)

For (external) animal use only

TRADE NAME OF PRODUCT

(Identical to that given in registration certificate.)

Reg. No. G….. (Act 36/1947)

Claim/s for product

(This/there must concur exactly with the registration certificate)

HAZARD WARNING STATEMENT

(In red, in accordance with poison classification, Groups I – IV. See Annexure 1)

STORAGE

E.g. Store in a cool, dry place below 25 °C/30°C

COMPOSITION

Contains (pure content of active principle (-s), given in g/kg or ml/l)

(In bold print)

Nett Mass or Volume e.g. 5 g

Name and address of Registration Holder

For full particulars see enclosed package insert

Batch No.

Expiry date

Date of Manufacture

Name and address of Registration Holder/Applicant

6.3 Annexure 3:

EXAMPLE: ABBREVIATED CARTON

(1 ℓ or 1 kg and smaller and cartons)

For (external) animal use only

NAME OF PRODUCT

(Identical to that given in registration certificate.)

Reg. No. G….. (Act 36/1947)

Claim/s for product

(This/there must concur exactly with the registration certificate)

HAZARD WARNING STATEMENT

(In red, in accordance with poison classification, Groups I – IV. See Annexure 1)

STORAGE

E.g. Store in a cool, dry place below 25 °C/30°C

COMPOSITION

Contains (pure content of active principle (-s), given in g/kg or ml/ℓ)

(In bold print)

Nett Mass or Volume eg. 00 g

Name and address of Registration Holder

For full particulars see enclosed package insert

Batch No.

Expiry date

Date of Manufacture

Name and address of Registration Holder/Applicant

7. REFERENCES

Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947)

Part II - Section 10 of the Regulations Regarding Stock Remedies. Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act 1947 (Act 36 of 1947 as amended). Department of Agriculture. 2006

Annexure D from the Document above: Labelling Requirements for the Registration of Stock Remedies under Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act 1947 (Act 36 of 1947 as amended). No date given.

Medicine and Related Substances Act 1965 (Act 101 of 1965 as amended). Section 18: Labelling and Advertisements

Regulations to the Medicines and Related Substances Act 1965 (Act 101 of 1965 as amended): Reg. 8.3

National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008).