

FERTILIZERS, FARM FEEDS AND REMEDIES (REMEDIES) REGULATIONS

ARRANGEMENT OF REGULATIONS

REGULATION

1. Citation
2. Interpretation
3. Application for registration
4. Registration
5. Import of experimental remedy
6. Approval of brands
7. Labelling of containers
8. Containers
9. Safety during use

10. Sampling, inspection and analysis
11. Prohibition
12. Savings
13. Offences and penalties

First Schedule

Second Schedule

Third Schedule

Fourth Schedule

Fifth Schedule

Sixth Schedule

Seventh Schedule

G.N. 94/1989

FERTILIZERS, FARM FEEDS AND REMEDIES (REMEDIES) REGULATIONS

under s. 16

1. Citation

These Regulations may be cited as the Fertilizer, Farm Feeds and Remedies (Remedies) Regulations.

2. Interpretation

In these Regulations—

“active ingredient” means the substance in a remedy which—

(a) prevents the establishment of, controls or destroys undesirable plants, insects or animals, or which prevents or cures a disease, infection or infestation or other unhealthy condition of a plant or a product derived therefrom; or

(b) stimulates or retards the rate of plant growth;

“common name” means the name assigned to the pesticide active ingredient as being internationally recognized as the common or generic name of the active ingredient;

“experimental remedy” means a chemical to be assessed in Malawi for primary biological activity, and not available to the public as a remedy;

“label” means the written, or graphic matter on, or attached to, a pesticide or the immediate container thereof and the outside container or wrapper of the package of the pesticide;

“pest” means any form of plant or animal life or any pathogenic agent which is injurious or potentially injurious to plants or plant products;

“pesticide” means any substance or mixture of substances intended for preventing, destroying or controlling any pest including unwanted species of plants during the production, processing, storage, transport or marketing of food and agricultural commodities, and includes substances intended for use as a plant growth regulator, defoliant, desiccant or fruit and substances applied to crops either before or shortly after harvest to protect the commodity from deteriorating during storage, but does not include fertilizers or other plant nutrients and agents such as veterinary medicines and feed additives;

“recognized research institution” means a research institution recognized by the Minister as competent to carry out research into remedy use;

“register” means a book where all remedies are recorded as an indication that their use in Malawi is authorized;

“season” means a period in which the plant is to be protected by the remedy under conditions in which the plant is normally grown;

“similar environment” means an environment that closely resembles the environment in which the pesticide will be used;

“trade name” means the name under which the pesticide is sold;

3. Application for registration

(1) Every application for registration of a remedy shall be submitted, in triplicate, to the registering officer on Form P.R. 1, set out in the First Schedule.

(2) Every application shall be accompanied with—

(a) three copies of the draft of the label which is intended for use on the container in which the remedy is to be sold; and

(b) any advertisement which is intended for immediate use in respect of such remedy if registration is successful; and

(c) two samples of the remedy, in an amount to be determined by the registering officer;
and

(d) a registration fee of K150.

(3) The registering officer shall consider an application in respect of a remedy manufactured outside Malawi only if the application is submitted through a representative who is registered with the Ministry of Trade, Industry and Tourism and is licensed as an importer of remedies in Malawi.

(4) No application for registration shall be considered by the registering officer unless such application—

(a) complies with the Malawi Standards in current use, the specification against which the remedy is manufactured or any internationally recognized specification for that remedy formulation;

(b) complies with the requirements of these Regulations and any such requirements that may, from time to time, be prescribed; and

(c) contains adequate experimental data and information collected in Malawi or similar environment on the efficacy of the pesticide, its toxicity, persistence, intended use and such further information as may be required to determine whether the remedy is suitable for the purpose for which it is intended and to determine whether the use of the pesticide will be beneficial to the user and the country as a whole.

(5) The proprietary rights in the data and information referred to in subregulation 3 (4) (c) shall be duly protected.

4. Registration

(1) The registering officer shall, when registering a remedy—

(a) issue a certificate of registration; and

(b) forward the certificate to the applicant.

(2) Registration shall not be complete unless a copy of the approved label or a facsimile thereof is received by the registering officer.

(3) A registration certificate issued under this regulation shall apply only to the remedy formulation to which the certificate relates.

(4) A remedy registered under this regulation shall not be altered in any way so as to change its formulation, composition or usage or in any other manner unless the registering officer so approves.

(5) Before the registering officer registers any remedy, he shall ensure that such a remedy has not been banned elsewhere, and that is registered in the country of origin.

5. Import of experimental remedy

(1) No person, except an approved research institution, shall import into Malawi any experimental remedy unless he is authorized in writing on Form P.R. 3 set out in the Third Schedule, by the registering officer to do so. No details of the remedy need be given at this stage except name, active ingredient, toxicity, approximate quantity and intended use.

(2) Any person who imports an experimental remedy shall, not later than seven days after the arrival of the remedy in Malawi, complete in triplicate, and forward to the registering officer Form P.R. 4 set out in the Fourth Schedule, except that where an experimental remedy is imported by an approved research institution, such an institution shall, at the discretion of the registering officer, only be required to supply the registering officer with the name or designation and intended experimentation of the experimental remedy using Form P.R. 6 set out in the Sixth Schedule.

(3) No experimental remedy shall be offered to any person other than a person approved by the registering officer to participate in the experimentation.

(4) In granting permission to import an experimental remedy under this regulation the registering officer shall issue a certificate in Form P.R. 5 set out in the Fifth Schedule within fourteen days after receipt of Form P.R. 4 and the registering officer may impose such conditions as may be necessary with regard to the experimentation with the remedy.

(5) It shall be a condition for the importation of experimental remedy that plants or products thereof treated with the experimental remedy shall not be sold or disposed of or consumed without the written authority of the registering officer.

(6) The experimental period shall be for a minimum of three seasons except where satisfactory proof is supplied that the remedy has been similarly tested and registered or approved in a similar environment, the Minister may reduce the period to one season.

(7) The label affixed to a container in which a remedy is imported for purposes other than sale shall be clearly marked with the words "FOR EXPERIMENTAL PURPOSES ONLY—NOT FOR SALE".

(8) A remedy imported into Malawi for re-export within a period of fourteen days while remaining in unopened original containers shall be subject to subregulation (1) and shall be exported within the said fourteen days and where repackaging will be done before re-export, such remedy shall be subject to subregulations (1), (2), (3) and (4), and shall be exported within a reasonable time as agreed upon with the registering officer.

6. Approval of brands

(1) Subject to subregulation (2) the registering officer shall, before registering any brand, receive confirmation from the Registrar of Trade Marks, and satisfy himself that the name of the brand does not resemble the name of any other brand.

(2) A remedy shall not be registered under a brand if in the opinion of the registering officer the brand is—

- (a) of an insufficiently distinctive nature; or
- (b) so similar to a brand under which a remedy had already been registered as to be liable to be mistaken for the other brand; or
- (c) of a quantity not complying with the specifications indicated on the label as specified in regulation 7 and such information shall be shown on certificate of analysis issued by the Malawi Bureau of Standards or any other institution recognized by the Minister; or
- (d) misleading in any other way.

7. Labelling of containers

(1) No person shall sell any remedy unless the label is securely affixed to the container and it is in the English language or, where the registering officer considers it appropriate, in the Chichewa language as well.

(2) The label, which shall be verbally and graphically identical in all respects to that approved by the registering officer under these regulations shall state—

- (a) the name and address of the applicant;
- (b) the company brand or symbol;
- (c) the brand of the remedy;
- (d) the registration number under which the remedy is registered, and the identity of each lot or batch of the product in numbers or letters that can be read, transcribed and communicated by anyone without the need for codes or other means of deciphering;
- (e) the net quantity by weight or volume in the container;
- (f) the common and trade names, and the percentage of active ingredient provided that such percentages and quantities of active and inert matter shall be verified by the Malawi Bureau of Standards or any other institution recognized by the Minister;
- (g) the purpose for which the remedy has been registered;
- (h) the directions for use of the remedy, the target pest, target crop, dosage, timing of treatment, safety period and any other similar information required by the registering officer;
- (i) the precautionary measures to be observed in handling and using the remedy;
- (j) the appropriate warning with regard to the poisonous nature of the remedy specified in this regulation;

- (k) the symptoms of poisoning;
- (l) the remedial treatment in the case of poisoning where applicable;
- (m) the date of manufacture and shelf life of the pesticide;
- (n) a warning against the re-use of containers and instructions for the safe disposal or decontamination of empty containers; and
- (o) any other information which the registering officer may approve or consider to be necessary.

(3) Remedies which are transported to premises where they are further to be processed or packed for the retail trade shall be clearly marked with the particulars specified under this regulation.

(4) A symbol shall be printed on, or securely affixed to, the label in a colour approved by the registering officer and such symbol shall occupy an area of not less than one-twentieth of the area of the label.

(5) The symbol of approved colour shall be located on the label in a position equi-distant from the two vertical sides and be delineated from the rest of the label by a black border to emphasize the approved colour.

(6) The symbol of approved colour shall be—

- (a) a triangle to denote marketing for agricultural use; and
- (b) a circle to denote marketing for stored products use.

(7) A symbol specified in subregulation (6) may be superimposed where the uses and marketing thereof are found to be the same or where the remedy is used for both purposes.

(8) The colour coding of the symbols and warning shall be as specified in the Seventh Schedule.

(9) Within the symbol of approved colour, there shall be printed such information in the English language or, where the registering officer considers it appropriate, in the Chichewa language as well as the registering officer thinks necessary to denote toxicity or hazardous nature.

(10) Within the symbol of approved colour there shall be printed, the words “skull and cross-bones”.

(11) Except with the permission of the registering officer, no label shall contain any information other than that provided for in this regulation.

(12) No label, approved by the registering officer, shall be altered without the written approval of the registering officer.

8. Containers

(1) No remedy shall be sold, transported or stored unless the registering officer is satisfied that the container in which the remedy is to be packed is of sufficiently durable construction and material.

(2) A container which contains any combustible substance shall be of suitable material.

(3) Remedies which contain inflammable or volatile ingredients shall be packed in durable containers.

(4) No remedy shall be packed in a container that resembles a container of a consumable product.

9. Safety during use

Any user of a remedy shall, when using such a remedy, be required to take appropriate safety precautions and to facilitate in these precautions being taken—

(a) every label shall bear warning or precautionary statements advising the user on how to handle, use and apply the product with safety;

(b) in the case of very toxic remedies bearing a “red label”—

(i) persons selling such category of remedy to the public shall also stock appropriate safety clothing and equipment such as face masks and gloves;

(ii) all persons who use such remedy shall ensure that they wear appropriate protective clothes and apparatus when handling and using the remedy;

(iii) all persons who buy such remedies shall ensure that if they employ other people to handle and apply the remedy and they shall cause such employees to wear appropriate protective clothes and apparatus;

(iv) a person who sells remedies shall have a register in which he shall enter all the details of his transactions such as names of buyers and quantity of the remedy sold; and such a register shall be made available to the registering officer or his nominee on demand for inspection.

10. Sampling inspection and analysis

(1) An inspector or any other officer charged with the collection of a remedy for the purposes of these Regulations shall collect a sample determined by an approved research institution.

(2) A sample of a remedy shall be analysed following methods prescribed from time to time by the Malawi Bureau of Standards or any other institution recognized by the Minister.

(3) A remedy shall be deemed to have complied with the provisions of these Regulations if, upon analysis, the composition is found to be in conformity with the declared percentages and quantities of ingredients referred to in regulation 7 (2) (f).

(4) The applicant may request an inspector or any authorized officer to collect samples from containers using approved sampling procedures and send such samples to the Malawi Bureau of Standards or any other institution recognized by the Minister for analysis.

(5) Sampling, inspection and analysis shall be conducted as need arises.

11. Prohibition

The Minister may, by General Notice in the Gazette, restrict or prohibit the use of a remedy specified in such notice and such restriction or prohibition may be either general or specific.

12. Savings

Upon the commencement of these Regulations—

(a) a remedy the registration of which was recommended upon the basis of whose recommendation was research work carried out in Malawi or similar environment prior to the commencement of these Regulations shall be automatically registered;

(b) any remedy for which there is insufficient data to support registration thereof, shall be treated as experimental remedy;

(c) where there is no data available concerning a remedy, no additional importations shall be permitted except as provided for in regulation 5.

13. Offences and penalties

Any person who fails to comply with the provisions of these Regulations shall be guilty of an offence and shall be liable to a fine of K200 or to imprisonment for a term of 6 months.

FIRST SCHEDULE

FORM P.R. 1

FERTILIZERS, FARM FEEDS AND REMEDIES ACT

(CAP. 67:04)

FERTILIZERS, FARM FEEDS AND REMEDIES (REMEDIES) REGULATIONS

APPLICATION FOR REGISTRATION OF A REMEDY

(UNDER REGULATION 3)

A. To be submitted to the registering officer, in triplicate.

1. Name of applicant:

2. Address of applicant:

(a) Postal:

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(b) Business:

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3. Type of remedy (fungicide, insecticide, etc.):

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B. Information to be submitted with this application for all remedies for which registration is sought.

1. Brand name:

2. Full chemical name of each ingredient:

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3. Common name of each active ingredient:

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4. The empirical and structural formulae for each active ingredient:
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5. Proposed formulation:

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6. Percentage of purity on a mass-by-mass or mass-by-volume basis (specify), of each active ingredient and other ingredients (including inert matter) in the remedy stating which method or percentage applies to each ingredient:

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7. Physical and chemical properties of each ingredient with specific reference to type of formation:

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8. Size of containers in which remedy is to be sold, and nett-weight:

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9. Nature of containers in which remedy is to be sold:

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10. Stability of formulation—

(a) on storage:

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(b) on dilution:

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(c) shelf life from date of manufacture:

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11. Corrossiveness of equipment:

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12. Phytotoxicity:

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13. Toxicology:

14. Safety precautions to be observed in handling, use and storage:.....

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15. Hazard to wild life:

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16. Residue data:

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17. Proposed use:

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18. Directions for use:

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19. Biological effectiveness and benefit in use:

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I hereby apply for the registration, under the Fertilizers, Farm Feeds and Remedies (Remedies) Regulations, 1989, of the remedy of which particulars are given above, and I certify that these particulars are to the best of my knowledge, true and correct.

Date:Signature of applicant and

Official Stamp

NOTE: The detailed information required under these regulations or any other information that the registering officer requires must accompany the application. Any claims made for biological effectiveness and statements made respecting residues, etc., must be supported by detailed relevant experimental data.

SECOND SCHEDULE

FORM P.R. 2

FERTILIZERS, FARM FEEDS AND REMEDIES ACT

(CAP. 67:04)

FERTILIZERS, FARM FEEDS AND REMEDIES (REMEDIES) REGULATIONS

CERTIFICATE OF REGISTRATION OF A REMEDY

(UNDER REGULATION 3)

Number:

It is hereby—

- (a) certified that the remedy referred to in Form P.R. 1 has been registered; and
- (b) approval has been granted of the labels and advertisements copies of which are attached hereto, and which are to be used in connexion with the said remedy.

This registration expires on and is subject to the following conditions:

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Date and Official Stamp

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Registering Officer

THIRD SCHEDULE

FORM P.R. 3

FERTILIZERS, FARM FEEDS AND REMEDIES ACT

(CAP. 67:04)

FERTILIZERS, FARM FEEDS AND REMEDIES (REMEDIES) REGULATIONS

APPLICATION FOR IMPORTATION OF A REMEDY TO BE USED ONLY FOR EXPERIMENTATION

(UNDER REGULATION 5)

To be submitted to the registering officer, in triplicate.

1. Name of applicant:

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2. Address of applicant—

(a) Postal:

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(b) Business:

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3. Type of remedy (fungicide, insecticide, etc.):

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4. Active ingredient:

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5. (a) Oral LD 50

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(b) Dermal LD 50

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6. Brand name:

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7. Common name:

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8. Approximate quantity:

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9. Intended use:

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10. Name of manufacturer:

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11. Address of manufacturer:

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12. Proposed use:

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I hereby apply for importing, under the Fertilizers, Farm Feeds and Remedies (Remedies) Regulations, 1989, the remedy for experimental purposes particulars of which are given above.

Date:

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Signature of Applicant and

Official Stamp

For Official use only—

Date application received:

Experimental Registration Number:

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Your application to import

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..... has not been/been approved.

Reasons for non-approval

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FOURTH SCHEDULE

FORM P.R. 4

FERTILIZERS, FARM FEEDS AND REMEDIES ACT

(CAP. 67:04)

FERTILIZERS, FARM FEEDS AND REMEDIES (REMEDIES) REGULATIONS

APPLICATION FOR REGISTRATION OF A REMEDY TO BE USED ONLY FOR EXPERIMENTATION

(UNDER REGULATION 5)

Information to be submitted, in triplicate, to the registering officer in respect of experimental remedy.

1. Name of applicant:

2. Address of applicant—

(a) Postal:

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(b) Business:

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3. Name, code or number of remedy:

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4. Type of remedy (fungicide, insecticide, etc.):

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5. Chemical group:

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6. Toxicological data, if available—

(a) humans and animals: LD 50 oral (state type of animal), LD 50 dermal, LD 50 inhalation:

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(b) symptoms of poisoning:

(c) first aid:

7. Weight or volume of remedy imported:

8. Suggested use:

9. Location of trials:

10. Plot size to be agreed:

11. Person conducting the trials:

Date:

.....

Signature of applicant and

Official Stamp

FIFTH SCHEDULE

FORM P.R. 5

FERTILIZERS, FARM FEEDS AND REMEDIES ACT

(CAP. 67:04)

FERTILIZERS, FARM FEEDS AND REMEDIES (REMEDIES) REGULATIONS

CERTIFICATE OF REGISTRATION OF A REMEDY TO BE USED ONLY FOR EXPERIMENTATION

(UNDER REGULATION 5)

Number:

I hereby certify that the remedy has been registered for
experimental purposes.

The registration number is:

The registration expires on: and is

subject to the following conditions:

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Date:

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Registering Officer and Official Stamp

SIXTH SCHEDULE

FORM P.R. 6

FERTILIZERS, FARM FEEDS AND REMEDIES ACT

(CAP. 67:04)

FERTILIZERS, FARM FEEDS AND REMEDIES (REMEDIES) REGULATIONS

FORM NOTIFICATION BY A RECOGNIZED RESEARCH INSTITUTE TO THE REGISTERING OFFICER FOR
POSSESSION OF A REMEDY UNDER TEST

(UNDER REGULATION 5)

To be submitted to the registering officer, in triplicate.

1. Name of the research institute:

2. Address of the research institute—

(a) Postal:

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(b) Business:

.....

3. Type of remedy (fungicide, insecticide, etc.):

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4. Registration number:

5. Brand name:

6. Common name:

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7. Approximate quantity:

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8. Proposed use:

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Date:

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Signature of Scientist and Official Stamp

SEVENTH SCHEDULE (reg. 7 (8))

Pesticide toxicitySymbol colour codeWarningAcute oral LD 50 up to mg/kgRedVery dangerous
poisonAcute dermal LD 50 up to 200 mg/kgRedVery dangerous poisonAcute inhalation LC 50 up to 200

mg/m³RedVery dangerous poisonAcute oral LD 50 51–500 mg/kgPurpleDangerous poisonAcute dermal
LD 50 201–2,000 mg/kgPurpleDangerous poisonAcute inhalation LD 50 201–2,000
mg/m³PurpleDangerous poisonAcute oral LD 50 501–5,000 mg/kgAmberPoisonAcute dermal LD 50
2,001–20,000 mg/kgAmberPoisonAcute inhalation LC 50 2,001–20,000 mg/m³AmberPoisonAcute oral
LD 50 greater than 5,000 mg/kgGreenHarmful if swallowedAcute dermal LD 50 greater than 20,000
mg/kgGreenHarmfulAcute inhalation LC 50 greater than 20,000 mg/m³GreenHarmful