

SOLUDOX 50%

Material Safety Data Sheet (Conforms to Reg. (EC) No 1907/2006, Reg. (EC) No 1272/2008 and their amendments.

Issue Date: 6-Mar-2008

Version No: 2.0

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

Soludox 50%

SUPPLIER

Company: Eurovet Animal Health B.V.
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PRODUCT USE

- Used according to manufacturer's directions.

Section 2 - HAZARDS IDENTIFICATION

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A DANGEROUS MIXTURE ACCORDING TO DIRECTIVE 1999/45/EC AND ITS AMENDMENTS.

RISK

DSD/DPD classification (classification according to Directive 67/548/EEC or Directive 1999/45/EC)

R22 Harmful if swallowed.

R36/37/38 Irritating to eyes, respiratory system and skin.

CLP classification (classification according to Regulation (EC) No 1272/2008)



Signal Word: DANGER

CLP classification

Acute Toxicity (Oral) Category 4

Skin Corrosion/Irritation Category 2

Eye Irritation Category 2A

Skin Sensitizer Category 1

Reproductive Toxicity Category 1B Lactation Effects

STOT - SE (Resp. irr.) Category 3

Hazard statement(s)

H302 Harmful if swallowed

H315 Causes skin irritation

H319	Causes serious eye irritation
H317	May cause allergic skin reaction
H360	May damage fertility or the unborn child
H362	May cause harm to breast-fed children
H335	May cause respiratory irritation

Supplementary statement(s)

Precautionary statement(s)

Prevention

P201	Obtain special instructions before use
P202	Do not handle until all safety precautions have been read and understood
P260	Do not breathe dust/fume/gas/mist/vapours/spray
P261	Avoid breathing dust/fume/gas/mist/vapours/spray
P263	Avoid contact during pregnancy/while nursing
P264	Wash thoroughly after handling
P270	Do not eat, drink or smoke when using this product
P271	Use only outdoors or in a well- ventilated area
P272	Contaminated work clothing should not be allowed out of the workplace
P280	Wear protective gloves/protective clothing/eye protection/face protection
P281	Use personal protective equipment as required

Response

P301+P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P302+P352	IF ON SKIN: Wash with plenty of soap and water
P304+P340	IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing
P305+P351+ P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P308+P313	IF exposed or concerned: Get medical advice/ attention
P312	Call a POISON CENTER or doctor/physician if you feel unwell
P330	Rinse mouth
P333+P313	If skin irritation or rash occurs: Get medical advice/attention
P337+P313	If eye irritation persists: Get medical advice/attention
P363	Wash contaminated clothing before reuse

Storage

P403+P233	Store in a well- ventilated place. Keep container tightly closed
P405	Store locked up

Disposal

P501	Dispose of contents/container to ...
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Other hazards

R21?	Skin contact may produce health damage*
R33?	Cumulative effects may result following exposure*
R43?	Possible skin sensitizer*
R61?	May be harmful to the fetus/embryo*
R64?	Possible risk of harm to breastfed babies*

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	INT HAZ
doxycycline hyclate	10592-13-9	Xn
EC NO: 234-198-7		

R CODES: R22, R36/37/38

COMPOSITION:

Contains per gram: 500 mg doxycycline hyclate

Section 4 - FIRST AID MEASURES

SWALLOWED

- IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY.
- For advice, contact a Poisons Information Centre or a doctor.
- Urgent hospital treatment is likely to be needed.
- In the meantime, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition.

EYE

- If this product comes in contact with the eyes:
 - Wash out immediately with fresh running water.
 - Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
 - Seek medical attention without delay; if pain persists or recurs seek medical attention.
 - Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

SKIN

- If skin contact occurs:
 - Immediately remove all contaminated clothing, including footwear.
 - Flush skin and hair with running water (and soap if available).
 - Seek medical attention in event of irritation.

INHALED

- If fumes aerosols or combustion products are inhaled remove from contaminated area.
- Other measures are usually unnecessary.

NOTES TO PHYSICIAN

- Treat symptomatically.

Section 5 - FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

- There is no restriction on the type of extinguisher which may be used.
- Use extinguishing media suitable for surrounding area.

FIRE FIGHTING

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves for fire only.
- Prevent, by any means available, spillage from entering drains or water courses.
- Use fire fighting procedures suitable for surrounding area.

FIRE/EXPLOSION HAZARD

- Solid which exhibits difficult combustion or is difficult to ignite.
- Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion.
- Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited; once initiated larger particles up to 1400 microns diameter will contribute to the propagation of an explosion.

- A dust explosion may release of large quantities of gaseous products; this in turn creates a subsequent pressure rise of explosive force capable of damaging plant and buildings and injuring people.

Combustion products include: carbon monoxide (CO), carbon dioxide (CO₂), hydrogen chloride, phosgene, nitrogen oxides (NO_x), other pyrolysis products typical of burning organic material. May emit poisonous fumes.

FIRE INCOMPATIBILITY

- Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result.

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

- Clean up waste regularly and abnormal spills immediately.
- Avoid breathing dust and contact with skin and eyes.
- Wear protective clothing, gloves, safety glasses and dust respirator.
- Use dry clean up procedures and avoid generating dust.

MAJOR SPILLS

- Moderate hazard.
 - CAUTION: Advise personnel in area.
 - Alert Emergency Services and tell them location and nature of hazard.
 - Control personal contact by wearing protective clothing.
 - Prevent, by any means available, spillage from entering drains or water courses.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.

Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.

- Do NOT cut, drill, grind or weld such containers.
- In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.
- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.

Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source

- Do NOT cut, drill, grind or weld such containers
- In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorization or permit.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

- doxycycline hyclate: CAS:10592-13-9 CAS:24390-14-5

DOXYCYCLINE HYCLATE:

■ It is the goal of the ACGIH (and other Agencies) to recommend TLVs (or their equivalent) for all substances for which there is evidence of health effects at airborne concentrations encountered in the workplace.

At this time no TLV has been established, even though this material may produce adverse health effects (as evidenced in animal experiments or clinical experience).

PERSONAL PROTECTION

RESPIRATOR

Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

EYE

■ When handling very small quantities of the material eye protection may not be required.

For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:

- Chemical goggles
- Face shield. Full face shield may be required for supplementary but never for primary protection of eyes
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly.

HANDS/FEET

■ Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:

- frequency and duration of contact,
- chemical resistance of glove material,
- glove thickness and
- dexterity
- Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
- Double gloving should be considered.
- PVC gloves.
- Protective shoe covers.
- Head covering.

Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.

- polychloroprene
- nitrile rubber
- butyl rubber
- fluorocautchouc

OTHER

- For quantities up to 500 grams a laboratory coat may be suitable.
- For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
- For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
- For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.

ENGINEERING CONTROLS

- Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation.

HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours. Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.

When handling quantities up to 500 gram in either a standard laboratory with general dilution ventilation.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Mixes with water.

State	Divided solid
Solubility in water (g/L)	Miscible

APPEARANCE

Powder; soluble in water.

Section 10 - CHEMICAL STABILITY AND REACTIVITY INFORMATION

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerisation will not occur.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

- Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.
 - Tetracyclines produce nausea, abdominal pain and burning, vomiting, transitory yellowish-brown discoloration of the tongue, loss of appetite, and diarrhea.
- Large oral doses may produce liver and kidney damage.

EYE

- Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterized by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result.

SKIN

- Entry into the blood-stream, though, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects.
- Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.
- Tetracyclines can cause yellow discoloration of the skin.
- Adverse effects can occur whether the drug is given orally or injected.

INHALED

■ The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

■ Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled. If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.

CHRONIC HEALTH EFFECTS

■ There is limited evidence that, skin contact with this product is more likely to cause a sensitization reaction in some persons compared to the general population. Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung. Prime symptom is breathlessness; lung shadows show on X-ray. Repeated or prolonged exposures to tetracyclines can cause sore throat, hoarseness, a black hairy tongue, bulky loose stools, fat in the faeces, inflammation of the mouth cavity, difficulty swallowing, damage to the anogenital area and ulcers of the oesophagus. Deposits in the eye may cause abnormal pigmentation of the conjunctivae. Tetracyclines can interfere with vitamin K function and impair blood clotting. They are deposited in the bones. If pregnant women take them, they can interfere with bone growth of the fetus. Hypersensitivity reactions include burning of the eyes, conjunctivitis, spotty and red rashes, dermatitis with sloughing, hives, itching, swollen cracked lips, an inflamed tongue, fever, asthma, fatty liver, blockage of bile, loss of platelets, neutrophils, white blood cells or all blood cells, swelling due to blood vessels and nerves, inflammation of the membranous sac surrounding the heart, exacerbation of lupus, anaphylactic shock and skin rash due to capillary bleeds. Other signs and symptoms include lung infiltrates, diabetes, temporary muscle disorders, blood poisoning, psychotic reactions and fatal liver damage. Sensitivity to light aggravated by sunlight may occur. Loosening and pigmentation of the nails may occur at the same time. Increased pressure in the head can cause swelling of the optic nerve, headache, vision impairment, and bleeding from the retina, especially in children. Pregnant women seem to be most susceptible to liver damage caused by tetracyclines. Jaundice followed by uraemia, acidosis and irreversible shock is usual. Tetracyclines are secreted in the breast milk and readily cross the placenta to affect the fetus. The fetus will show retardation of skeletal development and underdevelopment of the enamel of the teeth. Long-term use of oxytetracyclines often results in kidney damage and failure, with increased urinary output, extreme thirst, protein in the urine, acidosis, sugar and excess amino acids in the urine.

TOXICITY AND IRRITATION

■ Not available. Refer to individual constituents.

Section 12 - ECOLOGICAL INFORMATION

No data.

Ecotoxicity

Ingredient	Persistence: Water / Soil	Persistence: Air	Bioaccumulation	Mobility
Doxycycline hyclate	No data available	No data available	LOW	

Section 13 - DISPOSAL CONSIDERATIONS

- Recycle wherever possible.
- Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.

- Dispose of by: burial in a land-fill specifically licenced to accept chemical and / or pharmaceutical wastes or Incineration in a licenced apparatus (after admixture with suitable combustible material)
- Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

■ According to the European Waste Catalogue, Waste Codes are not product specific but application specific. Waste Codes should be assigned by the User based on the application in which the product is used.

Section 14 - TRANSPORTATION INFORMATION

HAZCHEM:

None

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: ADR, IATA, IMDG

Section 15 - REGULATORY INFORMATION



RISK

Risk Codes	Risk Phrases
R22	■ Harmful if swallowed.
R36/37/38	■ Irritating to eyes, respiratory system and skin.
R21?	■ Skin contact may produce health damage*.
R33?	■ Cumulative effects may result following exposure*.
R43?	■ Possible skin sensitiser*.
R61?	■ May be harmful to the fetus/embryo*.
R64?	■ Possible risk of harm to breastfed babies*.

SAFETY

Safety Codes	Safety Phrases
S22	■ Do not breathe dust.
S24	■ Avoid contact with skin.
S25	■ Avoid contact with eyes.
S36	■ Wear suitable protective clothing.
S37	■ Wear suitable gloves.
S39	■ Wear eye/ face protection.
S53	■ Avoid exposure - obtain special instructions before use.
S40	■ To clean the floor and all objects contaminated by this material, use water.
S13	■ Keep away from food, drink and animal feeding stuffs.
S26	■ In case of contact with eyes, rinse with plenty of water and contact Doctor or Poisons Information Centre.
S46	■ If swallowed, IMMEDIATELY contact Doctor or Poisons Information Centre (show this container or label).

Annex II of Directive 67/548/EEC: Indications of Danger

Xn Harmful

Annex VI of Regulation (EC) No 1272/2008



H302	Harmful if swallowed
H317	May cause allergic skin reaction
H360	May damage fertility or the unborn child
H362	May cause harm to breast-fed children
H335	May cause respiratory irritation
H315	Causes skin irritation
H319	Causes serious eye irritation

Supplementary statement(s)

Precautionary statement(s)

Prevention

P201	Obtain special instructions before use
P202	Do not handle until all safety precautions have been read and understood
P260	Do not breathe dust/fume/gas/mist/vapours/spray
P261	Avoid breathing dust/fume/gas/mist/vapours/spray
P263	Avoid contact during pregnancy/while nursing
P264	Wash thoroughly after handling
P270	Do not eat, drink or smoke when using this product
P271	Use only outdoors or in a well- ventilated area
P272	Contaminated work clothing should not be allowed out of the workplace
P280	Wear protective gloves/protective clothing/eye protection/face protection
P281	Use personal protective equipment as required

Response

P301+P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P302+P352	IF ON SKIN: Wash with plenty of soap and water
P304+P340	IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing
P305+P351+ P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P308+P313	IF exposed or concerned: Get medical advice/ attention
P312	Call a POISON CENTER or doctor/physician if you feel unwell
P330	Rinse mouth
P333+P313	If skin irritation or rash occurs: Get medical advice/attention
P337+P313	If eye irritation persists: Get medical advice/attention
P363	Wash contaminated clothing before reuse

Storage

P403+P233	Store in a well- ventilated place. Keep container tightly closed
P405	Store locked up

Disposal

P501	Dispose of contents/container to ...
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REGULATIONS

This safety data sheet is in compliance with the following EU legislation and its adaptations – as far as applicable - : 67/548/EEC, 1999/45/EC, 98/24/EC, 92/85/EEC, 94/33/EC, 91/689/EEC, 1999/13/EC, Regulation (EU) No 453/2010, Regulation (EC) No 1907/2006, Regulation (EC) No 1272/2008, and their amendments.

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE

- Skin contact may produce health damage*.
- Cumulative effects may result following exposure*.
- Possible skin sensitiser*.
- May be harmful to the foetus/ embryo*.
- Possible risk of harm to breastfed babies*.

* (limited evidence).

RISK

Explanation of risk codes used on this MSDS

Risk Codes	Risk Phrases
R22	■ Harmful if swallowed.
R36/37/38	■ Irritating to eyes, respiratory system and skin.

ANNEX 2: Indications of Danger

Xn Harmful

INGREDIENTS WITH MULTIPLE CAS NUMBERS

Ingredient Name	CAS
doxycycline hyclate	10592-13-9, 24390-14-5

- The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings.

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