

THE CONDITIONS OF USE OF COPPER SULPHATE FOR RUMINATING CATTLE AND GOATS IN AREAS OF TEART SOIL

Where ruminating cattle and goats are raised on teart soils, deficiency of copper in the diet will compromise animal health and welfare. To prevent the risk of copper deficiency, sufficient copper sulphate needs to be incorporated into the diet to provide up to 2000 mg of elemental copper per head per day.

1. Teart pastures are restricted to the South West of England and some areas of North Lancashire, Gloucestershire and Warwickshire. Teart pastures have a naturally occurring, high level of molybdenum concentration in the soil, which interferes with the uptake of copper from the diet and causes a copper deficiency in ruminating cattle and goats. Excess molybdenum can be directly toxic. Oral copper supplements, at a high level, are recognised as the only effective method in ruminating cattle herds and goats of preventing the absorption of excess molybdenum.
2. In order to prevent copper deficiency and the resulting animal health and welfare problems in animals grazing teart pastures, copper sulphate needs to be incorporated into the diet to provide up to 2000 mg of elemental copper per head per day. As a feed additive, copper sulphate is only permitted at an inclusion rate of up to 35 mg of copper per kg of final feed (approx 875mg of copper per head per day). Therefore, a marketing authorisation is required for the legal incorporation of Copper Sulphate over 35mg of copper per kg of final feed. The MA for Copper Sulphate has expired making the manufacture and use of this medicated feedingstuff an offence.
3. Prevention of copper deficiency is important to protect the health and welfare of ruminating cattle and goats in high molybdenum areas. Accordingly, the enforcement authority will give exceptional consideration when deciding whether or not to enforce the legislation, depending on certain factors being taken into account. This will be **only in the circumstances of ruminating cattle and goats grazing teart pastures** and in accordance with the conditions laid out in paragraph 5.
4. Exceptional consideration will not apply to farms on **all other** pastures which do not have teart soil. For farms on normal soils the inclusion level **must not** exceed the feed additive maximum inclusion level of 35 mg of copper per kg of the final feed.

5. In **specific areas of teart pastures**, the addition of a sufficient quantity of feed grade copper sulphate pentahydrate to the diet to provide up to 2000 mg per head per day of elemental copper, a general non enforcement policy will be applied, provided the following conditions are complied with:-
 - i) the supply is strictly for ruminating cattle and goats in teart pastures (high molybdenum);
 - ii) supply must be at the veterinary surgeon's discretion and only be on receipt of a veterinary written direction issued by a veterinary surgeon;
 - iii) the copper sulphate supplemented feed must be manufactured and supplied only by premises holding an appropriate VMD approval;
 - iv) The premixture, complementary feedingstuffs or medicated feedingstuffs containing the copper sulphate must be labelled and used in accordance with the labelling requirements in this Good Practice Note; and
 - v) the manufacture, supply and use must be in accordance with the Good Practice Note.
6. Paragraph 5 above sets out the exceptional circumstances which must be met. Where the conditions in paragraph 5 are not met, the VMD considers that in accordance with the VMR a marketing authorisation is required for the Copper Sulphate intended for incorporation into feed at rates to give more than 35mg of copper per kg of the final feed and any consideration of non enforcement will not apply. In the absence of such a marketing authorisation the VMD will take appropriate enforcement action in line with its published enforcement strategy.
7. Generally VMD policy is that enforcement action will not be taken under the derogation conditions outlined under Paragraph 5. However, it should be noted that the individual circumstances of any case brought to our attention would be considered carefully.
8. It should be made clear that the VMD will keep this policy under review. The VMD reserves the right to change the policy should circumstances change.
9. **VETERINARY SURGEONS PLEASE NOTE THE FOLLOWING:**
 - The severity of copper deficiency, whether of primary or secondary origin, varies greatly from farm to farm. Veterinarians will need to adapt their advice and the amount incorporated accordingly, with due consideration

given to other sources of dietary copper and its antagonists. 100g of feed grade copper sulphate pentahydrate provides approximately 25g of elemental copper.

- If significant doubt exists as to the dietary copper contribution, it is recommended that feedingstuffs including pasture/forage be analysed for copper content.
- In situations where the medicinal level of copper sulphate is deemed necessary, it is recommended that a full risk assessment should be employed before the veterinary written direction is written. Only issue a veterinary written direction if copper deficiency is known to exist or known to be a risk. Outcome monitoring, including copper status, should also be part of the process.
- The medicated feedingstuff is for ruminating cattle and goats only.
- The copper sulphate used is feed grade copper sulphate pentahydrate.
- For oral administration only by incorporation into dry feed.
- Only to be incorporated into a premixture, complementary feedingstuff or a feed on/or supplied by premises holding an appropriate VMD approval.
- Administration to animals with hepatic impairment should be avoided.
- Can be used during pregnancy and lactation.
- Any suspected adverse reactions can still be reported to the VMD in the usual way.

10. **MILLS PLEASE NOTE THE FOLLOWING:**

- Only supply the medicated feedingstuff to the end user on receipt of a veterinary written direction issued by a veterinary surgeon
- Carefully follow the written instructions on the veterinary written direction.
- A homogenous distribution of the product within the feed should be ensured. To ensure adequate distribution in the final feed, it is recommended that the product be mixed with a suitable quantity of feed ingredients before blending into the final feed.
- The premixture, complementary feedingstuff or medicated feedingstuff must be clearly and legibly labelled in accordance with the premixture and medicated feedingstuffs labelling conditions in Schedule 5 of The Veterinary Medicines Regulations.

- The following information must be included on the label of the copper sulphate premixture, mineral supplement (complementary feedingstuff) or medicated feedingstuff:-

PREMIXTURE or complementary feedingstuff that requires further mixing

1. The words MEDICATED PREMIXTURE or if it is to be labelled as “complementary feedingstuffs” and requires further mixing, MEDICATED COMPLEMENTARY FEEDINGSTUFFS.
2. The name copper sulphate and the amount of the copper sulphate (mg/kg) in the premixture and the equivalent amount of elemental copper in mg/kg.
3. The range of acceptable inclusion rates of the premixture into the final feed, the range of acceptable levels of elemental copper in the final feed and the words “refer to the veterinary written direction for the exact inclusion rate” or equivalent wording.
4. Species - ruminating cattle or goats to be specified as appropriate.
5. The following user warnings:
 - Wear either a disposable half-mask respirator conforming to European Standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143 when mixing or handling the feed.
 - Avoid contact with eyes by wearing protective goggles or safety glasses. In case of accidental eye contact, irrigate thoroughly with large quantities of water.
 - Avoid contact with skin by wearing protective clothing including impermeable gloves. In case of accidental skin contact, wash the exposed skin with soap and water.
 - Contaminated clothing should be removed and washed before being re-used.
 - In case of accidental ingestion, drink plenty of water and seek medical attention.
 - Wash hands after use.
6. A zero withdrawal period and a statement that, if the veterinary written direction requires a longer withdrawal period, that is the one that applies.
7. The expiry date.

8. The following storage instructions:
 - Store in a dry place.
 - Do not store above 25°C.
 - Store away from food, drink and other animal feedstuffs.
9. A statement to the effect that a veterinary written direction issued by a veterinary surgeon is required.
10. If there is more than one veterinary medicinal product used, a statement to the effect that the longest withdrawal period must be observed.
11. If the premixture also contains a feed additive, it must also contain the information required under Article 16 of Regulation 1831/2003 as amended by Regulation 767/2009.

MEDICATED FEEDINGSTUFFS or complementary feedingstuffs that do not require further mixing

1. The words MEDICATED COMPLETE FEED (or if it is to be labelled as a complementary feedingstuff and intended to be fed to animals without further mixing with feed materials) “MEDICATED COMPLEMENTARY FEEDINGSTUFF”.
2. The inclusion rate (kg/tonne or mg/kg) of the copper sulphate incorporated into the feedingstuff and the equivalent level of elemental copper in mg/kg.
3. The species of animal for which the feedingstuffs are intended - ruminating cattle or goats.
4. The following warnings and contra-indications:-
 - Do not use for animals other than ruminating cattle or goats, or allow other animals access to medicated feedingstuff as this can cause fatalities due to copper toxicity, particularly in sheep.
 - Do not exceed 2000 mg/head/day (as elemental copper) and consider all sources of copper including non-feed routes).
 - Only use on teart pastures where copper deficiency is known to exist or known to be a risk.
 - Copper toxicity may result from the effects of accumulation of copper leading to the following symptoms: thirst, apathy, haemolytic crises, icterus, hepatic necrosis and death.
 - Do not administer immediately before or concurrently with other copper containing products.

5. **The Following user warnings:**

- Avoid contact with skin and eyes. In case of accidental contact, wash skin/eyes with plenty of water.
 - Wash hands after use.
 - In case of accidental ingestion, drink plenty of water and seek medical attention.
6. Sufficient trough space and time should be provided to ensure an adequate intake, if animals are not fed individually.
7. The use of galvanised feed containers should be avoided.
8. A zero withdrawal period, and a statement that, if the veterinary written direction requires a longer withdrawal period, that is the one that applies.
9. The expiry date.
10. The following storage instructions:
- Store in a dry place.
 - Do not store above 25°C.
 - Store away from food, drink and other animal feedingstuffs.
11. A statement to the effect that the feedingstuffs must only be fed in accordance with its veterinary written direction.
12. The name and approval number of the manufacturer or the distributor.
13. If there is more than one veterinary medicinal product used, a statement to the effect that the longest withdrawal period must be observed.
14. If the medicated feedingstuff also contains a feed additive it must also contain the information required under Article 15 (f) and Annex VI of Regulation 767/2009.

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