



OPERATIONAL NOTICE

Policy on the registration of selenium products for use in sheep

Purpose

The purpose of this operational notice is to clarify the circumstances under which selenium products used in sheep require registration or not.

This notice should be read in conjunction with the 'Guideline for Stockfeed Supplement Products Containing Vitamins, Minerals or Amino Acids and Containing Only 'Nutritional Messages' at http://www.apvma.gov.au/guidelines/guideline_8_stockfeed_suppl.pdf

Definition of a veterinary chemical product

Section 5(3) of the Agvet Code states that a veterinary chemical product includes a vitamin, a mineral substance, or an additive, **if and only if**, the vitamin substance or additive is used for:

- (a) preventing, diagnosing, curing or alleviating a disease or condition in the animal or an infestation of the animal by a pest; or
- (b) curing or alleviating an injury suffered by the animal; or
- (c) modifying the physiology of the animal:
 - (i) so as to alter its natural development, productivity, quality or reproductive capacity; or
 - (ii) so as to make it more manageable; or
 - (iii) modifying the effect of another veterinary chemical product.

According to this definition of a veterinary chemical product provided by the Agvet Code, a selenium product whose label makes none of these claims is not a veterinary chemical product and does not require registration.

However, selenium and selenium salts are also approved active constituents. At certain concentrations, selenium and selenium salts are used for prevention or therapy of diseases such as white muscle disease in cattle and sheep, and for dermatological conditions in companion animals.

Which selenium products for sheep require registration?

The situation is described in Table 1:

Table 1: Selenium products for sheep which require registration.

Therapeutic product claims ?	Route of administration	Level of selenium	Dose of selenium	Registration required?	Label advisory statement
NO	Oral dosage forms administered in animal feed	Levels so that the product does not fall into S4 or S7 of the SUSDP	Any dose less than or equal to 0.1 mg/kg Se BW ¹ .	NO	Refer Label Advisory Statement below
YES	Any route	Any level	The APVMA will assess the safety and effectiveness of the label recommended dose	YES	To be decided during registration
NO	Oral dosage forms provided in animal feed	Levels so that the product does not fall into S4 or S7 of the SUSDP	Any dose greater than 0.1 mg/kg Se BW	YES	Refer Label Advisory Statement below
NO	(1) Injection (2) Oral dosage forms for dosing the animal directly, not administered in animal feed, eg boluses or pellets	Any level	The APVMA will assess the safety and effectiveness of the label recommended dose	YES	To be decided during registration
NO	Any route	Levels so that the product falls into S4 or S7 of the SUSDP	The APVMA will assess the safety and effectiveness of the label recommended dose	YES	To be decided during registration

Label advisory statement

Even if the selenium product need not be registered, the APVMA strongly advises manufacturers to include a warning on the product label that care should be taken to avoid over-supplementing with selenium. The use of selenium pellets and treatment of the pasture at the same time can lead to excessive tissue levels in sheep. A veterinarian or advisor should also be consulted to ascertain the animals' selenium status. The product should not be used in areas of seleniferous plants/soils in Queensland before a veterinarian has ascertained the selenium status.

¹ Feeding Standards for Australian Livestock Ruminants Standing Committee on Agriculture and Resource Management CSIRO Australia 1990 p 168

By way of example, the current label advisory statement on registered products reads:

SELENIUM

Contraindication

This product should not be used when selenium intake from pasture is high or selenium is provided by other means (such as pasture top dressing, vaccine, pellets or selenium drenches) if blood selenium levels at treatment are high. Users can determine the sheep's selenium status by consulting their veterinarian.

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