Australian Government

Australian Pesticides and Veterinary Medicines Authority

Agricultural and Veterinary Chemicals Code (Listed Chemical Product – Joint Health Products for Dogs and Horses) Standard 2014

I, Kareena Arthy, Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority:

a) make this Standard for the purposes of subsection 8U(2) of the Agricultural and Veterinary Chemicals Code, scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*; and
b) repeal the *Listable Chemical Product (Joint Health Products for Dogs and Horses) Standard 2007* with effect from the commencement of this Standard.

Kareena Arthy
Chief Executive Officer

Dated this 25th day of June 2014

Part 1 Preliminary

1 Name of Standard

This Standard is the *Agricultural and Veterinary Chemicals Code (Listed Chemical Product - Joint Health Products for Dogs and Horses) Standard 2014*.

2 Commencement

This Standard commences on the commencement of Schedules 1 to 6 to the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013*.

3 Object

The object of this Standard is to set out requirements in relation to a chemical product or class of chemical products to which the Standard applies, including in relation to the labelling and handling of the product or products.

4 Application of Standard

This Standard applies to the listed chemical products described in item 2 of the Listing Schedule Table.

Note The listed chemical products to which this Standard applies are veterinary chemical products, the long term use of which may help improve joint health and function in dogs and horses.

5 Interpretation

(1) Unless the contrary intention appears, an expression used in the Agvet Code or the Agvet Regulations and in this Standard has the same meaning in this Standard as in the Agvet Code or the Agvet Regulations.

(2) In this Standard, unless the contrary intention appears:

active constituent in the listed chemical product means an active constituent mentioned in column 2 of item 2 of the Listing Schedule Table.

Agvet Code means the Agricultural and Veterinary Chemicals Code, scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

Agvet Regulations means the *Agricultural and Veterinary Chemicals Code Regulations 1995*.

Listing Schedule Table means the table in Part 2 of Schedule 3B to the Agvet Regulations.

SUSMP means the *Standard for the Uniform Scheduling of Medicines and Poisons* in Schedule 1 to the Poisons Standard, as in force at the time this Standard is made.

Part 2 Requirements in relation to listed chemical products

6 Formulation requirements for listed chemical products

A listed chemical product must be formulated to provide:

(a) when used on dogs — at least 10 milligrams of the parent molecule contained in the salt of the active constituent in the listed chemical product for each kilogram of body weight of the dog each day up to a maximum of 100 milligrams for each kilogram of body weight each day; and

(b) when used on horses — at least 10 milligrams of the parent molecule contained in the salt of the active constituent in the listed chemical product for each kilogram of body weight of the horse each day up to a maximum of 50 milligrams for each kilogram of body weight each day.

7 Additional constituents in listed chemical products

(1) A listed chemical product may also contain 1 or more of the following constituents:

(a) vitamins, minerals (other than selenium) or amino acids that:

(i) are mentioned in Schedule 5 to the SUSMP; or

(ii) are not mentioned in a schedule other than Schedule 5 to the SUSMP;

(b) stockfood non-active constituents:

(i) of the kind specified in the *Agricultural and Veterinary Chemicals Code Act (Excluded Stockfood Non-active Constituents) Order 2014*; and

(ii) which are used in the product for the functions specified in that Order;

(c) non-active constituents:

(i) specified in the publication entitled 'Handbook of Pharmaceutical Excipients' published by the British Pharmaceutical Society and the American Pharmaceutical Association; and

(ii) used in the product for the functions listed in that publication;

(d) natural food ingredients.

(2) If a constituent of the kind mentioned in subsection (1) (a) (***additional constituent***) is included in the listed chemical product, the product must be labelled to include the following information:

(a) a heading containing the words 'other ingredients'; and

(b) under that heading:

(i) the name of each additional constituent; and

Federal Register of Legislative Instruments F2014L00863

(ii) the concentration of that constituent in the product.

(3) A claim about an additional constituent on a label for the listed chemical product must not state that the additional constituent is suitable for the purposes mentioned in paragraphs 5 (2) (a), (b), (c) or (d) of the Agvet Code.

8 Package limits

(1) A listed chemical product, when packaged, must not:

(a) contain more than 2 kg of the parent molecule contained in the salt of the active constituent in the listed chemical product; and

(b) if in powdered form — weigh more than 5 kg; and

(c) if the product is a medicated stockfood — weigh more than 25 kg.

(2) The package limit specified in paragraph (1) (a) applies to:

(a) if there is 1 active constituent in the listed chemical product — the weight of 1 active constituent; or

(b) if there are 2 or more active constituents in the listed chemical product — the total weight of all active constituents in the listed chemical product.

9 Labels

(1) The label on a container for a listed chemical product must comply with the label format set out in Schedule 1.

(2) Subject to subsection (3), the only claim about a listed chemical product that may be included on the label of a container for the product is ‘long term use may help improve joint health and function’, or words to that effect.

(3) If a listed chemical product also contains vitamins or minerals mentioned in paragraph 7 (1) (a), the label of a container for the product may contain a claim about the vitamins or minerals consisting only of the words ‘to supplement diets where levels may be low’, or words to that effect.

Schedule 1 Label format

(subsection 9 (1))

FRONT PANEL

CAUTION

KEEP OUT OF REACH OF CHILDREN

FOR ANIMAL TREATMENT ONLY

[PRODUCT NAME]

ACTIVE CONSTITUENT: [*Insert the following information:*

(a) the *Australian approved name of each active constituent, as described in Subdivision 3.2.1 of Part 3 of Schedule 3B to the Agvet Regulations; and*

(b) the concentration of each active constituent — use mg/kg, g/kg, or mg/capsule/tablet].

[*For chondroitin or naturally derived glucosamine – state tissue of origin (eg marine exoskeleton, shark cartilage, bovine cartilage etc)*].

OTHER INGREDIENTS: [*Insert the concentration and name of each additional constituent of the kind mentioned in section 7(1)(a) — use mg/kg, g/kg, or mg/capsule/tablet*].

Long term use may help improve joint health and function. [*Or insert words to that effect*]

Contents: [*Insert net weight or number of tablets/capsules*]

ANCILLARY PANEL

DIRECTIONS FOR USE

Not recommended for use in acute or infectious joint conditions. For a diagnosis to determine these conditions, or in the event of adverse experience (eg diarrhoea) or where response is unsatisfactory, consult your veterinarian. Use with caution in pregnant or lactating animals as safe use in these groups has not been established. Use with caution in animals with bleeding, liver or kidney disorders.

[*Insert the following information:*

(a) dosage instructions in accordance with section 6; and

(b) administration instructions consistent with the use information set out in column 3 of item 2 in the table in Part 2 of Schedule 3B to the Agvet Regulations. Give dose in mg/kg body weight followed by discrete dose per weight or weight range as applicable].

USER SAFETY INFORMATION: Avoid inhalation of dust.

[*The user safety information need only be included where relevant to the product's formulation type. For example, it should be included for powders, granules and pellets but need not be included for capsules or tablets.*]

FIRST AID: If poisoning occurs contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.

[*Insert registered company (or other legal entity) name, Australian street address and telephone number*]

DISPOSAL:
[*For containers less than or equal to 1 kg or 1 L*]
Dispose of empty container by wrapping with paper and putting in garbage.
[*For containers greater than 1 kg or 1 L*]
Fully empty container prior to disposal. Do not dispose of product on site. If not recycling, break, crush or puncture empty container/packaging and deliver to an approved waste management facility. Do not burn empty containers/packaging or product.

STORAGE: Store below 30 ºC (room temperature). Protect from moisture, heat and light. Keep container tightly closed.

APVMA Listed Product Number: [*Insert APVMA listed product number*]

EXPIRY DATE: [*Insert date – not to exceed 12 months from date of manufacture*]

BATCH NUMBER: [*Insert batch number*]