



ADVICE SUMMARY

APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT

Product name: CANINE ROSE-HIP VITAL
Applicant: ROSE-HIP VITAL PTY LIMITED
Product number: 66404
Application number: 53576

Purpose of Application and Description of Use: Registration of a 1000g/kg rosa canina (rosehip) fruit powder product which may be of benefit for improving the joint health and general well-being of active and aging dogs, in conjunction with approval of rosa canina (rosehip) fruit powder (**562/66404).

Active Constituent(s): ROSA CANINA (ROSEHIP)

Regulatory Decision:

To grant the application subject to the following conditions:

Standard Conditions of Registration/Approval

1. Containers must meet AgVet Code Regulation 18
2. Shelf Life - Label must contain an expiry date
3. Product must not be supplied without meeting GMP Requirements
4. Label must contain an Expiry Date and Batch Number
5. Product Label (MPL) must comply with Labelling Standard / Code
6. Statutory linking conditions MPL

For full conditions, refer to Standard Conditions for Applications on the APVMA website.

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External Efficacy Reviewer

Rose-Hip Vital Pty Ltd has applied to the APVMA to register a new product, **Canine Rose-Hip Vital (P66404)**. The proposed product contains the new active constituent *rosa canina* (*rosehip*) and is to be used as a complementary animal health product which may be of benefit for improving the joint health and general well-being of active and aging dogs. The product has been evaluated under APVMA Guideline #70 – Requirements and Guidelines for Veterinary Herbal Remedies, which allows for a reduced efficacy and safety data package.

An external reviewer has evaluated data presented by the applicant to support the safety and efficacy of the proposed new product **Canine Rose-Hip Vital (P66404)**. For products that meet the criteria stipulated in guideline 70, data requirements with respect to efficacy and safety are reduced. One form of acceptable efficacy data under this guideline is scientifically valid clinical data for a related formulation in a non-target species. The applicant submitted several studies for a related formulation in either humans or horses.

Three double blind, randomised, placebo-controlled clinical trials have been conducted in human patients with osteoarthritis and one double blind, placebo-controlled clinical trial has also been conducted in human patients with rheumatoid arthritis. These studies indicate that the active constituent *rosa canina* can reduce pain, improve mobility and decrease reliance on conventional medications in human patients.

The applicant also conducted a clinical trial in dogs to support efficacy of the proposed product. The study was conducted over 12 weeks in 80 dogs. The study demonstrated that the product is well tolerated in dogs at the proposed label dose, and that the product may be of benefit in improving the general well-being of dogs.

In accordance with Guideline 70, the applicant submitted a target animal safety study. The proposed product was administered to 5 animals at 5 times the recommended dose rate for a period of 3 months. There were no detectable differences in the general physical examination findings (including maintenance of bodyweight) or the haematology and biochemistry results, from the pre-trial sampling point to day 25, 65 or 85 in any dog. The product was well tolerated by all animals and no adverse effects were observed throughout the study.

The proposed product will be registered as a complementary animal health product (CAHP). Based on the advice of the external efficacy and safety reviewer, and the APVMA's internal assessment, the APVMA concludes that the product will be safe to target animals and efficacious as a CAHP when used under the proposed use pattern and label instructions.

Data relied on to provide the advice

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
54933	S	Rein E, Kharazmi A & Winther K	A herbal remedy, Hyben Vital (stand. Powder of Rosa canina fruits), reduces pain and improves general wellbeing in patients with osteoarthritis - a double-blind, placebo-controlled, randomised trial.	2004	Efficacy and Safety	Efficacy	Public	

54934	S	Winther K, Apel K & Thamsborg G	A powder made from seeds and shells of a rose-hip subspecies (<i>Rosa canina</i>) reduces symptoms of knee and hip osteoarthritis: a randomized, double-blind, placebo-controlled clinical trial.	2005	Efficacy and Safety	Efficacy	Public	
54935	S	Chrubasik C, Wiesner L, Black A, Muller-Ladner U & Chrubasik S.	A one-year survey on the use of a powder from <i>Rosa canina</i> lito in acute exacerbations of chronic pain.	2008	Efficacy and Safety	Efficacy	Public	
54936	S	Christensen R, Bartels E & Bliddal H.	Efficacy of glucosamine hydrochloride or specialised rosehip powder in osteoarthritis patients: an indirect comparison meta-analysis.	2009	Efficacy and Safety	Efficacy	Public	
54931	S	Richard N, Wolfram S and Schwager J	Anti-inflammatory and chondro-protective effects of Rose hip powder and its constituent galactolipid GOPO.	2008	Efficacy and Safety	Efficacy	Public	
54938	S	Winther K,	Report on in vitro and in vivo efficacy studies conducted in dogs.	2011	Efficacy and Safety	Efficacy	Applicant	
54939	S	Ragone A, Hansen S, Hansen P, Kharazmi A and Winther K.	A herbal remedy derived from subspecies of <i>Rosa canina</i> improves the immune response, working capacity and well-being of dogs? A parallel, placebo-controlled, double-blind randomised study.	2010	Efficacy and Safety	Efficacy	Applicant	
54940	S	Chrubasik C, Roufogalis B, Muller-Ladner U & Chrubasik S	A systematic review on the <i>Rosa canina</i> effect and efficacy profiles.	2008	Efficacy and Safety	Efficacy	Public	
54941	S	Winther K, Kharazmi A, Hansen A & Falk-Ronne J	A randomised placebo controlled double blind study on the effect of subspecies of rose hip (<i>Rosa canina</i>) on the immune system, working capacity and behaviour of horses.	2010	Efficacy and Safety	Efficacy	Public	
54942	S	SCEC Pty Ltd	A tolerance study of Lito Pet administered once daily at 5X the recommended dose rate in 5 dogs for 3 months.	2011	Efficacy and Safety	Efficacy	Applicant	
54943	S	Winther K et al	A randomised, controlled and parallel study on trotters during a three month training period.	2010	Efficacy and Safety	Efficacy	Applicant	
54930	S	Larsen E, Kharazmi A, Christensen L & Cristensen S	An anti-inflammatory galactolipid from Rose Hip (<i>Rosa canina</i>) that inhibits chemotaxis of human peripheral blood neutrophils in vitro.	2003	Efficacy and Safety	Efficacy	Public	

54929	S	Kharazmi A & Winther K	Rose hip chemotaxis and chemiluminescence of human peripheral blood neutrophils in vitro and reduces certain inflammatory parameters in vivo.	1999	Efficacy and Safety	Efficacy	Public	
54932	S	Warholm O, Skaar S, Hedman E, Molmen HM & Eik L	The effects of a standardized herbal remedy made from a subtype of Rosa canina in patients with osteoarthritis: A double blind, randomized, placebo-controlled clinical trial.	2003	Efficacy and Safety	Efficacy	Public	
54937	S	Willich S, Rossnagel K, Roll S, Wagner A, Mune O, Erlendson J, Kharazmi A, Sorensen H & Winther K.	Rose hip herbal remedy in patients with rheumatoid arthritis - a randomised controlled trial.	2010	Efficacy and Safety	Efficacy	Public	

* S = Data submitted with the application

I = Data inherited (that is, referenced) from another application