

Responses to NOSB Livestock Subcommittee Questions

1. **Additional ingredients.** Please provide more information on any additional ingredients that may be added during the manufacturing process or formulation. Examples of such ingredients include, but are not limited to, fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents. Please also describe whether any of these formulants are present in the final product.

The thymol for which we are petitioning is pure (at least 99.6%), there are no other ingredients added to the active in the manufacturing process. This pure form of thymol is well known in other "health" related industries, as it is used in pharmaceutical products, as well as, more commonly, in consumer products such as Listerine®.

2. **Environmental Impact of Manufacturing Process.** Please provide more information on the environmental impact of the manufacturing process for this material.

In preparing thymol, the only by-products of the process are thymol and water. Manufacturing facilities follow good manufacturing practices (GMP), and accordingly, the manufacturing facilities must follow strict policies in accordance with the prevailing local and/or national regulations, and there are no hazardous discharges to the environment.

3. **Impact on Human Health.** Please provide more information on any human health concerns while using this product.

None, thymol is listed as a 'generally recognize as safe' (GRAS) compound by the FDA. The compound itself is 'naturally occurring' or 'botanically derived', and found in thyme (and other edible plants), and of course, thyme is commonly used use as a food seasoning ingredient. For perspective, an animal health product, which uses thymol as the active ingredient, has been found safe and effective enough to be approved as a drug (as a disinfectant for animal skin) in Canada.

4. **International Status.** Please provide the status of this material on the Canadian Organic Permitted Substances List (CAN/CGSB-32.311-2006). Is this material approved under the Canadian organic standards?

Thymol is not yet listed on the Canadian Organic permitted substances list, but concurrent with this NOP petition, we are similarly petitioning the relevant agency in Canada, as well. To note, Canada and other counties do find thymol safe enough for use as a pesticide for honeybees (as highlighted):

Registration Decision RD2016-16, Thymol

Pest Management Regulatory Agency 05 May 2016ISSN: 1925-0940 (PDF version)

Catalogue number: H113-25/2016-16E-PDF (PDF version)The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value when used according to label directions. Conditions of registration may include special precautionary measures on the

product label to further reduce risk. To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and *Regulations*, has granted full registration for the sale and use of Thymol E_9509758 and Thymovar containing the technical grade active ingredient thymol to control Varroa mites (*Varroa destructor*) on honey bees (*Apis mellifera*). An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment. These products were first proposed for registration in the consultation document *Proposed Registration Decision PRD2010-18, Thymol*. This Registration Decision describes this stage of the PMRA's regulatory process for thymol, summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2010-18. This decision is consistent with the proposed registration decision stated in PRD2010-18.