

## Evaluation Report for Category L, Subcategory 1.2 Application

**Application Number:** 2023-0155  
**Application:** Application Subject to the Protection of Proprietary Interests in Pesticide Data (PIIP) Policy - Equivalency/Data Compensation Assessment  
**Product:** ProPhyt  
**Registration Number:** 35097  
**Active ingredient (a.i.):** Mono- and di-potassium salt of phosphorous acid  
**PMRA Document Number:** 3528381

### Purpose of Application

The purpose of this application was to register the commercial end-use product, ProPhyt, based on a registered precedent product.

### Chemistry Assessment

ProPhyt is formulated as a solution containing mono- and di-potassium salt of phosphorous acid at a concentration of 54.5% . This end-use product has a density of 1.45 g/cm<sup>3</sup> and pH of 6.03 (1% aqueous solution). The required chemistry data for ProPhyt have been provided, reviewed and found to be acceptable.

### Health Assessments

ProPhyt is of low acute toxicity by the oral, dermal, and inhalation routes, non-irritating to minimally irritating to the eyes, not irritating to the skin, and is not a dermal sensitizer.

Skin, eye, and inhalation exposure is possible when handling ProPhyt. The current label statements for ProPhyt are adequate to address the potential for exposure. Consequently, occupational, bystander, and residential exposure is not expected to result in health risks of concern when the product is used according to label directions.

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether dietary risks are acceptable from the consumption of foods treated with the pesticide when used according to the supported label directions. If acceptable, this means food containing that amount of residue is safe to eat, and maximum residue limits (MRLs) may be proposed. MRLs are the maximum amount of pesticide residue legally permitted to remain in/on food sold in Canada and are specified under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*.

Dietary risk to humans from the use of mono and di-potassium salts of phosphorous acid on agricultural crops was previously determined to be acceptable and MRLs are not required for crop use. Therefore, the specification of MRLs, under the *Pest Control Products Act*, continue to not be required for mono and di-potassium salts of phosphorous acid.

### **Environmental Assessment**

The uses on the ProPhyt label are within the currently registered use pattern of mono- and di-potassium salt of phosphorous acid. Therefore, the risk is acceptable when ProPhyt is used in accordance with the label, which includes statements to mitigate risks to the environment.

### **Value Assessment**

Based on a comparison of formulations between ProPhyt and the precedent product, it was concluded that these products can be expected to perform similarly, both in terms of efficacy and crop tolerance, when applied according to the use directions on the label. Therefore, all registered uses and claims of the precedent product were acceptable for extrapolation to the ProPhyt label.

The registration of ProPhyt will provide Canadian growers with an additional option for managing certain diseases on labelled crops.

### **Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the registration of ProPhyt.

## References

### PMRA

#### Document

Number	Reference
3425653	1999, Potassium phosphite: Determination of General Physico-Chemical Properties, DACO: 2.14.1,2.14.15,2.14.2,2.14.3,2.14.6,2.16,830.7000
3425657	1999, Potassium phosphite: Determination of Explodability, DACO: 2.16
3425676	2022, Product Chemistry Cross Reference for ProPhyt, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.2.1,3.2.2,3.2.3,3.3.1,3.4.1,3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9
3425655	1999, Potassium phosphite: Determination of Accelerated Storage Stability, DACO: 2.14.13,2.14.14 CBI
3425656	2000, Potassium Phosphite: Determination of long-term storage stability and corrosion characteristics (3, 6 & 12 months), DACO: 2.14.14 CBI
3425669	2022, Potassium Phosphonates Technical: Preliminary Analysis, DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI

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