

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2017-2556

Application: L.1.2: Submissions subject to PPIP policy – Equivalency/Data

Compensation Assessment

Product: Total Water Repair

Registration Number: 34461

Active ingredients (a.i.): Nonylphenoxy polyethoxy ethanol

PMRA Document Number: 3078317

Purpose of Application

The purpose of this application was to register the adjuvant, Total Water Repair based on a precedent product.

Chemistry Assessment

Total Water Repair is formulated as a solution containing nonylphenoxy polyethoxy ethanol at a concentration of 17.5%. This end-use product has a density of 1.325 g/mL and pH of 2.18. The required chemistry data for Total Water Repair have been provided, reviewed and found to be acceptable.

Health Assessments

Total Water Repair is considered to be of low acute toxicity via the oral route in rats and the dermal route in rabbits, and of slight acute toxicity to rats via the inhalation route. It is moderately irritating to the eye and slightly irritating to the skin of rabbits. It is not considered to be a dermal sensitizer in guinea pigs tested using the Buehler method. Total Water Repair is considered to be negative in the bacterial reverse mutation assay.

Total Water Repair used in combination with the end-use products listed on the adjuvant label for use on food, feed and non-crop land is not expected to result in increased potential occupational or bystander exposure over the registered uses of the end-use products. No health risks of concern are expected when workers follow label directions and wear the personal protective equipment as stated on the label.

Environmental Assessment

No additional risk to the environment is expected from the registration of the adjuvant, Total Water Repair. The use pattern for this product fits within the registered use pattern of the active ingredient.



Value Assessment

The availability of Total Water Repair would provide farmers another adjuvant option for use with a number of pest control products or crop desiccants or plant growth regulators. Registration of generic products may increase product competition in the marketplace, which may in turn reduce purchasing costs of similar products.

Value information submitted for review consisted of data from replicated field research trials. The information demonstrated that efficacy and crop tolerance of each of the listed pest control products or crop desiccants or PGRs applied with Total Water Repair can be expected to be similar to those applied with the cited precedent product at a similar active ingredient concentration.

Based on the weight of evidence, Total Water Repair was concluded to be agronomically equivalent to the cited precedent when applied at their respective label rates with each of the products listed on the label. Therefore, all products listed on the label of the precedent product are supported for inclusion on the Total Water Repair label.

Conclusion

The PMRA has reviewed the information in support of the registration of the adjuvant, Total Water Repair. Based on the results of this review, Total Water Repair is acceptable for registration.

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