

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.5, 3.1 Application

Application Number: 2017-3382
Application: New End-use Product Chemistry - Guarantee, Identity of Formulants, Proportion of Formulants, Formulation Type; New Product Labels - Application Rate Increase or Decrease
Product: Manzate Max
Registration Number: 33299
Active ingredient (a.i.): Mancozeb
PMRA Document Number: 2878551

Purpose of Application

The purpose of this application was to register a new product, Manzate Max, based on a precedent product, for the control of a variety of diseases.

Chemistry Assessment

Manzate Max is formulated as a flowable (suspension) containing mancozeb at a concentration of 480 g/L. This end-use product has a density of 1.306-1.307 g/mL and pH of 7.08. The required chemistry data for Manzate Max have been provided, reviewed and found to be acceptable.

Health Assessments

Manzate Max is of low acute oral and dermal toxicity. It is moderately acutely toxic by the inhalation route. It is minimally irritating to the eye and non-irritating to the skin of the rabbit. It is considered to be a dermal sensitizer.

The use of Manzate Max is not expected to result in health risks of concern to workers or bystanders when label directions are followed and the appropriate PPE is used. The risk assessments on file for this active ingredient are adequate to address the potential exposure from the uses.

No new residue chemistry data for mancozeb were submitted to support the registration of Manzate Max. When compared to the precedent product, the only difference in the use pattern is the new suspension formulation type. Residue data on file for each crop are adequate to support the registration of Manzate Max. Based on this assessment, the dietary exposure to residues of mancozeb is not expected to increase and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

No additional risk to the environment is expected from the registration of Manzate Max .The proposed use pattern for this product fits within the registered use pattern for mancozeb. Environmental concerns have been mitigated through adequate label statements.

Value Assessment

Value information reviewed to support the registration of Manzate Max included a rationale and bridging trials. The rationale was based on a precedent fungicide product. The results of the bridging trials demonstrated biological equivalency between Manzate Max and the precedent product. In addition, Manzate Max offers an easy-to-use, liquid formulation for growers to use as a foliar spray in an integrated pest management program. Therefore, the use of Manzate Max to control listed diseases on apples, grapes, carrots, celery, field cucumber, ginseng, onions (dry bulb), potatoes, greenhouse tomatoes, field tomatoes, sugar beets, specified ornamentals, wheat, tobacco, lentils, specified cucurbits and alfalfa grown for seed is supported from a value perspective.

Conclusion

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

The active ingredient mancozeb is undergoing re-evaluation. Its regulatory status may change as a result of that activity, which may affect end-use products containing mancozeb.

References

PMRA Document Number	Reference
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2781155	2017, Manufacturing Process of Mancozeb 480 SC , DACO: 3.2.1, 3.2.2 CBI
2781156	1998, Penncozeb Flowable (TD-2396-01) - Enforcement Analytical Method, DACO: 3.4.1
2781157	2000, Penncozeb Flowable (TD-2396-01): Physical and Chemical Properties, DACO: 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.6, 3.5.7, 3.5.8, 3.5.9
2781145	2017, Value Summary for Manzate Max: A Liquid Formulation Containing Mancozeb, DACO: 10.1, 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.3, 10.2.4, 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 10.5.5
2781146	2011, Leaf Disease Control In Onions With KFD-43-02, KDF-43-03, KFD-86-02, KDF-86-03, and KDF-90-01, DACO: 10.2.3.3(D)
2839810	2017, Evaluate EBDC formulations for early blight in potatoes , DACO: 10.2.3.3(D)
2839811	2017, UPI Early Blight , DACO: 10.2.3.3(D)
2839812	2018, Value Deficiency Response for Manzate Max: A Liquid Formulation Containing Mancozeb, DACO: 10.2.3.3,10.2.4
2781158	1986, Evaluation of the acute oral toxicity of Penncozeb flowable in the rat., DACO: 4.6.1
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2781162	1986, Assessment of primary skin irritation/corrosion by Penncozeb flowable in the rabbit , DACO: 4.6.5
1214232	1986. Skin Sensitization Test of Manzate 200 DF in guinea pigs for EPA Pesticide Registration, DACO: 4.6.6

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