

Evaluation Report for Category B, Subcategory 4.6 Application

Application Number: 2019-0293
Application: B.4.6: Fulfill conditions of registration
Product: Technical Tolpyralate Herbicide
Registration Number: 32900
Active ingredient (a.i.): Tolpyralate
PMRA Document Number : 3137344

Purpose of Application

The purpose of this application was to address the condition of registration for Technical Tolpyralate Herbicide.

Chemistry Assessment

The condition of registration for Technical Tolpyralate Herbicide was the provision of commercial scale batch data at all approved manufacturing sites. Data have been provided for one of the manufacturing sites, reviewed and found to be acceptable. As such, the chemistry requirements for Technical Tolpyralate Herbicide have been fulfilled for one of the manufacturing sites.

Health, Environmental and Value Assessments

Health, environmental and value assessments were not required for this application.

Conclusion

PMRA has reviewed the information provided. Based on the results of this review, the conditions of registration for Technical Tolpyralate Herbicide have addressed for one of the manufacturing sites.

Additional Information Being Requested

Since this technical product is manufactured at pilot scale before registration, five-batch data representing commercial-scale production at all approved manufacturing sites will be required as post-market information after registration.

References

- 2954513 2019, Technical Tolpyralate Manufacturing Information - [CBI-removed] (batch manufacturing dates), DACO: 2.13.3 CBI
- 2954514 2018, Content analysis of SL-573 TGAI, DACO: 2.13.2,2.13.3 CBI

3093573 2018, Quantitative analysis of [CBI-removed] in SL-573 TGAI, DACO: 2.13.4
CBI
3093574 2020, Content analysis of SL-573 TGAI, DACO: 2.13.4 CBI
3105321 2020, Justification to increase UCLs of [CBI-removed], DACO: 2.12 CBI

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