

Evaluation Report for Category B, Subcategory 1.3 Application

Application Number: 2009-3796
Application: Changes to the TGAI Product Chemistry-Specifications
Product: KnockOut Tech
Registration Number: 29265
Active ingredients (a.i.): Glyphosate [GPS]
PMRA Document Number: 1916323

Purpose of Application

The purpose of this application is to amend the specifications of the currently registered product, KnockOut Tech (Reg. No. 29265), by adding a new manufacturing process.

Chemistry Assessment

Common Name: Glyphosate
 Chemical Name: N-(phosphonomethyl)glycine

KnockOut Tech has the following properties:

Property	Result
Colour and physical state	White solid
Nominal concentration	98.1 %
Odour	Odourless
Specific gravity @ 20°C	1.705
Vapour pressure @ 25°C	1.31×10^{-2} mPa
pH	2.16
Solubility in water	10.5 g/L (pH 1.9, 20°C)
n-Octanol/water partition coefficient (K_{ow})	$\text{Log } K_{ow} = < -3.2$ (pH 2-5)

The chemistry requirements for KnockOut Tech have been completed.

A toxicology assessment was not required as the KnockOut Tech produced by the new manufacturing process/method is considered toxicologically equivalent to the precedent product. As an improvement of the manufacturing method, the concentration of impurities of potential toxicological concern at greater concentrations has dropped significantly.

No new residue data for glyphosate were submitted in support of the registration of the new process of manufacture for this active ingredient. A review of the proposed label and specification forms was conducted in the context of this submission. As this technical active ingredient will be used to formulate registered end-use products within the existing use pattern, from a food residue exposure point of view, no changes in the magnitude of the residues in food and feed crops are expected and therefore, no increase in dietary exposure is anticipated.

Environmental and Value Assessment

Environmental and value assessments were not required for this submission.

Conclusion

The PMRA has completed the assessment of all available information for this application and has concluded that the changes to the specifications of the product KnockOut Tech is acceptable.

References

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- 1804173 2008, Identification and determination of the relevant impurities [CBI Removed] in five batches of Glyphosate technical, Batch Nos. RFYP1089, RFYP1090, RFYP1091, RFYP1092 and RFYP1093, DACO: 2.11.4 CBI
- 1804175 2009, Product Specification of Glyphosate Tech, DACO: 2.13.2 CBI
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- 1885530 2010, Clarification Cover letter, DACO: 0.8.1
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