Evaluation Report for Category B, Subcategory B.1.3, B.3.13 Application

Application Number: 2006-3396
Application: Category B, subcategory 1.3 (New / Changes TGAI or ISP Prod Chemistry-Specifications) and 3.13 (New or Changes to Product Labels-Precautions)
Product: Difenoconazole Technical Fungicide
Registration Number: 25631
Active ingredients (a.i.): contained in product: Difenoconazole at 95%
PMRA Document Number: 1424512

Background

Difenoconazole Technical Herbicide has been registered since July 14, 1998 for manufacturing purposes. For specific details of use, precautions and restrictions, refer to the product label.

Purpose of Application

The purpose of this application was to amend the product specifications for the technical grade active ingredient difenoconazole to reflect the presence of a new impurity (SYN 509466). The applicant also reported a modification to the manufacturing process involving a new final purification step to eliminate the presence of isopropanol in the TGAI.

Chemistry Assessment

Common Name:	Difenoconazole
IUPAC Chemical Name:	3-chloro-4-[(2*RS*,4*RS*;2*RS*,4*SR*)-4-methyl-2-(1*H*-1,2,4-triazol-1-yl methyl)-1,3-dioxolan-2-yl]phenyl 4-chlorophenyl ether
CAS Chemical Name:	1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan -2-ylmethyl]-1*H*-1,2,4-triazole

Difenoconazole Technical Fungicide has the following properties:

Property	Result
Colour and physical state	White to beige solid crystals
Nominal concentration	95%
Odour	Slightly sweet
Density	1.37 - 1.4 g/cm^3
Vapour pressure	3.3 x 10^{-8} Pa (at 25°C) 6.6 × 10-^{8} Pa (at 20°C)
pH	N/A
Solubility in water	0.0033 g/L
n-Octanol/water partition coefficient	Log K_{OW} = 4.2

The chemistry requirements for Difenoconazole Technical Fungicide are complete.

Health Assessment

The new impurity found in the formulation has always been present in the EP and thus does not change the toxicology profile of the product. This impurity has been found now because of a more sensitive analytical method than previously used.

An occupational/bystander exposure assessment is not required for technical grade active ingredient products.

Residues of difenoconazole on treated crops resulting from the amendment to the product specifications to reflect the presence of a new impurity are expected to be covered by the established maximum residue limits (MRLs) for various commodities, since the impurity had already been considered in the toxicological profile of the product. There is no expectation of increased dietary exposure due to presence of the impurity or the amendment to the product specifications. This change in Difenoconazole Technical Fungicide will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The subject application is for minor changes in the technical grade material (presence of certain process-related impurities) which, when formulated, diluted further in water, and then applied over crops, will result in substantial dilution in the environment. This will result in negligible exposure of the environment to the impurities in the parent compound. Therefore, the subject amendment does not increase the environmental risk and additional environmental data are not required to support this amendment.

Value Assessment

A value assessment is not required for technical grade active ingredient products.

Conclusion

The PMRA has completed an assessment of available information for Difenoconazole Technical Fungicide and has found the information sufficient to support the amendment of the product specifications to reflect the presence of the new impurity (SYN 509466).

References List

List of Studies/Information Submitted by Registrant

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