

# Evaluation Report for Category B, Subcategory B.1.1, 1.3-S-A-TGAI Application

| <b>Application Number:</b>  | 2006-5168                                   |
|-----------------------------|---------------------------------------------|
| Application:                | Category B, subcategory B.1.1, 1.3-S-A-TGAI |
| Product:                    | Isoxaben Technical Herbicide                |
| <b>Registration Number:</b> | 24204                                       |
| Active ingredients (a.i.):  | Isoxaben at 93.5%                           |
| <b>PMRA Document Number</b> | : 1710384                                   |

#### **Purpose of Application**

The purpose of this application is to update the guarantee of Isoxaben Technical Herbicide (Reg. No. 24204) from minimum to nominal, to register two new sources of manufacture, and to discontinue manufacturing at the current site.

#### **Chemistry Assessment**

Common Name:IsoxabenIUPAC Chemical Name:N-[3-(1-ethyl-1-methylpropyl)isoxazol-5-yl]-2,6-dimethoxybenzamideCAS Chemical Name:N-[3-(1-ethyl-1-methylpropyl)-5-isoxazolyl]-2,6-dimethoxybenzamide

| Property                                               | Result                      |
|--------------------------------------------------------|-----------------------------|
| Colour and physical state colourless crystalline solid |                             |
| Nominal concentration                                  | 93.3% as determined by HPLC |
| Odour                                                  | not required                |
| Density                                                | 0.52 - 0.56 g/mL            |
| Vapour pressure                                        | 5.5 x 10- <sup>4</sup> mPa  |
| рН                                                     | not required                |
| Solubility in water                                    | 1.42 g/mL at pH 7           |
| n-Octanol/water partitionLog Kow = 3.94 (pH 5.1)       |                             |
| coefficient                                            |                             |

Isoxaben Technical Herbicide has the following properties:



The chemistry requirements for Isoxaben Technical Herbicide are complete.

#### Health Assessments

The application for updating the guarantee and addition of two new manufacturing sites of Isoxaben Technical Herbicide was based on the currently registered product (Reg. No. 24204). This was considered acceptable as the updated formulation was chemically equivalent to the registered formulation, and therefore, is expected to have similar toxicity. No additional toxicological data were required.

An occupational/bystander exposure assessment is not required as Isoxaben Technical Herbicide is only used in the manufacture of an end-use product.

### **Environmental Assessment**

An environmental assessment is not required as Isoxaben Technical Herbicide is only used in the manufacture of an end-use product.

#### Value Assessment

A value assessment is not required for the manufacturing process of Isoxaben Technical Herbicide.

#### Conclusion

The Agency has completed an assessment of available information for Isoxaben Technical Herbicide and has found the information sufficient to amend the registration to update the guarantee to 93.5% nominal, to discontinue manufacturing at the current site, and add two new manufacturing sites.

#### References

## A. Studies/Information Provided by Applicant/Registrant

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