# Evaluation Report for Category B, Subcategory 1.1 Application

**Application Number:** 2010-0307
**Application:** Changes to the technical grade active ingredient – new source (site) same registrant
**Product:** Kixor
**Registration Number:** 29369
**Active ingredients (a.i.):** Saflufenacil
**PMRA Document Number : 1943129**

## Purpose of Application

The purpose of this application is to add a new site of manufacture of the active ingredient saflufenacil to the currently registered product Kixor, Registration Number 29369, by the same registrant.

## Chemistry Assessment

Common Name:     Saflufenacil
Chemical Name:   N'-[2-chloro-4-fluoro-5-(3-methyl-2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2H)-pyrimidinyl)benzoyl-N-isopropyl-N-methylsulfamide

Kixor has the following properties:

| Property | Result |
|---|---|
| Colour and physical state | White solid powder |
| Nominal concentration | 97.4% |
| Odour | Odourless |
| Density | 0.736 g/mL (Packed bulk) |
| Vapour pressure | $4.5 \times 10^{-15}$ Pa at 20°C |
| pH | 4.43 at 25°C (1% solution) |
| Solubility in water | 0.0014 g / 100 mL (pH 4) <br> 0.0025 g / 100 mL (pH 5) <br> 0.21 g / 100 mL (pH 7) |
| n-Octanol/water partition coefficient | Log $K_{ow}$ = 2.6 |

The chemistry requirements for Kixor have been completed.

**Health, Environmental and Value Assessments**

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

**Conclusion**

The PMRA has conducted a review of the available information for this application and has concluded that the addition of a new site for the production of Kixor is acceptable.

**References**

PMRA No.     Title

1546913     2006, BAS 800 H: Physical state and melting point of pure active ingredient (PAI), DACO: 2.14.4,IIA 2.1.1
1546914     2008, Boiling Point / Boiling Range, DACO: 2.14.5,IIA 2.1.2
1546915     2007, BAS 800 H TGAI: Storage stability and corrosiveness, DACO: 2.14.14,2.16,IIA 2.17.1,IIA 2.18
1546916     2007, BAS 800 H (TGAI): Stability to normal and elevated temperature, metal and metal ions, DACO: 2.14.13,IIA 2.17.2
1546917     2007, BAS 800 H (MP): Determination of oxidation/reduction, physical state, pH, bulk density, explodability and odor, DACO: 2.14.1,2.14.2,2.14.3,2.14.6,IIA 2.13,IIA 2.15,IIA 2.16,IIA 2.2,IIA 2.4.1,IIA 2.4.2

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| 1546918 | 2005, BAS 800 H - Reg. No. 4054449: Physical properties of the pure active ingredient, DACO: 2.14.9,IIA 2.3.1 |
| 1546919 | 2007, Determination of the Henrys law constant for BAS 800 H at 25°C, DACO: 2.16,IIA 2.3.2 |
| 1546920 | 2007, BAS 800 H: Spectroscopic characterization by NMR, MS, IR and UV/Vis, DACO: 2.13.2,2.14.12,IIA 2.5.1.1,IIA 2.5.1.2,IIA 2.5.1.3,IIA 2.5.1.4 |
| 1546923 | 2005, BAS 800 H: Water solubility at 20°C by shake flask method, DACO: 2.14.7,IIA 2.6 |
| 1546924 | 2007, BAS 800 H: Solubility of 800 H in organic solvents, DACO: 2.14.8,IIA 2.7 |
| 1546925 | 2005, BAS 800 H: Partition coefficient (n-octanol/water) estimation by high performance liquid chromatography, DACO: 2.14.11,IIA 2.8.1 |
| 1546930 | 2006, BAS 800 H: Dissociation constant, DACO: 2.14.10,8.2.3.2,IIA 2.9.5 |
| 1848921 | 2010, Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient (TGAI) or an Integrated System Product (ISP) DACO 2.1, 2.10, DACO: 2.1,2.10,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9 |
| 1848922 | 2009, Saflufenacil Documentation of Equivalency and Qualification of Technical Grade Active Ingredient Produced by the Source: [CBI Removed], DACO: 2.11,2.11.1,2.11.2,2.11.3,2.11.4,2.12.1 CBI |
| 1848924 | 2009, Composition Analysis for Saflufenacil Technical Grade Ingredient (TGAI), DACO: 2.13,2.13.1,2.13.2,2.13.3,2.13.4 CBI |
| 1901872 | 2007, Determination of [CBI Removed] in BAS 800H (Validation of the GC/MS-method), DACO: 2.13.1 CBI |