

## Evaluation Report for Category B, Subcategory 1.1 Application

**Application Number:** 2009-2316  
**Application:** B.1.1, New Source (site) same registrant  
**Product:** Kixor  
**Registration Number:** 29369  
**Active ingredients (a.i.):** Saflufenacil  
**PMRA Document Number :** 2456453

### Purpose of Application

The purpose of this application was to add a new manufacturing site to the technical grade active ingredient, Kixor.

### Chemistry Assessment

**Common Name:** Saflufenacil  
**IUPAC Chemical Name:** *N'*-{2-chloro-4-fluoro-5-[1,2,3,6-tetrahydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)pyrimidin-1-yl]benzoyl}-*N*-isopropyl-*N*-methylsulfamide  
**CAS Chemical name:** 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl]-4-fluoro-*N*-[[methyl(1-methylethyl)amino]sulfonyl]benzamide

Kixor has the following properties:

Property	Result										
Colour and physical state	White powdery solid										
Nominal concentration	97.4%										
Odour	Odourless										
Packed bulk density	0.736 kg/L										
Vapour pressure	$4.5 \times 10^{-15}$ Pa @ 20°C by extrapolation										
pH	4.43 for a 1% suspension										
Solubility in water	<table border="0"> <thead> <tr> <th>pH</th> <th>Solubility (g/100 mL)</th> </tr> </thead> <tbody> <tr> <td>4 (buffer)</td> <td>0.0014</td> </tr> <tr> <td>5 (buffer)</td> <td>0.0025</td> </tr> <tr> <td>7 (buffer)</td> <td>0.21</td> </tr> <tr> <td>9 (buffer)</td> <td>could not be determined due to degradation</td> </tr> </tbody> </table>	pH	Solubility (g/100 mL)	4 (buffer)	0.0014	5 (buffer)	0.0025	7 (buffer)	0.21	9 (buffer)	could not be determined due to degradation
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	4 (buffer)	0.0014									
	5 (buffer)	0.0025									
	7 (buffer)	0.21									
9 (buffer)	could not be determined due to degradation										

Property	Result
n-Octanol/water partition coefficient	log K <sub>ow</sub> = 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 completed an assessment of the subject application and has found the provided data to be sufficient to permit the addition of a new manufacturing site to Kixor (Registration Number 29369).

### References

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

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- 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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- 1546923 2005, BAS 800 H: Water solubility at 20°C by shake flask method, DACO: 2.14.7,IIA 2.6
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- 1546925 2005, BAS 800 H: Partition coefficient (n-octanol/water) estimation by high performance liquid chromatography, DACO: 2.14.11,IIA 2.8.1
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- 1776734 2009, Saflufenacil - documentation of equivalency and qualification of technical grade active ingredient produced by the source: [PRIVACY INFORMATION REMOVED], DACO: 2.11,2.11.1,2.11.2,2.11.3,2.11.4,2.12.1 CBI

- 1776735 2009, Preliminary analysis of five batches Saflufenacil (BAS 800 H) TGAI, DACO:  
2.13,2.13.1,2.13.2,2.13.3,2.13.4 CBI
- 1822990 2009, Determination of [CBI REMOVED] in "BAS 800 H Anhydrat, TGAI, DACO:  
2.13.3 CBI

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