



## Evaluation Report for Category B, Subcategory 1.3 Application

**Application Number:** 2011-5064  
**Application:** New / Changes TGAI or ISP Prod Chemistry - Specifications  
**Product:** Famoxadone Technical  
**Registration Number:** 27436  
**Active ingredients (a.i.):** famoxadone (FAD)  
**PMRA Document Number :** 2135777

### Purpose of Application

The purpose of this application was to amend the specification of Famoxadone Technical (Registration Number 27436) in order to account for a new impurity. This impurity has recently been characterized in Famoxadone Technical that is currently being produced and this has been reported to the Agency via the incident reporting process (Submission Number 2011-4481).

DuPont became aware of the impurity as a result of a request from the US EPA as follows: DuPont USA made a submission to the US EPA in order to add alternate sources of starting materials. As a result of this submission, the US EPA requested an analysis of Famoxadone Technical product for the impurity. The submission was subsequently withdrawn, but at the request of the US EPA, DuPont proceeded with the analysis. DuPont has subsequently submitted a position paper addressing the toxicology and risks of this impurity.

### Chemistry Assessment

**Common Name:** Famoxadone  
**IUPAC Chemical Name:** (RS)-3-anilino-5-methyl-5-(4-phenoxyphenyl)-1,3-oxazolidone-2,4-dione  
**CAS Chemical Name:** 5-methyl-5-(4-phenoxyphenyl)-3-(phenylamino)-2,4-oxazolidinedione

Famoxadone Technical Fungicide has the following properties:

Property	Result
Colour and physical state	Pale cream solid
Nominal concentration	97.8 %
Odour	Characteristic of burnt plastic and similar to vanilla
Density at 25°C	1.31 g/cm <sup>3</sup>
Vapour pressure at 20°C	6.4 × 10 <sup>-7</sup> Pa m <sup>3</sup> mol <sup>-1</sup>
pH	6.56

Property	Result	
Solubility in water	<u>pH</u> unbuffered	<u>µg/L ± sd</u> 52 ± 4
	2	143 ± 96
	3	191 ± 114
	5	243 ± 271
	7	111 ± 89
	9	38 ± 16
n-Octanol/water partition coefficient	<u>pH</u>	<u>log K<sub>ow</sub> ± sd</u>
	3.0	4.59 ± 0.06
	5.0	4.80 ± 0.13
	7.0	4.65 ± 0.40
	9.0	5.55 ± 0.26

The chemistry requirements for Famoxadone Technical have been completed.

### Health Assessments

The impurity present in Famoxadone Technical is not considered to affect the toxicity of the technical. Subsequently no toxicological data were submitted or were required.

The amendment of the specifications of Famoxadone Technical is not expected to alter the residues in crops treated with famoxadone. Therefore, the dietary exposure to famoxadone is not expected to increase and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

An occupational exposure assessment was not required for this application.

### Environmental and Value Assessments

Environmental and value assessments were not required for this application.

### Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, Famoxadone Technical, and has found the information sufficient to amend the specification form with respect to this newly identified impurity.

### References

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- 2118326 2011, TECHNICAL GRADE FAMOXADONE (DPX-JE874) MANUFACTURING DESCRIPTION AND FORMATION OF IMPURITIES, DACO: 2.11.1,2.11.2,2.11.3,2.11.4
- 2118327 2011, FAMOXADONE (DPX-JE874) IDENTITY, COMPOSITION, AND CERTIFIED LIMITS, DACO: 2.12.1 CBI

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- 2118338 1999, TECHNICAL GRADE FAMOXADONE (DPX-JE874) ANALYSIS AND CERTIFICATION OF PRODUCT INGREDIENTS, DACO: 2.13.3 CBI
- 2118339 1999, TECHNICAL GRADE FAMOXADONE (DPX-JE874) ANALYSIS AND CERTIFICATION OF PRODUCT INGREDIENTS, DACO: 2.13.3 CBI
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- 2118341 2011, FAMOXADONE TECHNICAL: RISK ANALYSIS OF A TRACE IMPURITY, DACO: 2.13.4,4.1

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