

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4. 3.3 Application

Application Number: Application:	2016-1490 B.2.1: Guarantee
	B.2.3: Identity of Formulants
	B.2.4: Proportion of Formulants
	B.3.3: Application Number or Frequency
Product:	Signature Xtra Stressgard
Registration Number:	32800
Active ingredients (a.i.):	Fosetyl-Al
PMRA Document Number:	: 2741842

Purpose of Application

The purpose of this application was to register the end use product Signature Xtra Stressgard.

Chemistry Assessment

Signature Xtra Stressgard is formulated as a wettable granules containing fosetyl-Al at a nominal concentration of 60%. This end-use product has a density of 0.56 g/mL and pH of 3.5. The required chemistry data for Signature Xtra Stressgard have been provided, reviewed and found to be acceptable.

Health Assessments

In rats, Signature Xtra Stressgard is of low acute toxicity by the oral, dermal, and inhalation routes of exposure. The formulation is mildly irritating to the rabbit eye but is not irritating to the rabbit skin. It is a not a skin sensitizer in mice.

An updated health risk assessment was conducted for re-entry workers. With revised precautions, no risks of concern were identified for the use of fosetyl-AL on turf (including golf courses and sod farms). No health risks of concern are expected when workers follow the label directions and wear the personal protective equipment identified on the label.

Environmental Assessment

The registration of Signature Xtra Stressgard is acceptable from an environmental perspective. Environmental concerns have been mitigated through adequate statements on the product label.



Value Assessment

A combination of efficacy data and scientific rationales were provided in support of the registration. Based on the value information provided, the crop-disease claims were supported.

This fosetyl-AL formulation contains 25% less active ingredient than the currently registered formulation. The addition of a lower rate and a shorter application interval will provide turfgrass managers with another option for using fosetyl-AL, with greater flexibility in use directions.

Conclusion

PMRA has reviewed the information provide in support of proposed product. Based on the results of this review, Signature Xtra Stressgard is acceptable for registration.

References

2618348	2014. 12ESP705: Acute Oral Toxicity – Up-And-Down Procedure In Rats. PSL Report
	38595; DACO 4.6.1.
2618349	2014. 12ESP705: Acute Dermal Toxicity in Rats. PSL Report 38596; DACO 4.6.2.
2618350	2014. 12ESP705: Acute Inhalation Toxicity in Rats. PSL Report 38597; DACO 4.6.3.
2618351	2014. 12ESP705: Primary Eye Irritation in Rabbits. PSL Report 38598; DACO 4.6.4.
2618352	2014. 12ESP705: Primary Skin Irritation in Rabbits. PSL Report 38598; DACO 4.6.5.
2618353	2014. 12ESP705: Local Lymph Node Assay (LLNA) in Mice. PSL Report 38600;
	DACO 4.6.6.

- 2618346 2016, Signature Xtra Stressgard Information to Address PMRA DACO Elements 3.1.1, 3.1.2, 3.1.3 and 3.1.4, DACO: 3.1.1,3.1.2,3.1.3,3.1.4 CBI
- 2618347 2014, Product Chemistry of 12ESP705, DACO: 3.2.1,3.2.2,3.3.1,3.4.1,3.5.1,3.5.10,3.5.11, 3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9 CBI
- 2776943 2017, Packaging Storage Stability and Corrosion Characteristics of Signature Xtra, DACO: 3.5.10,3.5.14 CBI

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