



AGENCE FRANÇAISE
DE SÉCURITÉ SANITAIRE
DES ALIMENTS

Maisons-Alfort, 14 November 2008

OPINION

of the French Food Safety Agency
concerning a request for the renewal
of marketing authorisation
for the phyto-pharmaceutical preparation, **CRUISER, No.AMM 2070196**

LA DIRECTRICE GENERALE

On 10 November 2008, the French Food Safety Agency (Afssa) received a request from SYNGENTA AGRO S.A.S., for renewal of its marketing authorisation for the insecticide CRUISER, containing thiamethoxam, for which AFSSA's opinion is required under Article L.253-4 of France's Rural Code.

Considering that CRUISER insecticide has already been granted a marketing authorisation, no. 2070196, which is still valid;

Considering the Opinions issued by Afssa following its assessments of the benefits and hazards of CRUISER insecticide, dated 21 November 2007, 20 December 2007, 25 January 2008, 13 June 2008 and 23 October 2008;

The French Food Safety Agency has issued a **favourable** Opinion for the renewal of the marketing authorisation for CRUISER insecticide, for the purposes and subject to the conditions of use detailed in the Annex.

Pascale BRIAND

Annex

List of authorised uses for CRUISER

Uses	Prescribed application rate	Maximum dose of active substance	Maximum number of applications
15551101 – Maize * seed treatment * <i>Oscinella</i> sp. (frit fly)	0.09 L fp/U*	69.3 g a.s./ha**	1 per crop
15551103 – Maize * seed treatment * <i>Agriotes lineatus</i> (wireworm)			

* fp/U: formulated product per unit of seed. 1 unit = 50 000 grains

** on the basis of a seed rate of 2.2 U/ha (i.e. 110 000 grains/ha).

Classification of the product, risk and safety phrases

N, R50/53 S60 S61

- N : Dangerous for the environment
 R50/53 : Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
 S60 : This material and its container must be disposed of as hazardous waste.
 S61 : Avoid release to the environment. Refer to special instructions/Safety data sheets.

To comply with Directive 2006/8/EC¹, the label must also bear the following phrase: "Contains 1,2-benzisothiazoline-3-one. May produce an allergic reaction."

Conditions for use

- Wear gloves and protective clothing during all seed treatment operations and breathing equipment (minimum level P2) during the cleaning phase.
- SP1: Do not contaminate water with the product or its container. [Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads].
- SPe1: To protect groundwater do not use this or any other product containing ingredients from the same family to treat seed on consecutive crops in the rotation cycle.
- SPe5: To protect birds/wild mammals the treated seed must be entirely incorporated in the soil; ensure that treated seed is also fully incorporated at the end of rows.
- SPe8: Dangerous to bees. Do not include plants in the crop rotation that could become attractive to bees, or alternatively take measures to limit exposure of bees (e.g. by cutting before the crop flowers). For sweet-corn or male seed-maize, during the flowering period keep a minimum distance of 3 km between hives and crops grown from treated seed.
- **Maximum seed rate:** 110 000 grains/ha.
- **Re-entry interval:** not applicable for a seed treatment.
- **Maximum residue levels (MRL):** see European MRLs²
- **Pre-harvest interval:** no pre-harvest interval has been set, as the preparation is applied as a seed treatment.

¹ COMMISSION DIRECTIVE 2006/8/EC of 23 January 2006 amending, for the purposes of their adaptation to technical progress, Annexes II, III and V to Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous mixtures.

² Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005, on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJEC of 16/03/2005) and regulations modifying its Annexes II, III and IV relative to the maximum applicable limits for residues of products listed in its Annex I.

Overview of other recommendations issued

The French Food Safety Agency has also recommended:

- concerning risks for workers,
 - that a study be set up to monitor the exposure of workers (working on seed drills) to confirm estimates made by the competent German authorities;
- concerning environmental hazards,
 - that levels of thiamethoxam and the metabolites CGA 322704, NOA 459602 and SYN 501406 be monitored in water tables that could be fed from areas in which seed is treated with CRUISER insecticide. A protocol must be drawn up beforehand with the competent authorities;
- concerning the danger to bees,
 - that drill-sowing be restricted for grain maize, silage maize and female seed-bearing maize to a period terminating on 15 May when using seed treated with CRUISER insecticide;
 - that SYNGENTA AGRO S.A.S. prolong and conclude the long-term trials already underway;
 - that pilot beehives be installed under realistic conditions to quantify the potential level of contamination in hives, to allow a closer study of the incidence and nature of long-term risks and, in particular, that arrangements be made for 2008 for an independent organisation to monitor hives that are particularly exposed relative to fields of treated maize;
 - that supplementary technical measures be taken to reduce the emission and dispersal of dust during drill-sowing;
- concerning the efficacy of the CRUISER insecticide,
 - that post-authorisation trials be carried out for seed-bearing maize to study the effect of seed treatments on the germination rates of treated seed;
 - that post-authorisation monitoring be carried out to verify the efficacy of protection provided against soil-borne pests over time;
 - that insecticides of the neonicotinoids family not be used for foliar treatment of crops where seed has been treated with thiamethoxam, in order to avoid the risk of cross-resistance developing.

Afssa's Opinion is subject to amendment as other information becomes available.