A8207M

Fludioxonil 25 g/L FS

NOTIFICATION OF AN ACTIVE SUBSTANCE UNDER COMMISSION REGULATION (EU) 844/2012

DOCUMENT M-CP, Section 4

FURTHER INFORMATION ON THE PLANT PROTECTION PRODUCT

Version history[1]

Date	Data points containing amendments or additions and brief description	Document identifier and version number

[1] It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment Report

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CP 4 FURTHER INFORMATION ON THE PLANT PROTECTION PRODUCT

This document supports the application for renewal of the regulatory approval of fludioxonil under Commission Implementing Regulation (EU) 844/2012 of 18 September 2012. This document reviews the further information for the product A8207M containing:

- 25 g/L fludioxonil

A8207M is a flowable concentrate for seed treatment (FS), containing 25 g/L fludioxonil, for the treatment of wheat and oat seeds to control a wide range of seed and soil-borne diseases. A8207I an older variant of A8207M was together with A9219B (containing 250 g/kg fludioxonil and 350 g/kg cyprodinil) the representative formulation in the EU review of fludioxonil.

Fludioxonil was included into Annex I of Council Directive 91/414/EEC (Commission Directive 2007/76/EC; 20 December 2007). This active substance is an approved active substance under Regulation (EC) 1107/2009 (repealing Commission Directive 91/414/EEC) as specified in Commission Implementing Regulation (EU) No. 540/2011 of 25 May 2011.

In accordance with Commission Implementing Regulation (EU) 844/2012, this document summarises new information which are relevant for the renewal of the approval of fludioxonil under Regulation (EC) 1107/2009. Where appropriate this document refers to the Commission Implementing Regulation (EU) No. 540/2011 for fludioxonil and to the EFSA report for fludioxonil (**EFSA Scientific Report (2007) 110, 1-85**), and in particular the endpoints provided in Appendix I.

This document covers data and risk assessments which were not part of the original dossier and which are necessary to reflect changes:

- In requirements under Commission Regulation (EU) No 284/2013, and the associated Annex, which repeals Commission Regulation (EU) No 545/2011 which, under Regulation (EC) 1107/2009, replaced the requirements of Annex III to Directive 91/414/EEC
- In scientific and technical knowledge since the approval or last renewal of the approval
- To representative uses

The representative use pattern proposed for EU review of fludioxonil is included in Document D1.

Each section of this document provides the agreed EU endpoints and if relevant proposals for amended endpoints.

Where new guidance documents have been introduced since the EU review of fludioxonil, an updated evaluation of fludioxonil and A8207M has been included. To adequately assess fludioxonil to the new guidance documents, it may have been necessary to provide new data, if so these are also included.

Information on the detailed composition of A8207M can be found in the confidential dossier of this submission (Document J).

CP 4.1 Safety Intervals and Other Precautions to Protect Humans, Animals and the Environment

Pre-harvest interval (in days) for each relevant crop: Not applicable as seed treatment.

Re-entry period (in days) for livestock, to areas to be grazed: Not applicable as wheat and oat crops are not to be grazed.

Re-entry period (in hours or days) for man to crops, buildings or spaces treated: The risk assessment for the representative uses for the loading and sowing of treated seeds has been presented in MCP 7.2.1 of the dossier. Re-entry for scouting or harvesting is not applicable for seed treatments.

Withholding period (in days) for animal feeding stuffs: An additional period of withholding after harvest is not required for livestock feed commodities.

Waiting period (in days) between application and handling of treated products: The risk assessment for the representative use for the loading and sowing of treated seeds has been presented in MCP 7.2.1 of the dossier. Re-entry for scouting or harvesting is not applicable for seed treatments.

Waiting period (in days) between last application and sowing or planting succeeding crops: Waiting periods for seed treatment uses are not required.

Information on specific conditions under which the preparation may or may not be used: Not applicable.

CP 4.2 Recommended Methods and Precautions

Cleaning procedures

Application equipment:
Immediately after use, clean the application equipment thoroughly. Drain the system completely and rinse the apparatus with excess water until it is visually clean.

Protective clothing:
Rinsing with water and detergent.

Effectiveness of cleaning procedures:

The effectiveness of the cleaning procedure can be inspected visually. If no residue is left in the equipment, all formulation has been removed.

Detailed handling procedures for storage:

Requirements for storage areas and containers:
No special storage conditions required.
Keep containers tightly closed in a dry, cool and well-ventilated place.
Keep out of the reach of children.
Keep away from food, drink and animal feeding stuffs.

Advice on safe handling:
No special protective measures against fire required.
Avoid contact with skin and eyes.

When using do not eat, drink or smoke.

Transport:

Not dangerous goods – full transport

Land transport
ADR/ RID:

UN-Number:	Not applicable
Class:	Not applicable
Labels:	Not applicable
Packaging group	Not applicable
Proper shipping name:	Not applicable

Sea transport
IMDG:

UN-Number:	Not applicable
Class:	Not applicable
Labels:	Not applicable
Packaging group:	Not applicable
Proper shipping name:	Not applicable
Marine pollutant :	Not applicable

Air transport
IATA-DGR

UN-Number:	Not applicable
Class:	Not applicable
Labels:	Not applicable
Packaging group:	Not applicable
Proper shipping name:	Not applicable

Fire

Suitable extinguishing media:
Extinguishing media - small fires: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Extinguishing media - large fires: Use alcohol-resistant foam or water spray.
Extinguishing media which shall not be used for safety reasons: Do not use a solid water stream as it may scatter and spread fire.

Specific hazards during fire fighting: As the product contains combustible organic components, fire will produce dense black smoke containing hazardous products of combustion. Exposure to decomposition products may be a hazard to health.

Special protective equipment for firefighters: Wear full protective clothing and self-contained breathing apparatus.

Further information minimise the hazards arising: Do not allow run-off from fire fighting to enter drains or water courses. Cool closed containers exposed to fire with water spray.

Hazardous decomposition products likely to be generated in the event of fire: Combustion or thermal decomposition will evolve toxic and irritant vapours.

Hazardous reactions: None known. Hazardous polymerization does not occur.

CP 4.3 Emergency Measures in the Case of an Accident

a) Containment of spillages

Containment and/or segregation is the most reliable technical protection measure if exposure cannot be eliminated. The extent of these protection measures depends on the actual risks in use. If airborne mists or vapours are generated, use local exhaust ventilation controls. Assess exposure and use any additional measures to keep airborne levels below any relevant exposure limit.

Where necessary, seek additional occupational hygiene advice.

b) Decontamination of areas, vehicles and buildings

Environmental precautions:
Prevent further leakage or spillage if safe to do so. Do not flush into surface water or sanitary sewer system.

Methods for cleaning up:
Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations.
If the product contaminates rivers and lakes or drains inform respective authorities.

Where possible recycling is preferred to disposal or incineration.
It must undergo special treatment, e.g. at suitable disposal site, to comply with local regulations.

c) Disposal of damaged packaging, absorbents and other materials

Dispose of as unused product.

d) Protection of emergency workers and residents, including bystanders

Protective measures:
The use of technical measures should always have priority over the use of personal protective equipment. When selecting personal protective equipment, seek appropriate professional advice. Personal protective equipment should be certified to appropriate standards.

Respiratory protection:
A particulate filter respirator may be necessary until effective technical measures are installed.

Hand protection:
Chemical resistant gloves are not usually required. Select gloves based on the physical job requirements.

Eye protection:
Eye protection is not usually required. Follow any site specific eye protection policies.

Skin and body protection:
No special protective equipment required. Select skin and body protection based on the physical job requirements.

e) First aid measures

General advice:
Have the product container, label or Material Safety Data Sheet with you when calling the Syngenta emergency number, a poison control centre or physician, or going for treatment.

Inhalation:
Immediately move to fresh air. If breathing is irregular or stopped, administer artificial respiration. Keep patient warm and at rest. Call a physician or Poison Control Centre immediately.

Skin contact:
Take off all contaminated clothing immediately. Wash off immediately with plenty of water. If skin irritation persists, call a physician. Wash contaminated clothing before re-use.

Eye contact:
Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses. Immediate medical attention is required.

Ingestion:
If swallowed, seek medical advice immediately and show this container or label. Do NOT induce vomiting.

Medical advice:
There is no specific antidote available. Treat symptomatically.

CP 4.4 Packaging, Compatibility of the Plant Protection Product with Proposed Packaging Materials

1 litre canister	**Material**	:	High Density Polyethylene (HDPE)
	Dimensions (L x W x H)	:	89 mm x 231 mm (diameter x height)
	Capacity	:	1 litre
	Size opening	:	45 mm
	Seals	:	Screw cap closure (45 mm diameter) with induction heat seal or compression wad and tamper evident ring.
5 litre canister	**Material**	:	High Density Polyethylene (HDPE)
	Dimensions (L x W x H)	:	190 x 135 x 318 mm
	Capacity	:	5 litre
	Size opening	:	63 mm
	Seals	:	Screw cap closure (63 mm diameter) with induction heat seal or compression wad and tamper evident ring.
10 litre canister	**Material**	:	High Density Polyethylene (HDPE)
	Dimensions (L x W x H)	:	240 x 179 x 375 mm
	Capacity	:	10 litre

	Size opening	:	63 mm
	Closure	:	Screw thread cap
	Seals	:	Screw cap closure (63 mm diameter) with induction heat seal or compression wad and tamper evident ring.
20 litre canister	**Material**	:	High Density Polyethylene (HDPE)
	Dimensions (L x W x H)	:	293 x 243 x 400 mm
	Capacity	:	20 litre
	Size opening	:	DIN 60
	Seals	:	Screw cap closure DIN 60 with induction heat seal or compression wad and tamper evident ring.
50 litre drum	**Material**	:	High Density Polyethylene (HDPE)
	Dimensions (L x W x H)	:	380 mm x 605 mm (Diameter x Height)
	Capacity	:	50 L
	Size opening	:	380 mm
	Closure	:	2 bungs + Trisure cap
200 litre drum	**Material**	:	High Density Polyethylene (HDPE)
	Dimensions (L x W x H)	:	580 mm x 960 mm (Diameter x Height)
	Capacity	:	200L
	Closure	:	2 bungs and SK 70 screw cap closure with tamper evident ring and SK 160 screw cap closure with tamper evident ring
200 litre drum	**Material**	:	High Density Polyethylene (HDPE)
	Dimensions (L x W x H)	:	580 mm x 940 mm (Diameter x Height)
	Capacity	:	200L
	Closure	:	2 x 2 inch “Tri-Sure” plugs
1000 litre RIBC	**Material**	:	High Density Polyethylene (HDPE) liner and galvanised steel frame
	Dimensions (L x W x H)	:	1200 x 1000 x 1160 mm
	Capacity	:	1000 litre
	Closure	:	TOP 150mm screw cap. with gasket and facility for tamper evidence Bottom 50mm valve spout closed by aluminium sealing disc

Compatibility of the Plant Protection Product with Proposed Packaging Materials

As part of the storage stability study, packs were examined to ensure that no significant interaction with the formulation, affecting the stability of the packaging material, had taken place during storage. The studies have been carried out according to CIPAC MT 46.3.

Report:	K-CP 4.4/01, Naegele M. (2008) A8207M – Storage Stability and Shelf Life Statement (2 years 20°C) in Packaging made of HDPE, Syngenta Crop Protection Münchwilen AG, Switzerland; Unpublished report no. 10336786; Issue date 28.2.2008; Syngenta File No. A8207M_10104

It can therefore be concluded that the packaging will be resistant to its contents for at least two years under normal storage conditions.

CP 4.5 Procedures for the Destruction or Decontamination of the Plant Protection Product and its Packaging

CP 4.5.1 Neutralisation procedures

In the event of accidental spillage, neutralisation (with acid or base to neutral pH) is not an effective procedure for the destruction or decontamination of the formulation.

Therefore, the spilled liquid formulation should first be adsorbed onto a solid, such as sand, inert clay filler, saw dust or soil, before being swept up into a safe container to await disposal.

CP 4.5.2 Controlled incineration

As the halogen content of A8207M is below the 60% trigger value, high temperature incineration is the preferred means of disposal for the active substances, formulated products, contaminated materials or contaminated packaging. Directive 96/47/EEC defines the controlled conditions for incineration. Incineration should be carried out in a licensed incinerator operating at a temperature above 800°C and with a minimum gas phase residence time of two seconds.