Draft Assessment Report

Evaluation of Active Substances

Plant Protection Products

Prepared according to **Regulation (EC) 1107/2009**
as it applies in Great Britain

Pydiflumetofen

Volume 3 – B.4 (PPP) – Miravis Plus

Further Information

Great Britain

June 2023

Version History

When	What
October 2022	Initial GB DAR
June 2023	Post Expert Committee on Pesticides (ECP) Independent Scientific Advice (ISA)

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B.4. FURTHER INFORMATION

This document supports the application for regulatory approval of the new active substance SYN545974 under Regulation (EC) 1107/2009.
A21857B is a Emulsifiable concentrate (EC) containing 62.5 g/L SYN545974 for use as a fungicide in spring and winter barley, durum wheat, spring and winter oats, spring and winter wheat, spelt, winter and spring rye, spring and winter oilseed rape. Information on the detailed composition of A21857B can be found in the Volume 4 (Confidential information) .

SYN545974 (ADEPIDYN™; ISO common name: pydiflumetofen) is a new broad spectrum fungicide of the chemical group of N-methoxy-(phenyl-ethyl)-pyrazole-carboxamide. The mode of action of the active substance is respiration inhibition at complex II (Succinate-DeHydrogenase) in mitochondria of phytopathogenic fungi, thus SYN545974 belongs to the SDHI fungicide group. There is no cross resistance between compounds belonging to this group and strobilurin (QoI) or triazole (DMI) chemistry.
This document summarises the further information which are relevant for approval of SYN545974 and the proposed representative uses under Regulation (EC) 1107/2009 in accordance with the requirements under Commission Regulation (EU) No 284/2013.

B.4.1. SAFETY INTERVALS AND OTHER PRECAUTIONS TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT

The draft product label for MIRAVIS PLUS includes the follow precautions for protect humans, animals and the environment:

Avoid release to the environment.
Wear protective eye protection/face protection.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTRE or doctor/physician.
Collect spillage.
Dispose of contents/container to an approved waste disposal plant/contractor. Except empty containers which may be disposed of as non-hazardous waste.

To avoid risks to human health and the environment comply with the instructions for use.

RESTRICTIONS
For resistance management reasons, on cereal crops, MIRAVIS PLUS must always be used in mixture with another product, recommended for control of the same target disease that contains a fungicide from a different cross resistance group and is applied at a dose that will give robust control.

FOLLOWING CROPS
There are no restrictions on succeeding crops in a normal rotation.

Re-entry period (in days) for livestock, to areas to be grazed: not applicable as the representative crops are not typically grazed by livestock.
Re-entry period (in hours or days) for man to crops, buildings or spaces treated: The worker re-entry risk assessments for the representative uses have been presented in Section MCP 7 of the dossier for product A21857B. No re-entry period is required for scouting activities for the proposed uses or for harvesting at the proposed PHIs.

Withholding period (in days) for animal feeding stuffs and for post-harvest uses: 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 worker re-entry risk assessments for the representative uses were conducted assuming the maximum rate with no allowance for any decline in the default dislodgeable foliar residue; no unacceptable risks were identified. No waiting period between last application and handling treated products is deemed necessary.

Waiting period (in days) between last application and sowing or planting succeeding crops: As presented in CA 6.6, significant residues levels in the edible parts of succeeding crops are not expected provided that SYN545974 is applied according to the proposed GAP. Thus, a waiting period between last application and sowing or planting of succeeding crops is not required.
Information on specific conditions under which the preparation may or may not be used: Not applicable.

B.4.2. RECOMMENDED METHODS AND PRECAUTIONS

Recommended cleaning procedure

The cleaning procedure on the draft product label for Miravis Plus is as follows:

'After spraying thoroughly wash out sprayer according to manufacturer's guidelines and dispose of washing and clean containers according to DEFRA Code of Practice and local water authority guidelines.'

A vegetative vigour test and a seedling emergence test were conducted in accordance with the OECD 227 and OECD 208 Guidelines respectively to assess the effects of Miravis Plus on non-target plants. No phytotoxic effects were observed in the seedling emergence test and no effects were observed in the vegetative vigour test at an application rate of 400 mL/ha. This is equivalent to 12.5% of the maximum application rate of Miravis Plus. According to ISO 16119, up to 2.6% of the spray solution will remain in the application equipment after spraying. Therefore, it is unlikely that any remaining residues of Miravis Plus will have a negative effect on crops subsequently treated with the same application equipment.

Cleaning procedures
Application equipment:
Immediately after use, clean the spray equipment thoroughly. Drain the system completely and rinse spray tank, boom and nozzles two to three times with clean water until the foam and all traces of product have been removed.
Protective clothing:
Rinsing with water and detergent.
Effectiveness of cleaning procedures:
A study on the effectiveness of cleaning procedures performed on A19649B is provided below:

Report:	K-CP 4.2, [redacted] (2014). A19649B - The Effectiveness of the Spray Tank Cleaning Procedure. Syngenta Crop Protection AG, Münchwilen, Switzerland. Unpublished Report Number: 409466. Issue date 01.12.2014 (Syngenta File No. A19649B_10066)

Tests have been carried out to determine the effectiveness of the tank cleaning procedure for A19649B (SYN545974 SC (200)). After applying the cleaning procedure, 0.01 % residue was found in the refilled spray tank.
Therefore the cleaning procedure is deemed effective.
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.

Land transport

ADR/ RID:	
UN-Number:	3082
Class:	9
Labels:	9

Packaging group	III	
Proper shipping name :		ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (PYDIFLUMETOFEN)

Sea transport

IMDG:	
UN-Number:	3082
Class:	9
Labels:	9
Packaging group III	
Proper shipping name :	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (PYDIFLUMETOFEN)
Marine pollutant :	Marine pollutant

Air transport

IATA-DGR	
UN-Number:	3082
Class:	9
Labels:	9
Packaging group III	
Proper shipping name :	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (PYDIFLUMETOFEN)

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: No hazardous reactions by normal handling and storage according to provisions.

B.4.3. EMERGENCY MEASURES IN CASE OF AN ACCIDENT

The safety data sheet, which contains advice for emergency measures in case of an accident is available in Doc H of the dossier.

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.
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.
Do not contaminate ponds, waterways or ditches with chemical or used container.
Do not dispose of waste into sewer.
Where possible recycling is preferred to disposal or incineration.
If recycling is not practicable, dispose of in compliance with local regulations.

Additional advice:
If the product contaminates rivers and lakes or drains inform respective authorities.
Disposal of damaged packaging, absorbents and other materials
Empty remaining contents.
Triple rinse containers.
Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not re-use empty containers.
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:
No personal respiratory protective equipment normally required. A particulate filter respiriator may be necessary until effective technical measures are installed.

Hand protection:
Chemical resistant gloves should be used. 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.
First aid measures
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.

B.4.4. PACKAGING, COMPATIBILITY OF THE PLANT PROTECTION PRODUCT WITH PROPOSED PACKAGING MATERIALS

The packaging proposed for A21857B are 1 liter bottle, 5, 10 and 20 liter canisters. Information/data on packaging type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport and handling, resistance to and compatibility with the contents of the packaging, have been submitted, evaluated and are considered to be acceptable.

Table 4.4-1: Packaging information for 1 liter bottle

Type	**Description**
Material:	High density polyethylene (HDPE) or Co-extruded high density polyethylene/polyamide (PE/PA)
Shape/size:	89mm × 230mm (diameter × height)
Opening:	Screw cap closure (45 mm diameter) with induction heat seal or compression wad and tamper evident ring
Closure:	Screw cap closure (45 mm diameter)
Seal:	Induction heat seal or compression wad and tamper evident ring
Manner of construction	extruded
UN/ADR	compliant

Table 4.4-2: Packaging information for 5 liter canister

Type	**Description**
Material:	High Density Polyethylene (HDPE) or Fluorinated high density polyethylene (f-HDPE)
Shape/size:	190mm × 135mm × 315mm (Length × Width × Height)
Opening:	Screw cap closure (63 mm diameter) with induction heat seal or compression wad and tamper evident ring.
Closure:	Screw cap closure (63 mm diameter)
Seal:	Induction heat seal or compression wad and tamper evident ring
Manner of construction	extruded
UN/ADR	compliant

Table 4.4-3: Packaging information for 10 liter canister

Type	**Description**
Material:	High Density Polyethylene (HDPE) or Fluorinated high density polyethylene (f-HDPE)
Shape/size:	240mm × 180mm × 375mm (Length × Width × Height)
Opening:	Screw cap closure (63 mm diameter) with induction heat seal or compression wad and tamper evident ring.
Closure:	Screw cap closure (63 mm diameter)
Seal:	Induction heat seal or compression wad and tamper evident ring
Manner of construction	extruded
UN/ADR	compliant

Table 4.4-4: Packaging information for 20 liter canister

Type	**Description**
Material:	High Density Polyethylene (HDPE) or Fluorinated high density polyethylene (f-HDPE)
Shape/size:	295mm × 245mm × 400mm (Length × Width × Height)
Opening:	Screw cap closure (63 mm diameter) with induction heat seal or compression wad and tamper evident ring.
Closure:	Screw cap closure DIN 60
Seal:	Induction heat seal or compression wad and tamper evident ring
Manner of construction	extruded
UN/ADR	compliant

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.

Report:	K-CP 2.7, [redacted] (2017). A21857B - Storage Stability and Shelf Life Statement (2 Weeks 54 °C) in Packaging Made of HDPE according to CIPAC MT 46.3. Syngenta Crop Protection AG, Münchwilen, Switzerland. Unpublished report no. 300074164, Issue date 08.09.2017 (Syngenta File No. VV-468697)

Report:	K-CP 2.7, [redacted] (2019). A21857B - A21857B - Storage Stability and Shelf Life Statement (2 Years 20°C) in Packaging Made of HDPE. Syngenta Crop Protection AG, Münchwilen, Switzerland. Unpublished report no. 300140168, Issue date 30/04/2019 (Syngenta File No. VV-471984)

B.4.5. PROCEDURES FOR DESTRUCTION OR DECONTAMINATION OF THE PLANT PROTECTION PRODUCT AND ITS PACKAGING

B.4.5.1. Neutralisation procedure

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.

B.4.5.2. Controlled incineration

As the halogen content of A19649B 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.

B.4.6. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCP 2.7	[redacted]	08/09/2017	A21857B - Storage Stability and Shelf Life Statement (2 Weeks 54 °C) in Packaging Made of HDPE according to CIPAC MT 46.3 Report No. 300074164 Document No. VV-468697 , A21857B_10025 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	Y	Data/study report never submitted before to this country	SYN	N
KCP 2.7	[redacted]	30/04/2019	A21857B - Storage Stability and Shelf Life Statement (2 Years 20°C) in Packaging Made of HDPE Report No. 300140168 Document No. VV-471984 , A21857B_10166 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	Y	Data/study report never submitted before to this country	SYN	N