

Art. 51
Extension of authorisation for minor uses

REGISTRATION REPORT

Part A

Risk Management

Product code: AMISTAR

Active Substance:

Azoxystrobin 250 g/L

COUNTRY: Germany

Central Zone

Zonal Rapporteur Member State: Germany

NATIONAL ASSESSMENT

Applicant: Syngenta Agro GmbH

Date: 18/11/2014

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PART A – Risk Management

This document describes the acceptable use conditions required for extension of the registration of AMISTAR containing Azoxystrobin in Germany.

The risk assessment conclusions are based on the already existing registration of the PPP.

Assessments for the safe use of AMISTAR have been made using endpoints agreed in the EU reviews of Azoxystrobin.

Appendix 1 of this document provides a copy of the final product authorisation in Germany.

1 Details of the application

Application to extend the authorisation of a plant protection product (PPP) already authorised in Germany to minor uses not yet covered by that authorisation.

The application is intended for use in Germany only.

1.1 Application background

Details on applicant and application

Plant protection product	AMISTAR
Type of application	Zonal application according to Article 51, ZRMS=DE, first application (GV1)
Registration number	025090-00/01
Applicant	Syngenta Agro GmbH , Am Technologiepark 1 -5, 63477 Maintal, Deutschland
Authorisation holder	Syngenta Agro GmbH , Am Technologiepark 1 -5, 63477 Maintal, Deutschland
Function	Fungicide
Type of formulation	Suspension concentrate (SC)
Expiration of authorisation	31.12.2014

1.2 Annex I inclusion

The active substances included in the plant protection product are approved according Regulation (EC) No 1107/2009. The present application is in line with the provisions of the approvals.

Active substance (BVL Number)

Azoxystrobin (0902)

Content in PPP	250 g/L
Approval status	Approved according Regulation (EC) No 1107/2009
Approval	Regulation (EU) No 703/2011
Expiration of approval	31/12/2021

1.3 Regulatory approach

The PPP is already registered in Germany according to Directive 91/414/EEC taking into account the uniform principles of Annex VI. Therefore the evaluation of the current application is limited to the points not covered by the existing registration.

1.3.1 Uses applied for and registration decision

Number of use	Plant/commodity/object	Harmful organism/purpose	decision
001	oats	crown rust of oats (<i>Puccinia coronata</i>)	Authorise

1.3.2 Public interest and minor use

According to Article 51 (2) a and c of the Regulation (EC) No 1107/2009 extensions of authorisation are only possible if the intended use applied for is minor in nature and in public interest.

In Germany the cultivated area of oats is about 141000 ha, of which approx. 14100ha need to be controlled. Calculation shows that authorisation holder will not profit from an authorisation of the requested use.

Upon this calculation and the examination of available alternative measures for the applied use it can be stated that the applied use is minor in nature and the authorisation is in the public interest.

1.4 Data protection claims

The applicant is the registration owner and claims data protection to the studies submitted to the plant protection product. There were no extra studies submitted with this application to extend the use to oats.

1.5 Letters of Access

Not necessary

2 Details of the authorisation

2.1 Product identity

Product name	AMISTAR
Authorisation number	025090-00
Composition	Azoxystrobin 250 g/L
Type of formulation	Suspension concentrate (SC)
Function	Fungicide
Authorisation holder	Syngenta Agro GmbH , Am Technologiepark 1 -5, 63477 Maintal, Deutschland

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

<i>Symbol(s)/Indication(s) of danger:</i>	
N	Dangerous for the environment
<i>Risk phrases:</i>	
R50/53	R 50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
<i>Safety phrases:</i>	
S 36/37	Wear suitable protective clothing and gloves.
S2	Keep out of the reach of children
S24	Avoid contact with skin
S35	This material and its container must be disposed of in a safe way.
S46	If swallowed, seek medical advice immediately and show this container or label
S57	Use appropriate container to avoid environmental contamination.
<i>Specific labelling requirement:</i>	
To avoid risks to man and the environment, comply with the instructions for use.	
Contains 1,2-benzisothiazole-3(2H)-one. May produce allergic reactions.	

2.2.2 Classification and labelling under Regulation (EC) No 1272/2008

<i>Hazard classes and categories:</i> (kein Labelling-Requirement!)
none
<i>Hazard pictograms:</i>

GHS09	environment
<i>Signal word:</i>	
<i>Hazard statements:</i>	
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
<i>Precautionary statements:</i>	
Not proposed by zRMS Germany, to be decided by applicant	
<i>Special rule for labelling of PPP:</i>	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
<i>Further labelling statements under Regulation (EC) No 1272/2008:</i>	
EUH 208 - Contains 1,2-benzisothiazole-3(2H)-one. May produce allergic reactions.	

2.2.2 R and S phrases under Regulation (EC) No 547/2011

none

2.2.3 Other phrases

2.2.3.1 Restrictions linked to the PPP under Regulation (EC) No 547/2011

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Human health protection	
SB001	Avoid any unnecessary contact with the product. Misuse can lead to health damage.
SB010	Keep out of the reach of children.
SE110	Wear tight fitting eye protection when handling the undiluted product.
SF245-01	Treated areas/crops may not be entered until the spray coating has dried.
SS110	Wear standard protective gloves (plant protection) when handling the undiluted product.
SS2101	Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.
SS610	Wear a rubber apron when handling the undiluted product.
Integrated pest management (IPM)/sustainable use	
NN291	The product is classified as slightly harmful for populations of the species <i>Episyrphus balteatus</i> (hover fly).
WMFC3	Mode of action (FRAC-group): C3 (for azoxystrobin)
Ecosystem protection	

NW 262	The product is toxic for algae.
NW 264	The product is toxic for fish and aquatic invertebrates.
NW 265	The product is toxic for higher aquatic plants.
NW 468	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use	
NN130	The product is classified as harmless for populations of the species <i>Pardosa amentata</i> and <i>palustris</i> (lycosid spiders).
NN161	The product is classified as harmless for populations of the species <i>Coccinella septempunctata</i> (seven-spotted ladybird).
NN165	The product is classified as harmless for populations of the species <i>Poecilus cupreus</i> (ground beetle).
NN170	The product is classified as harmless for populations of the species <i>Chrysoperla carnea</i> (lacewing).
NN1842	The product is classified as harmless for populations of the species <i>Aphidius rhopalosiphii</i> (braconid wasp).
NB6641	The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorisation is applied. (B4)

2.2.3.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions (mandatory labelling):
See 2.3 (Product uses)

Integrated pest management (IPM)/sustainable use	
Ecosystem protection (for use 01-001)	
NW 609-01	When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water-bearing surface waters - the product must be applied observing the minimum buffer zone stated below. It is not necessary to observe this buffer zone if the product is applied using equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended. Irrespective of this, in addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times. Violations may be punished by fines of up to 50 000 EUR. 5 m

2.3 Product uses

PPP (product name/code) **AMISTAR (025090-00)**
active substance 1 **Azoxystrobin**

Formulation type: **SC**
Conc. of as 1: **250 g/L**

safener -
synergist -

Conc. of safener: -
Conc. of synergist: -

Applicant: **Syngenta Agro GmbH**
Zone(s): **central EU**

professional use
non professional use

Verified by MS: yes

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	oats (AVESS)	F	crown rust of oats (<i>Puccinia coronata</i>) (PUCCCA)	spraying	BBCH 32-59 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 2 (14-28 days)	a) 1 L/ha b) 2 L/ha	a) 0,25 kg as/ha b) 0,5 kg as/ha	200-400	F	Restrictions (see 2.2.3.2) NW609-1 (5 m)

3 Risk management

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

Not relevant for extension of authorisation according article 51.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Not relevant for extension of authorisation according article 51.

3.1.2.2 Analytical methods for residues

Oats belong to the group of dry commodities. Sufficiently validated analytical are available for enforcing azoxystrobin in cereals.

3.1.3 Mammalian Toxicology

The PPP is already registered in Germany according to Directive 91/414/EEC.

If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected.

3.1.4 Residues and Consumer Exposure

The residue behaviour of the active substances Azoxystrobin has been evaluated within the EU review process. Information about metabolism is sufficient to evaluate the intended use in oats.

3.1.4.1 Residues

The available residue information is sufficient to perform an adequate assessment. Residues that are expected from the intended use of the plant protection product will not exceed the MRL set in Regulation (EC) No 396/2005 for Azoxystrobin.

3.1.4.2 Consumer exposure

An assessment of residue uptake by consumers (TMDI calculation, EFSA PRIMo) results in the following maximum ADI consumption:

Azoxystrobin (0.2 mg/kg bw/d) – 55 % (NL children)

Long-term dietary intake of residues of Azoxystrobin is unlikely to present a public health concern for European consumers.

No acute risk is expected from the consumption of oats treated according to the intended use.

3.1.5 Environmental fate and behaviour

No new studies are presented; all data were reviewed within the EU review and approval of the national authorisation 025090-00/00 according the uniform principles of directive 91/414/EEC.

3.1.6 Ecotoxicology

No new studies are presented; all data were reviewed within the EU review and approval of the national authorisation 025090-00/00 according the uniform principles of directive 91/414/EEC.

The PPP AMISTAR and the active substance azoxystrobin are toxic to the aquatic environment (aquatic invertebrates EC50 of 5.5 µg/L and a safety factor of 40). Subsequently no additional entries as those according to the evaluated use pattern and good agricultural practise are acceptable. No new risk assessment was necessary. The risk assessment for the authorised use 025090-00/00-001 also covers the use which is applied for here. Therefore the safety phrases and conditions of use NW262, NW264, NW265, NW468 and NW 609-1 with 5 m are assigned, see also 2.2.

Risk Assessment for Honeybees

The honeybee risk assessment for the main application covers the use in accordance with Article 51 of regulation (EC) No 1107/2009 (see also point 2.2).

3.1.7 Efficacy

Labelling in accordance with the requirements of ANNEX III General principles of integrated pest management under directive 2009/128/EC (see also point 2.2):

- The classification of effects on beneficial arthropods for the main application covers the use applied for under the terms of Article 51 of regulation (EC) No 1107/2009.
- The categories and labelling for mode of action for the main application cover the use applied for under the terms of Article 51 of regulation (EC) No 1107/2009.

According to Article 51 of the regulation (EC) No 1107/2009 the requirements for approval concerning the sufficient effect and any unacceptable effects on plants and plant products not need to be checked.

3.2 Conclusions

PPP AMISTAR is already registered in Germany according to Directive 91/414/EEC taking into account the uniform principles of Annex VI. The intended use is minor in nature and the extension of authorisation is in public interest. Effects on bees and other beneficials were evaluated in the frame of the already authorised uses. No additional effects are anticipated because of the extension of use.

The intended use in oats will not result in residues above the MRLs set in Regulation (EC) No 396/2005. A risk for consumers through the consumption of food with these residues of azoxystrobin is not expected. There is no special risk mitigation necessary which deviate from the existing registration.

Considering an application in accordance with the evaluated use pattern and good agricultural practise as well as strict observance of the conditions of use no harmful effects on groundwater or adverse effects on the ecosystem are to be apprehended.

3.3 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

None

Appendix 1 – Copy of the product authorisation

See below.

Appendix 2 – Copy of the product label

No product label available. Not mandatory according to Article 51 (5)

Appendix 3 – Letter of Access

No letter of access necessary. The applicant is authorisation holder.



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Verbraucherschutz und
Lebensmittelsicherheit

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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22200.025090-00/01.63637
(bitte bei Antwort angeben)

DATUM 18. November 2014

GV1 025090-00/01

AMISTAR

**Verfahren zur Erweiterung einer Zulassung nach Artikel 51 Abs. 1 der Verordnung (EG)
Nr. 1107/2009**

Bescheid

Die Zulassung des oben genannten Pflanzenschutzmittels

mit dem Wirkstoff: 250 g/l Azoxystrobin

Zulassungsnummer: 025090-00

Versuchsbezeichnung: SYD-90240-F-1-SC

Antrag vom: 12. Januar 2012

wird wie in Anlage 1 beschrieben auf der Grundlage von Art. 51 der Verordnung (EG) Nr. 1107/2009 des Europäischen Parlaments und des Rates vom 21. Oktober 2009 über das Inverkehrbringen von Pflanzenschutzmitteln und zur Aufhebung der Richtlinien 79/117/EWG und 91/414/EWG des Rates (Abl. L 309 vom 24.11.2009, S. 1) um folgende Anwendungsgebiete bzw. Anwendungen erweitert:

Anwendungsnummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
025090-00/01-001	Haferkronenrost (Puccinia coronata)	Hafer	

Festgesetzte Anwendungsbestimmungen

Es werden folgende Anwendungsbestimmungen gemäß § 36 Abs. 1 S. 1 des Gesetzes zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz - PflSchG) vom 6. Februar 2012 (BGBl. I S. 148, 1281), zuletzt geändert durch Artikel 4 Absatz 87 des Gesetzes vom 7. August 2013 (BGBl. I S. 3154) festgesetzt:

Siehe anwendungsbezogene Anwendungsbestimmungen in Anlage 1, jeweils unter Nr. 3.

Auflagen

Die Zulassung wird mit folgenden Auflagen gemäß § 36 Abs. 3 S. 1 PflSchG verbunden:

Siehe Anlage 1, jeweils unter Nr. 2.

Vorbehalt

Dieser Bescheid wird mit dem Vorbehalt der nachträglichen Aufnahme, Änderung oder Ergänzung von Anwendungsbestimmungen und Auflagen verbunden.

Abgelehnte Anwendungsgebiete bzw. Anwendungen

Für folgende Anwendungsgebiete bzw. Anwendungen lehne ich Ihren Antrag ab (siehe Anlage 2):

- keine -

Rechtsbehelfsbelehrung

Gegen diesen Bescheid kann innerhalb eines Monats nach Bekanntgabe Widerspruch erhoben werden. Der Widerspruch ist bei dem Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Messeweg 11/12, 38104 Braunschweig, schriftlich oder zur Niederschrift einzulegen.

Mit freundlichen Grüßen
im Auftrag

gez. Dr. Karsten Hohgardt
stellvertretender Abteilungsleiter

Dieses Schreiben wurde maschinell erstellt und ist daher ohne Unterschrift gültig.

Anlage

Anlage 1 zugelassene Anwendung: 025090-00/01-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Haferkronenrost (*Puccinia coronata*)

Pflanzen/-erzeugnisse/Objekte: Hafer

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Ackerbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Nein

Stadium der Kultur: 32 bis 59

Anwendungszeitpunkt: Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 2

- für die Kultur bzw. je Jahr: 2

- Abstand: 14 bis 28 Tage

Anwendungstechnik: spritzen

Aufwand:

- 1 l/ha in 200 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F) Freiland: Hafer
Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW609-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mindestens mit unten genanntem Abstand erfolgen. Dieser Abstand muss nicht eingehalten werden, wenn die Anwendung mit einem Gerät erfolgt, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr.

205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Unabhängig davon ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten. Zuwiderhandlungen können mit einem Bußgeld bis zu 50.000 Euro geahndet werden.

5 m

Begründung:

Das Pflanzenschutzmittel Amistar bzw. der darin enthaltene Wirkstoff Azoxystrobin weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere aquatische Invertebraten auf. Bewertungsbestimmend ist hier die EC50 für Azoxystrobin von 5,5 µg/L. Ausgehend von den geltenden Modellen zur Abdrift und einem angepassten Sicherheitsfaktor von 40 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 609-1 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Azoxystrobin in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Bewertungsbericht zu entnehmen.