

Art. 51 amendment
REGISTRATION REPORT
Part A

Risk Management

Product code: ProFume
Active Substances:
Sulfuryl fluoride 998 g/kg

COUNTRY: Germany
Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Landesbetrieb Wald und Holz NRW

Date: 10/05/2012

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PART A – Risk Management

This document describes the acceptable use conditions required for extension of the registration of ProFume containing sulfuryl fluoride in Germany.

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

Assessments for the safe use of ProFume have been made using endpoints agreed in the EU reviews of sulfuryl fluoride.

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	ProFume
Type of application	Zonal application according to Article 51, ZRMS=DE, first application (GV1)
Registration number	025395-00/02
Applicant	Landesbetrieb Wald und Holz NRW , Steinmüllerallee 13, 51643 Gummersbach, Deutschland
Authorisation holder	Dow AgroSciences GmbH, Truderinger Str. 15, 81677 München, Deutschland
Function	Insecticide
Type of formulation	Gas (packed in pressure bottle or pressure tank)
Expiration of authorisation	2021-12-31

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)

Sulfuryl fluoride (1048)

Content in PPP	998 g/kg
Approval status	Approved according Regulation (EC) No 1107/2009
Approval	Regulation (EC) No 540/2011
Expiration of approval	31/10/2020

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
02-001	deciduous trees, conifers (roundwood for shipment)	insects (bark- and timberbreeding beetles)	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 estimated treated amount of roundwood for shipment (deciduous trees, conifers) is about 358000 m³. Calculation shows that authorisation holder will not profit from authorisation in that use.

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

1.4 Data protection claims

No new studies were submitted.

1.5 Letters of Access

As no new studies were submitted no letter of access is required.

Authorisation holder agrees to the current application to extend the authorisation.

2 Details of the authorisation

2.1 Product identity

Product name	ProFume
Authorisation number	025395-00
Composition	Sulfuryl fluoride 998 g/kg
Type of formulation	Gas (packed in pressure bottle or pressure tank)
Function	Insecticide
Authorisation holder	Dow AgroSciences GmbH, Truderinger Str. 15, 81677 München, Deutschland

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC or Regulation (EC) No 1272/2008

N	Dangerous for the environment
T	Toxic
RX050	R 50: Very toxic to aquatic organisms.
RK022	R 48/20: Harmful: danger of serious damage to health by prolonged exposure through inhalation.
RX023	R 23: Toxic by inhalation
RX037	R 37: Irritating to respiratory system
SK001	S 1/2: Keep locked away and out of the reach of children
SX 23	S 23: Do not inhale gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer)
SX045	S 45: In case of an accident, or if you feel unwell, seek medical advice immediately (where possible, show this label)
SX063	S63
SP001	To avoid risks to man and the environment, comply with the instructions for use.

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

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

Operator protection

SB001 Avoid any unnecessary contact with the product. Misuse can lead to health damage.

SF160 Rooms must be aired for 24 hours.

VS005-1 Fumigations with substances stated in "GefStoffV" (Hazardous Substances Ordinance) annex I no.4.1 (1) till (3) require permission according to GefStoffV annex I no. 4.2 (1). When applying the product, the special regulations in GefStoffV annex I no. 4 in addition to the technical regulations for hazardous substances (TRGS 512 - Fumigations) must be observed.

Ecosystem protection

NW262 The product is toxic for algae.

NW264 The product is toxic for fish and aquatic invertebrates.

NW467 The product and its remains, empty containers and packaging 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.

Honeybee

NB663 Due to the manner in which authorisation governs application of the product, bees are not endangered. (B3)

Active substance

2.2.3.2 Specific restrictions linked to the intended uses

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

Ecosystem protection

–

2.3 Product uses

PPP (product name/code) active substance **ProFume (025395-00) Sulfuryl fluoride**

Formulation type: Gas (packed in pressure bottle or pressure tank)
Conc. of as: 998 g/kg

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

Applicant: **Landesbetrieb Wald und Holz NRW** **professional use**
Zone(s): **central EU** **non professional use**

Verified by MS: y

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:
					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		
02-001	DE	deciduous trees, conifers (roundwood for shipment)	I	insects (bark- and timberbreeding beetles), larvae to imago	fumiga- tion	all year round in case of investigation	a) 1 b) 1	a) 1500 g h/m ³ b) 1500 g h/m ³	a) 1497 as g h/m ³ b) 1497 as g h/m ³		N	Restrictions (see 2.2.3.2): To achieve satisfactory efficacy for robust species and development stages the temperature in the fumigation objects has to be T ≥ 20 °C. Application time of about 20 to 25 hours. Maximum gas concentration: 128 g/m ³ per single fumigation. Maximum amount per year: 4500 g h/m ³ . Use the ProFume Fumiguide to

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

The product uses applied for are for principle reasons of no concern regarding residues from the PPP.

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

Not relevant.

3.1.4.1 Residues

Not relevant.

3.1.4.2 Consumer exposure

Not relevant.

3.1.5 Environmental fate and behaviour

No new studies were presented; all data were reviewed within the EU review for the active substance sulfuryl fluoride and the national authorisation procedure for the product *ProFume* (025395-00/00), respectively, and assessed according to the uniform principles of Directive 91/414/EEC.

The environmental exposure evaluation for the minor use extension applied for (fumigation of containers) is covered by the uses already authorised.

Neither accumulation in soil nor leaching to groundwater of the active substance or relevant metabolites in concentrations above 0.1 µg/L has to be expected. Specific additional risk mitigation measures are not required.

3.1.6 Ecotoxicology

No new studies were presented; all data were reviewed within the EU review for the active substance sulfuryl fluoride and the national authorisation procedure for the product *ProFume* (025395-00/00), respectively, and assessed according to the uniform principles of Directive 91/414/EEC.

The risk for non-target organisms as a consequence of the minor use extension applied for is considered acceptable since exposure due to the intended use (fumigation of containers) is covered by the uses already authorised. Specific additional risk mitigation measures are not required.

The product *ProFume* as well as the active substance sulfuryl fluoride is very toxic to the aquatic environment. Therefore, additional labelling with risk (NW262, NW264) and safety phrases (NW467) is assigned, particularly to encourage prevention of any point source entry into surface waters; see also chapter 2.2.

The honeybee risk assessment for the main application covers the use(s) 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).

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 have not to be met.

3.2 Conclusions

PPP ProFume 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 uses(s).

The intended use in roundwood for shipment will not result in toxicologically relevant residues. A risk for consumers can therefore be excluded.

There is no special risk mitigation necessary which deviate from the existing registration.

Considering the minor use extension applied for neither harmful effects on groundwater nor unacceptable effects on the environment have to be apprehended as a consequence of proper use consistent with good plant protection practice. Specific additional risk mitigation measures are not required.

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

Authorisation see next page.

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. No new studies submitted.



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IHR ZEICHEN
IHRE NACHRICHT VOM
AKTENZEICHEN 200.22200.025395-00/02.56371
(bitte bei Antwort angeben)

DATUM 10. Mai 2012

GV1 025395-00/02

ProFume

Verfahren zur Erweiterung einer Zulassung nach Art. 51 der Verordnung (EG)

Nr. 1107/2009

Bescheid

mit dem Wirkstoff: 998 g/kg Sulfurylfluorid

Zulassungsnummer 025395-00 in weiteren Anwendungsgebieten

Versuchsbezeichnung: DOW-10000-I-0-GA

Ihr Antrag vom 10. August 2011

Die Zulassung des oben genannten Pflanzenschutzmittels wird wie in Anlage 1 beschrieben auf der Grundlage von Art. 51 der Verordnung (EG) Nr. 1107/2009 um folgende Anwendungsgebiete erweitert:

Dienstszitz Braunschweig
Bundesallee 50, Geb. 247
38116 Braunschweig
Tel: +49 (0)531 21497-0
Fax: +49 (0)531 21497-299

Abt. Pflanzenschutzmittel
Messeweg 11/12
38104 Braunschweig
Tel: +49 (0)531 299-5
Fax: +49 (0)531 299-3002

Dienstszitz Berlin
Mauerstraße 39-42
10117 Berlin
Tel: +49 (0)30 18444-000
Fax: +49 (0)30 18444-89999

Referatsgr. Untersuchungen
Diedersdorfer Weg 1
12277 Berlin
Tel: +49 (0)30 18412-0
Fax: +49 (0)30 18412-2955

Schadorganismus/ Zweckbestimmung	Pflanzen/ -erzeugnisse/Objekte	Anwendungsnummer
Insekten	Laubholz, Nadelholz	025395-00/02-001

Folgende Auflagen werden gemäß § 36 Abs. 3 S. 1 PflSchG erteilt :

Siehe anwendungsbezogene Auflage in Anlage 1, unter 3.

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

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.

Im Auftrag

gez.

Dr. Johannes Siebers

Anlage

Dieses Schreiben ist maschinell gefertigt und daher ohne Unterschrift gültig.

Anlage 1 genehmigte Anwendung: 025395-00/02-001

1 Anwendungsgebiet:

Schadorganismus/Zweckbestimmung	Insekten
Pflanzen/-erzeugnisse/Objekte	Laubholz, Nadelholz

2 Einsatzgebiet: Vorratsschutz

3 Kennzeichnungsauflagen:**3.1 Angaben zur sachgerechten****Anwendung:**

Anwendungsbereich	Container (für Warensendungen)
Erläuterung zum Schadorganismus	Rinden- und holzbrütende Käfer
Stadium des Schadorganismus	Larven bis Imago
Erläuterung zur Kultur	Rundholz zur Verschiffung
Anwendungszeitpunkt	Ganzjährig bei Befall
Maximale Zahl der Behandlungen	
- in dieser Anwendung	1
- für die Kultur bzw. je Jahr	1
Anwendungstechnik	begasen
- <i>Erläuterungen</i>	Für eine hinreichende Wirksamkeit ist eine Temperatur von 20 °C im Begasungsobjekt erforderlich. / aus Gasflasche
Aufwand	1500 g h/m ³
- <i>Erläuterungen</i>	maximale Gaskonzentration: 128 g/m ³ pro Begasung / Je Jahr darf insgesamt nicht mehr als 4500 g h/m ³ angewendet werden / Einwirkungszeit und Dosierung werden in Abhängigkeit von relevanten Einflussfaktoren durch den ProFume Fumiguide berechnet. Anwendung des Mittels nur bei Nutzung des spezifischen Computerprogrammes ProFume Fumiguide

3.2 Sonstige Kennzeichnungsauflagen:

- keine -

3.3 Wartezeiten:

(N) Container (für Warensendungen): Laubholz, Nadelholz
Die Festsetzung einer Wartezeit ist ohne Bedeutung.

4 Anwendungsbezogene Anwendungsbestimmungen:

- keine -