Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

PUBLICLY AVAILABLE VERSION

Sumilarv® 0.5G

Product type(s) 18

Pyriproxyfen as included in the Union list of approved active substances

R4BP3 Assset No: GR-0013034-000

Evaluating Competent Authority: Greece

Date: December 2017

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1 CONCLUSION

Sumilarv 0.5G is a Granule (GR) containing 0.525% w/w pyriproxyfen. Its physicochemical properties are considered acceptable. Acceptable analytical methods have also been submitted.
Sumilarv 0.5G is of low acute oral, dermal and inhalation toxicity, it is not a skin or eye irritant or a skin sensitiser. Sumilarv 0.5G does not contain any substance of concern based on toxicological data.
For professional users, safe uses have been identified for the loading of application equipment and/or application of Sumilarv® 0.5G according to the list of intended uses, when appropriate PPE is considered. The recommended type of PPE for each application scenario is as follows:

- Single layer of clothing and gloves, for manual application by hand (Scenario 1),
- Single layer of clothing, for mechanical application by hand granule spreader (Scenario 2),
- Coveralls over single layer of clothing and gloves for mechanical application by blower with granule nozzle (Scenario 3),
- No PPE for mechanical application using a crawler mount type power granular feeder (Scenarios 4 & 5).

For professional users an acceptable risk is demonstrated for the washing of Sumilarv® 0.5G contaminated clothing.
For the combined exposure of professional users, safe uses have been identified for the loading of application equipment and/or application of Sumilarv® 0.5G, followed by the cleaning of contaminated clothing, when appropriate PPE is considered, as above.

It is considered that there will be no significant indirect exposure following application of the product to animal houses, since in practice adults and children will not enter treated areas. If however adults and children were to enter treated animal houses, it is unlikely that children/toddlers will be exposed to such an amount of manure after application of the product that would result in undesirable health effects.

Concerning the Environmental exposure assessment, all calculations were conducted according to ECHA BPR Guidance and the TGD for PT18 for Stables and manure storage systems and are verified by the eCA. A potential for groundwater contamination was identified for the metabolite PYPAC, as the estimated concentrations using FOCUS PEARL 4.4.4 in groundwater slightly exceed the 0.1 µg/L limit for groundwater, for the Jokioinen and Hamburg scenarios only. These scenarios are though not representative of the conditions or climate found in Southern Europe and are therefore considered not relevant for the Sumilarv® 0.5G applications, as stated by the applicant Sumitomo Chemical. In all other cases, the 80th percentile average annual concentrations in groundwater for the worst-case application did not exceed <0.000001 µg/L for pyriproxyfen and the metabolite 4'-OH-pyr.

According to the Environmental risk assessment an acceptable risk from the use of Sumilarv® 0.5G at an application rate of 10 g a.s./m2 every month can be proposed for 11 animal sub-categories and manure storage types (i.e. 1, 2, 4, 5, 6, 7, 9, 10, 13, 14, and 15) and the use at an application rate of 20 g a.s./m2 every 3 months can be proposed for 12 animal subcategory and manure storage types (i.e. 1, 2, 3, 4, 5, 6, 7, 9, 10, 13, 14, and 15). As noted in the aquatic risk assessment, for all animal house uses which release waste water to an STP i.e. poultry housing (categories 8, 11, 12, 16, 17 and 18), the PEC/PNEC ratios for Pyriproxyfen are greater than 1 and consequently the product fails the surface

water risk assessment. Therefore, uses for these specific animal housings are not claimed by the applicant. In addition the Pyriproxyfen PEC/PNEC ratio for animal sub-category and manure storage type 3 (veal calf) is greater than 1 for the proposed application rate of 10 g a.s./m2 every month and this use is also not claimed by the applicant.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier	**Country (if relevant)**
Sumilarv® 0.5G	Greece

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Sumitomo Chemical (U.K.) Plc
	Address	Hythe House 200 Shepherds Bush Road London W6 7NL United Kingdom
Authorisation number	XX	
Date of the authorisation	XX	
Expiry date of the authorisation	XX	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	SC Environmental Science Co., Ltd
Address of manufacturer	2-8 Doshomachi 2-chome, Chuo-ku 541-0045 Osaka Japan
Location of manufacturing sites	312 Aza-Hirose, Aoyama, Yoka-cho, Yabu City 667-0001 Hyogo Japan

2.1.1.4 Manufacturer(s) of the active substance(s)

Active substance	Pyriproxyfen
Name of manufacturer	Sumitomo Chemical Co. Ltd
Address of manufacturer	27-1 Shinkawa 2-chome Chuo-ku 104-8260 Tokyo Japan
Location of manufacturing sites	Misawa Works, Aza-Sabishirotaira, Oaza-Misawa 033-0022 Misawa, Aomori Japan

2.1.2 Product composition and formulation

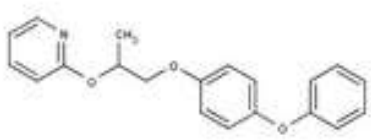
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes* ☒
No ☐

The product has a minor change compared to the one evaluated in the CAR of Pyriproxyfen.

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Pyriproxyfen
IUPAC or EC name	IUPAC name: 4-phenoxyphenyl (RS)-2-(2-pyridyloxy)propyl ether International Chemical Identification: 2-(1-Methyl-2-(4-phenoxyphenoxy)ethoxy)pyridine
EC number	429-800-1 (ELINCS)
CAS number	95737-68-1
Index number in Annex VI of CLP	613-303-00-3
Minimum purity / content	970 g/kg (sum of isomers; racemate)
Structural formula	

2.1.2.2 Candidate(s) for substitution

None.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Pyriproxyfen	4-phenoxyphenyl (RS)-2-(2-pyridyloxy)propyl ether	Active substance	95737-68-1	429-800-1	0.525 (TGAI) 0.51 (PAI)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
		Non-active substances			99.475

2.1.2.4 Information on technical equivalence

Not required as the active substance contained in the product is provided from an approved source, owned by Sumitomoto Chemical, used during the inclusion of pyriproxifen to Annex I of the BPD. The source of the active substance was already assessed on the EU level, and was a base of the reference specificiation. No technical equivalence is therefore provided.

2.1.2.5 Information on the substance(s) of concern

The product Sumilarv® 0.5G does not contain any substance of concern (for justification see Confidential Annex).

2.1.2.6 Type of formulation

GR - Granule

2.1.3 Hazard and precautionary statements

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Proposed classification and labelling:

Classification	
Hazard category	Aquatic Chronic 1
Hazard statement	H410
Labelling	
Signal words	Warning
Hazard statements	H410 - Very toxic to aquatic life with long lasting effects.
Precautionary statements	P103 Read label before use. P260 Do not breathe dust. P264 Wash contaminated skin thoroughly after handling. P280* Wear protective gloves/protective clothing/eye protection/face protection. P308+313 IF exposed or concerned: Get medical advice/attention. P405 Store locked up. Supplementary Precautionary Statements: P270 Do not eat, drink or smoke when using this product. P273 Avoid release to the environment. P307+311 IF exposed: Call a POISON CENTER or doctor/physician. P391 Collect spillage. P501 Dispose of contents/container in accordance with local/regional/national/international regulations
Note	* Based on the occupational risk assessment of Sumilarv® 0.5G (see below), P280c (Wear suitable protective clothing and gloves) should be included on the product label.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Animal housing and manure heaps

Proposed use description:

Product Type	PT18
Where relevant, an exact description of the authorised use	Control of flies in animal housing such as cattle pens, pig houses and poultry houses. Sumilarv® 0.5G is also intended to be used in indoor manure heaps.
Target organism (including development stage)	Flies (Muscidae) - larvae
Field of use	Indoor
Application method(s)	Spreading
Application rate(s) and frequency	For small infestations of flies: One application at 20 g/m^2 (2 kg/100 m^2) provides sufficient fly larvae control 2 months after the application. - Max 2 applications per year with 90 days interval. For large infestations of flies: Three repeated applications at 10 g product/m^2 each (1 kg/100 m^2) with an interval of 1

	month between applications provide sufficient fly larvae control 3 months after the first application. - Max 6 applications per year with 30 days interval.
Category(ies) of users	Professionals only
Pack sizes and packaging material	Please see the relevant section.

Use-specific instructions for use

Proposed use-specific instructions for use:

Efficacy

Applied manually or by mechanical granule spreader.

- for animal housing applications: scattering of Sumilarv® 0.5G as evenly as possible over the surface of the manure. Pay particular attention around pillars, posts, corners where manure is easily accumulated.
- for indoor manure heaps applications: scattering of Sumilarv® 0.5G as evenly as possible over the entire surface of the manure heap.

The product should be applied at the beginning of the presence of flies and when temperatures are favourable to their spreading.

For a more rapid action against flies, an adulticide may be used in addition to this product.

Sumilarv® 0.5G is a product effective on larval stage of insects. Imitating the natural hormones, it acts on the normal cycle of insects impeding the development from the stage of larva to that of the adult. As an insect growth regulator a delay will be seen in reducing the number of adult insects.

Strategies for avoiding and/or managing the development of resistance are provided as follows:

- Where an extended period of fly control is required, treatments should be alternated with products with different mode of action.
- Fly infestation in the animal house can be estimated by monitoring methods (e.g. monitoring of (re)-appearance of larvae in the manure or adult fly population with glue strips) prior to chemical treatment.
- The use of the product can be combined with other sanitation measures (e.g. frequent removal of dung) or non-chemical means of control (for example biological control including the use of parasitoids) within an integrated fly control program.
- Levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance, noting that sanitary conditions and proximity of untreated refuges can contribute to the risk of re-infestation.
- Check the efficacy of the product on site : if needed, causes of reduced efficacy must be investigated to ensure that there is no resistance or to identify potential resistance.
- The users should inform if the treatment is ineffective and report straightforward to the registration holder
- The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

Do not breathe dust. Wear protective clothing, gloves, eye and face protection*. Wash contaminated skin thoroughly after handling.

* to be confirmed by the applicant based on product classification.

Use-specific risk mitigation measures

Proposed risk mitigation measures specific to the use:

Please refer to the general directions below.

Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Proposed particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment specific to the use:

None specific to the use. Please refer to the general instructions below.

Where specific to the use, the instructions for safe disposal of the product and its packaging

Proposed instructions for safe disposal of the product and its packaging specific to the use:

None specific to the use. Please refer to the general instructions below.

Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Proposed instructions for safe disposal of the product and its packaging specific to the use:

None specific to the use. Please refer to the general instructions below.

2.1.5 General directions for use

2.1.5.1 Instructions for use

See above

2.1.5.2 Risk mitigation measures

Proposed risk mitigation measures:

Avoid release of Sumilarv® 0.5G into the environment. The product shall not be applied in animal housings and manure heaps at the same time. Sumilarv® 0.5G at 10 g a.s./m^2 every month should not be used in the following animal subcategories and storage types: • Veal Calf (3) • Laying hen, battery cages with aeration (8) • Laying hen, free range with litter floor (11)

- Broiler, free range with litter floor (12)
- Turkey, free range with litter floor (16)
- Duck, free range with litter floor (17)
- Geese, free range with litter floor (18)
-

Sumilarv® 0.5G at 20 g a.s./m^2 every 2 months month should not be used in the following animal subcategories and storage types:

- Laying hen, battery cages with aeration (8)
- Laying hen, free range with litter floor (11)
- Broiler, free range with litter floor (12)
- Turkey, free range with litter floor (16)
- Duck, free range with litter floor (17)
- Geese, free range with litter floor (18)

For professional users, safe uses have been identified for the loading of application equipment and/or application of Sumilarv® 0.5G according to the list of intended uses, when appropriate PPE is considered. The recommended type of PPE for each application scenario is as follows:

- Single layer of clothing and gloves, for manual application by hand,
- Single layer of clothing, for mechanical application by hand granule spreader,
- Coveralls over a single layer of clothing and gloves for mechanical application by blower with granule nozzle,
- No PPE for mechanical application using a crawler mount type power granular feeder.

For professional users an acceptable risk is demonstrated for the washing of Sumilarv® 0.5G contaminated clothing.

For the combined exposure of professional users, safe uses have been identified for the loading of application equipment and/or application of Sumilarv® 0.5G, followed by the laundering of contaminated clothing, when appropriate PPE is considered, as above.

2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Proposed particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment:

First aid measures:

- Inhalation: Remove victim immediately from source of exposure.
- Ingestion: Rinse mouth thoroughly. Get medical attention.
- Skin contact: Wash the skin immediately with soap and water.
- Eye contact: Not relevant

First aid measures may be required in case of accidental exposure, inhalation or ingestion of the product. Get medical attention if in doubt.

Environmental precautions:

- Do not allow to enter drains, sewers or watercourses.

Methods and material for containment and cleaning up:

- Dam and absorb spillages with sand, earth or other non-combustible material. Collect spillage in containers, seal securely and deliver for disposal according to local regulations. Do not contaminate water sources or sewer.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Proposed instructions for safe disposal of the product and its packaging

Waste treatment methods:

- Dispose of waste and residues in accordance with local authority requirements.
- Do not allow runoff to sewer, waterway or ground.
- Residues and empty containers should be taken care of as hazardous waste according to local and national provisions.

2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Proposed conditions of storage and shelf-life of the product under normal conditions of storage:

The product remains stable for 2 years when stored in its original, unopened container under cool, dry and well-ventilated conditions.

Conditions for safe storage, including any incompatibilities: Do not store near heat sources or expose to high temperatures.

2.1.6 Other information

Proposed application codes:

Application codes:

Main target / target organisms to be controlled: flies / I.3.12.6 Muscidae

Developmental stages of target organisms to be controlled: II.1.2 Larvae

Function/Mode of action of a.s./b.p./ type of effect: III.2.4 Growth regulating effect

Field of use: Indoor use: IV 1.3.4 Animal House, IV 1.3.5 Others

User category: V.2 professional

Method of application: VI.9 Other method of application: Spreading

Application aim: VII.2 Health protection and VII.3 Material protection (household)

Type of formulation: VIII.4 solid formulation

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Standardized pouch	5 kg Horizontal width (mm) 210 ± 2.5 Vertical width (mm) 320±2.0	PET (polyethylene terephthalate) // PA (polyamide (nylon)) // M (aluminum foil) // PP (polypropylene) Thickness respectively: 12 // 16 // 9 // 60 µm	Head flat ended seal Seal width (mm) 10±2.0	Professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Please refer to the list of data submitted by the applicant and relied on in Appendix 3.1

2.1.8.2 Access to documentation

Confidential information

2.2 Assessment of the biocidal product

2.2.1 Intended use(s) as applied for by the applicant

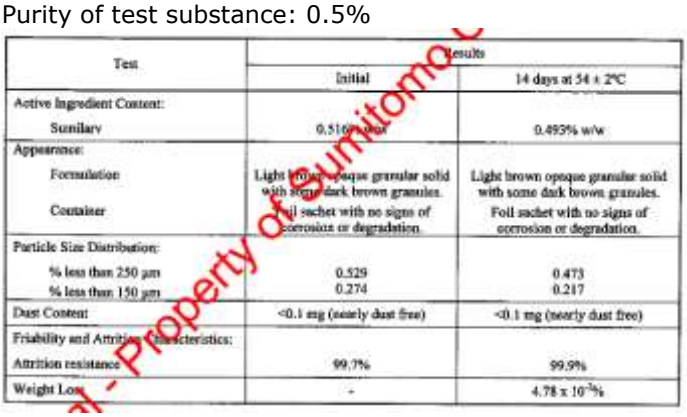
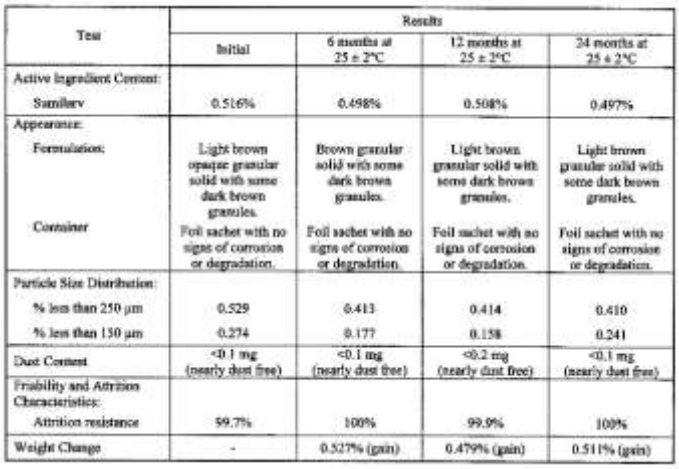
Table 2. Intended use # 1 – Animal housings and manure heaps

Product Type(s)	PT18
Where relevant, an exact description of the authorised use	Controlling flies in farm applications such as cattle pens, pig houses and poultry houses. This list is not intended to be exhaustive and instead a general claim for the *'control of flies in animal housing'* is requested. Sumilarv® 0.5G is also intended to be used in indoor manure heaps.
Target organism (including development stage)	Muscidae (flies) (larvae)
Field of use	Indoor
Application method(s)	Spreading
Application rate(s) and frequency	Sumilarv® 0.5G should be applied either as an application at a rate of 20 g of product/m2 (equivalent to 0.1 g a.s./m2) every 3 months, or with repeated applications at 10 g product/m2 (equivalent to 0.05 g a.s./m2) at 1 month intervals.
Category(ies) of user(s)	Professionals only
Pack sizes and packaging material	Please see the relevant section.

2.2.2 Physical, chemical and technical properties

Note: the biocidal product has been evaluated in the CAR of Pyriproxyfen.

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**
Physical state at 20 °C and 101.3 kPa	Visual Inspection at room temperature	0.5%	Solid (granular)	Confidential information IUCLID 3.1
Colour at 20 °C and 101.3 kPa	Visual Inspection at room temperature	0.5%	Light brown opaque granule	Confidential information IUCLID 3.1
Odour at 20 °C and 101.3 kPa	No guideline		No signs of odour indicated	
Acidity / alkalinity	Sumilarv® 0.5G is a granule to be applied directly. Therefore, an acidity/alkalinity study is not technically feasible.			
Relative density / bulk density	EC METHOD A.3 (pycnometer method)	0.5%	2.06 at 22.0 ± 0.5°C	relative density Confidential information IUCLID 3.3
Storage stability test – **accelerated storage**	Assumed according to CIPAC MT 46.3			Confidential information IUCLID 3.4.1.1 - 001.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	Purity of test substance: 0.5%  No significant decrease of active ingredient content and no significant changes in technical properties after storage for 14 days at 54 ± 2°C			
Storage stability test – **long term storage at ambient temperature**	Assumed according to FAO manual Purity of test substance: 0.5%  No significant decrease of active ingredient content and no significant changes in technical properties after storage for 24 months at 25 ± 2°C in foil sachets.			Confidential information IUCLID 3.4.1.1 - 002.
Storage stability test – **low temperature stability test for liquids**	Not applicable.			
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Not required. Sumilarv® 0.5 G is packed in single use, opaque foil sachets. Therefore, the light cannot infiltrate the packaging and cause any effects on the product contained within them - as such, a study of the effects of light is not required as it is unjustified given the nature of the packaging.			
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	The storage stability tests were run for 14 days at 54 ± 2°C and for 24 months at 25 ± 2°C in foil sachets (Confidential information). There was no significant change in the apparance of the formulation of the test material during storage. No relevant effects of the temperature is expected. Based on experience, no relevant effects of the humidity on the product is also expected.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	The storage stability tests were run for 14 days at 54 ± 2°C and for 24 months at 25 ± 2°C in foil sachets (Confidential information). The packaging used in the shelf-life study show no signs of corrosion or degradation and is representative to the commercial packaging. Based on experience the product has been previously under the same type of packaging and no compatibility issues have been identified.			
Wettability	Not required. The product is not intended to be dispersed in water.			
Suspensibility, spontaneity and dispersion stability	Not required. The product is not intended to be dispersed in water.			
Wet sieve analysis and dry sieve test	The particle size distribution has been determined according to the CIPAC MT58 test and the dust content according to the CIPAC MT171 test.			
Emulsifiability, re-emulsifiability and emulsion stability	Not applicable. The product is a granular formulation.			
Disintegration time	Not applicable. The product is a granular formulation			
Particle size distribution, content of dust/fines, attrition, friability	Size distribution: CIPAC MT 187 and CIPAC MT58 Dust : CIPAC MT 171 Attrition: CIPAC MT 178	0.5%	CIPAC MT187 : Particle size distribution: d(0.1) µm : 93±7; d(0.5) µm: 501±6; d(0.9) µm: 1011± 17 CIPAC MT58: Granules of Sumilarv 0.5G range from 150 to 850 µm in size, with 98% of granules being 355 µm or bigger.Only 0.117% of granules are smaller than 150 µm in size. Content of dust: < 0.1 mg or 0.1 mg Attrition resistance: 99.7%	Studies Confidential information IUCLID 3.5
Persistent foaming	Not required. The product is not intended to be applied in water.			
Flowability/Pourability/ Dustability	CIPAC MT 172	0.5%	The substance is fully flowable through a 4.75 mm aperture sieve.	Confidential information IUCLID 3.5
Burning rate — smoke generators	Not required according to the proposed use			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Burning completeness — smoke generators	Not required according to the proposed use			
Composition of smoke — smoke generators	Not required according to the proposed use			
Spraying pattern — aerosols	Not required according to the proposed use			
Physical compatibility	No specific incompatibility known			
Chemical compatibility	No specific incompatibility known			
Degree of dissolution and dilution stability	Not required according to the proposed use			
Surface tension	Not applicable. The product is a granular formulation			
Viscosity	Not applicable. The product is a granular formulation			

Conclusion on the physical, chemical and technical properties of the product
The product Sumilarv® 0.5G is a granular insecticide. The appearance of the product is light brown granules, with no odour. It is not explosive, flammable and has no oxidising properties. It has a self-ignition temperature above 400°C. The packaging material was resistant to its content in the 2-year storage stability study. The stability data indicate a shelf life of at least 2 years when stored at 25 ± 2°C in foil sachets. The technical characteristics of Sumilarv® 0.5G are acceptable for a granular formulation.

2.2.3 Physical hazards and respective characteristics

Explosives	Argumentation based on the co-formulants	Not applicable	Neither the active ingredient pyriproxyfen or any of the co-formulants in the formulation Sumilarv® 0.5G exhibit any explosive properties. Therefore, it can be inferred that the formulation itself will not demonstrate any explosive properties.	Expert statement IUCLID 4.1
Flammable gases	Not applicable for the formulation.			
Flammable aerosols	Not applicable for the formulation.			
Oxidising gases	Not applicable for the formulation.			
Gases under pressure	Not applicable for the formulation.			
Flammable liquids	Not applicable for the formulation.			
Flammable solids	EC METHOD A.10	0.5%	No combustion is propagated over the 200 mm of the preliminary screening test.	Confidential information IUCLID 4.2

			Therefore, the product is not combustible.	
Self-reactive substances and mixtures	Not applicable. The product is thermally stable and does not have explosive or self-reactive properties.			
Pyrophoric liquids	Not applicable for the formulation			
Pyrophoric solids	Not required. The product is stable at room temperature for prolonged periods of time and does not ignite spontaneously on coming into contact with air at normal temperatures			
Self-heating substances and mixtures	Not required. The experience in manufacture or handling shows that the product is not is liable to self-heat.			
Substances and mixtures which in contact with water emit flammable gases	Not required. The experience in handling and use shows that the substance or mixture does not react with water			
Oxidising liquids	Not applicable for the formulation			
Oxidising solids	Argumentation based on the co-formulants	Not applicable	Neither the active ingredient Sumilarv or any of the co-formulants in the formulation Sumilarv® 0.5G exhibit any oxidising properties. Therefore, it can be inferred that the formulation itself will not demonstrate any oxidising properties	Expert statement IUCLID 4.4
Organic peroxides	Not required considering the structure of the coformulants. The product is also thermally stable and does not have self-reactive properties.			
Corrosive to metals	Not required. Experience may have proven the absence of corrosivity to metals.			
Auto-ignition temperatures of products (liquids and gases)	Not applicable for the formulation.			
Relative self-ignition temperature for solids	EC METHOD A.16	0.5%	There was no significant exothermic reaction of the test item, indicating that it does not self-ignite under the conditions of the test.	Confidential information IUCLID 4.17.2
Dust explosion hazard	The product should not exhibit any oxidising properties and based on experience of handling and using the product, no dust explosion hazard is expected			

Conclusion on the physical hazards and respective characteristics of the product

Based on the composition of the product it is considered unlikely to have explosive or oxidising properties. It is not flammable. Stability was confirmed in an accelerated storage stability test (14 days at 54°C) and in a shelf-life study of 24 months at ambient temperature. The assessment did not reveal any physico-chemical properties which could adversely affect the use of the product, and showed the product to have no effects on the packaging proposed for use. An evaluation of the safety data sheets of all ingredients in Sumilarv® 0.5G did not indicate a risk due their physico-chemical properties. In conclusion, users are not considered to be at risk due to the physical-chemical properties of the formulated product.
No classification is therefore considered necessary Sumilarv® 0.5G.

Concerning the packaging in the storage stability studies the applicant has stated that:

"The proposed commercial packaging for Sumilarv® 0.5G is a standardized pouch from PET (polyethylene terephthalate) II PA (polyamide (nylon)) II M (aluminium foil) II PP (polypropylene) with thickness respectively: 12 II 16 II 9 II 60 µm.
Sumitomo Chemical Co. Ltd confirmed the GLP 2-year storage stability study (confidential information) and the LP accelerated storage stability (confidential information), even if not specified in the studies, were done with foil sachet with, as an inside layer, LLDPE (linear low density polyethylene) - 12-µm PETIDL/9-µm AL/DL/15-µm ONYIDL/70-µm LLDPE.
The stability of formulated content in the foil bag is influenced mainly by inner material, provided there is no water penetration.
Sumilarv® 0.5G is a granular, semi-solid, formulation, which would not be absorbed into polyethylene or polypropylene.
The stability of Sumilarv 0.5G itself is therefore determined by the formulation composition.
The packaging of solids requires in particular a selection of materials to ensure the absence of leakage from the packaging. Polypropylene and polyethylene are polyolefins widely used for multilayer packaging. They have well established good physical, thermal and mechanical properties and both present good chemical resistance and are easy to seal.
Based on the above rationale further testing of Sumilarv® 0.5G and the packaging interactions during storage stability is considered unnecessary and scientifically unjustified".

The applicant has also stated that the packaging material is of "equal" flexibility.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active substance	GC-FID	0-1.50 x 10^3 mg/L / 5	Linear – r^2 = 1.00	GC-MS and external standard	101%-102%	101%	0.245%	3.82x10^{-3} % w/w	Confidential information IUCLID 5

Analytical methods for monitoring
The analytical methods mentioned below are detailed in the document IIIA with th assessment report established by The Netherlands (version 2 of September 2012) for the approval of Pyriproxyfen, and are therefore not resubmitted in the process of the biocidal product authorisation. The Netherlands evaluated the different available studies and confirmed their suitability for the determination of pyriproxyfen in soil, in air, in drinking water and in surface water.

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analy-tical method**	**Fortification range / Number of measu-rements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantifycation (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active substance	BBA multi method L 00.00-34 GC-NPD (confirmation by GC-MS)	0.01 mg/kg /5 0.10 mg/kg /5 Overall /10	The response over the range 0.01 to 1.0 µg/mL was linear[1]. r^2 typically >0.9995	No interferen-ce being observed in control samples (<30% LOQ 0.01 mg/kg). Peak identity and recovery confirmed by GC-MS	Confidential information	Confidential information	Confidential information	0.01 mg/kg	Confidential information summari-sed in the original document IIIA (AR, 2012)

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortifica-tion range / Number of measure-ments**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active substance	GC-NPD (confirmation by GC-MS)	0.1 µg/m^3 /5 1.0 µg/m^3 /5 Overall / 10	The response over the range 0.01 to 1.0 µg/mL was linear[2]. r^2 typically >0.998	No interference being observed in control samples (<30% LOQ 0.1 µg/L). Peak identity and recovery confirmed by GC-MS	Confidential information	Confidential information	Confidential information	0.1 µg/ m^3	Confidential information summari-sed in the original document IIIA (AR, 2012) IUCLID 5

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active substance	GC-NPD	0.01 /5 0.1 /5 Overall / 10	The response of the GC-NPD and GC-MS to	The method was shown to be specific with no	Confidential information	Confidential information	Confidential information	0.01 µg/L	Confidential information summaris

1 although correlation was performed using a least squares fit of a non-linear function

2 although correlation was performed using a least squares fit of a non-linear function

Analytical methods for water									
			pyriproxyfen over the range 0.01 to 0.5 µg/ml was shown to be linear[3]. r^2 = 0.9999 using GC-NPD and 0.991 using GC-MS	interference being observed in control samples (<30% LOQ 0.01 µg/L). The confirmatory method was adequately shown as the determination was performed using GC-MS					ed in the original document IIIA (AR, 2012) IUCLID 5
a.s.	GC-NPD	0.01 /5 0.1 /5 Overall / 10	The response of the GC-NPD and GC-MS to pyriproxyfen over the range 0.01 to 1.0 µg/mL was linear[4]. r^2 was typically >0.998	No interference being observed in control samples (<30% LOQ 0.1 µg/L). Peak identity and recovery confirmed by GC-MS	Confidential information	Confidential information	Confidential information	0.1 µg/L	Confidential information summarised in the original document IIIA (AR, 2012) IUCLID 5

Analytical methods for animal and human body fluids and tisues
No such methods are required since pyriproxyfen is not classified as toxic or highly toxic

Analytical methods for monitoring of active substances and residues in food and feeding stuff
No such methods are required since the product is not intended for use on food or feedstuffs

Conclusion on the methods for detection and identification of the product
The methods are available for the analysis of the active substance in product. No revelant impurities or residues in the products occur, therefore no methods are presented, nor deemed necessary. Sufficiently validated methods are available for post-registration monitoring in soil water and air. No methods are required for animal and human body fluids and tissues nor for residues in food and feeding stuff.

[3] although correlation was performed using a least squares fit of a non-linear function for GC-MS

[4] although correlation was performed using a least squares fit of a non-linear function

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Sumilarv® 0.5G is intended to be used as an insecticide for the control of fly larvae in animal housing and in associated manure heaps. Flies are a common pest in such facilities and, if conditions for the establishment of significant populations are permitted to develop, can present a serious threat to human and animal health.

Through its effect on the insect maturation processes of flies, including all stages of larval development, Sumilarv® 0.5G acts to directly supress the build-up of such populations, resulting in a significant reduction in the emergence of adults and therefore effectively managing the build-up of flies before they become a nuisance and are able to transmit disease.

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

Sumilarv® 0.5G is intended for the control of flies in animal housing and in associated manure heaps. A general claim for the *'control of flies'* is requested by the applicant.

Sumilarv® 0.5G is intended to be used in a range of housing facilities, including, but not limited to: i) stables; ii) cattle pens; iii) pig houses; and iv) poultry houses. This list is not intended to be exhaustive and instead supports the request for a general claim of *'control of flies in animal housing'*.

Sumilarv® 0.5G is also intended to be used on indoor manure heaps.

The product is only intended to be applied directly to manure and other fly-breeding sites by professional pest control operators (PCO) or other suitably trained professionals.

The dosage is calculated based on the surface area of the breeding sites to be treated and not on the area of the facility.

2.2.5.3 Effects on target organisms, including unacceptable suffering

Sumilarv® 0.5G is intended to be used as an insecticide for the control of flies in animal housing. Sumilarv® 0.5G contains Pyriproxyfen, which is an insect juvenile hormone analogue that inhibits the insect maturation processes. It has activity as a growth regulator, through suppression of embryogenesis and the inhibition of metamorphosis and reproduction. The key measurement of the product's efficacy is through its capacity to suppress the emergence of adult flies following application to eggs and early stages of fly development.

2.2.5.4 Mode of action, including time delay

Sumilarv® 0.5G contains the active substance Pyriproxyfen (0.525% w/w of technical active substance; CAS number 95737-68-1). Pyriproxyfen is a juvenile hormone mimic that inhibits the insect maturation processes at multiple stages in the life cycle. It is classified by IRAC into group 7C. Pyriproxyfen acts as a insect growth regulator, through suppression of embryogenesis and inhibition of metamorphosis and reproduction. Pyriproxyfen has a wide range of public health uses for the control of insect pests, including flies. Morphogenic effects are seen during egg hatching, larval-to-pupal or nymph-to-adult transformation.

The key measure of the product's efficacy is therefore through its capacity to inhibit the emergence of adult flies and disrupt the establishment of a population, and because of this a time delay will be seen between product application and a decrease in the number of adult insects.

2.2.5.5 Efficacy data

Below is a summary of the data generated in the submitted efficacy studies provided by the applicant to support label claims for the efficacy of Sumilarv® 0.5G.

Table 2.2.5-1. Control of *Musca domestica* and *Stomoxys calcitrans*: efficacy of Pyriproxyfen when applied in the form of the biocidal product Sumilarv® 0.5G

Experimental data on the efficacy of the biocidal product against target organism(s)					
Test substance	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Sumilarv 0.5G	*Musca domestica* (housefly), and *Stomoxys calcitrans* (stable fly) (natural populations).	Field study carried out in Spain in cattle housing. Confidential information identified as having an infestation of the housefly and the stable fly in cattle farm settings having different husbandry practices. Testing areas at each site include animal housing and manure heaps.	The product was distributed at the sites using a professional backpack sprayer/duster. Efficacy was assessed at two application rates, 10 g of product/m^2 (5 sites as replicates), and 20 g of product/m^2 (4 sites as replicates), over a 3-month period. Product application for the lower rate of 10 g/m^2 was repeated at 1 month and at 2 months' time points (3x applications in total). A single application only was performed for the higher rate of 20 g/m^2.Three (3) sites were used as untreated control in order to monitor natural fluctuations of fly populations. A minimum of 10 sticky traps were placed *per* site to assess the infestation level (i.e.population of free flying flies) before and after treatment. Additionfally, a minimum of 5 samples of manure were collected *per* site and stored under natural conditions in the lab over a 2-week period after which time the number of emerging adult flies was recorded in order	Confidential information Overall, the product was effective in terms of decreasing adult emergence of both the housefly, *Musca domestica*, and the stable fly, *Stomoxys calcitrans*, when applied either at 10 g/m^2 (confidential information) or at 20 g/m^2 (confidential information). The 10 g/m2 application regime gave sufficient overall control of fly larvae (adult emergence inhibition) at 3 months after the 1st application while sufficient fly larvae control (adult emergence inhibition) was observed 2 months after a single application of the product at 20 g/m^2. Statistical analysis showed that both application rates of 10 and 20 g/m2 significantly decreased housefly and stable fly adult emergence when compared to the untreated control. Confidential information High decrease in trapped flies was recorded in utreated control sites, thus 46-67% 2 months and	Confidential information IUCLID 6.7

			to assess adult fly emergence before and after treatment. Assessments at 14, 7 and 0 days before treatment and at 7 and 14 days, 1, 2 and 3 months post-treatment application. The percentage decrease in fly numbers at each site was calculated, compared with the average of the three pre-assessments. A General Linear Model (GLM) on the emergence decrease for each species was performed using the effects of treatment and time as two individual factors. In addition individual one way ANOVA for each assessment time point was performed.	61-76% 3 months post application. The percentage decrease of free-flying insects in the treated sites is less characteristic for the evaluation of the emergence from the manure samples, due to the reinvasion of the natural population from outside the test site and also because of the difficulties incurred to assess the density of the population using a limited number of sticky fly papers in large premises.	
Sumilarv 0.5G (Confidential information)	*Musca domestica* (house fly) collected in advance in the farm. Confidential information	Semi-field test in large containers containing 10 kg of cow dung based culture medium.	Inoculation of larvae in the test medium confidential informaiton The containers were incubated under ambient conditions. 3 dose rates tested: 10 g/m^2, 20 g/m^2 and 50 g/m^2 Pupae are collected at fixed interval and adult emergence is assessed in the laboratory. The number of dead pupae, abnormal adult emergence and normal adult emergence for 8 weeks was evaluated/tested.	Mean inhibition of adult emergence: Confidential information Adult emergence in untreated controls however was generally low: Confidential information	Confidential informaiton IUCLID 6.7 Confidential information
Sumilarv 0.5G (Confidential information)	*Musca domestica* (house fly) (natural population)	Field study in outdoor heap of pig manure Japanese farm	Treatment of manure heap of about 1m height (7 m * 3 m) enclosed by a concrete frame. Single treatment of one half of the heap at rate 10 g/m^2 and the other half at rate 50 g/m^2.	Confidential information; reduction in the number of flying insects in shed adjacent to treated heap only occurred from week 5, but this was possibly due to a fall in temperature (no untreated control).	Confidential information IUCLID 6.7 Confidential information

			Collection of treated manure populated by the larvae was taken back to the lab at fixed intervals. Evaluation of adult emergence. Assessment of adults flying with fly catching ribbon. Pupae were collected as a control from an untreated section of the manure heap. Evaluation of the adult emergence corrected by Abott correction. Evaluation for 7 weeks.		
Sumilarv 0.5G (Confidential information)	*Musca domestica* (house fly) (natural population)	Field studies in pig sheds and cow sheds. Japanese farm.	(1) Treatment of floor with cow dung inside shed (20 g/m^2), once per week (2) Treatment of floor with cow dung inside shed (10 g/m^2), once per week (3) Treatment of heap of pig dung twice with 3 weeks interval (10 g/m^2) (2^{nd} treatment after addition of fresh dung) (4) 2 treatments of heap of cow/pig dung with an interval of 14 days at rate (5 g Sumilarv 0.5G/m^2), in both cases in combination with adulticide pyrethroid air spray Percent adult emergence recorded following treatment of floor with dung or of heap of dung. Evaluation of the percent adult emergence from pupae collected. Assessment of adults flying with fly catching ribbon.	Confidential information	Confidential information IUCLID 6.7 Confidential information
Sumilarv 0.5G (Confidential information)	*Musca domestica* (house fly) *A susceptible strain: Takaki strain.2 organophosphor*	Simulated-use study using cow manure with various strains of resistant flies	1 week and 3 weeks after treatment with 10 g/m2 once per week (test 2 above), 150 g of dung recovered from the shed was mixed with powdered animal rearing feed and water. The number of pupae and	Confidential information There was no significant difference between the OP resistant strains and the pyrethroid resistant strains.	

	us resistant strains: Yachiyo strain; Misaki strain. *2 pyrethroid resistant strains: Maruyamachi strain; Tendo strain.*		adult emergence are observed after inoculation of larvae.		
Sumilarv 0.5G (Confidential information)	*Musca domestica* (house fly) (natural population)	Field study on manures heaps of pig or cow sheds in Japan. 1) Manure farmyard A attached to pig shed (hogpen). (2) Manure farmyard B attached to a beef cattle cowshed. (3) Manure farmyard C attached to pig shed (hogpen). (4) Manure farmyard D attached to a dairy cattle cowshed. (5) A pig and cow shed (E) was reported to be an untreated control section with a manure farmyards of 130 m^2 but aerial application of organophosphorus was carried out on day 3 and on day 14.	(1) 10 g product/m^2 was spread on the manure heap (2) 10 g product/m^2 was spread on the manure heap. And a pyrethroid (permethrin) was applied before and after the treatment. (3) 20 g product/m^2 was spread on the manure heap. And a second treatment (pig farm +attached manure heap) was conducted at the rate of 5 g product/m^2 on day 38. (4) 50 g product/m^2 was spread on manure heap. Observations were made once weekly for up to 70 days of: - the number of flies, caught on 3-4 fly-catching ribbons put up in each shed; - emergence of pupae collected from treated heaps at sheds 1, 2, 3, 5. No pre treatment counts were made.	(1) Effective against adult emergence from pupae in laboratory from day 1-29 (Confidential information). The decrease of the inhibition rate after day 29 followed by the increase on day 56 was reported to a parasitization by wasps. The number of adult flies captured was 0-45 before day 36. From the figures (no raw data) provided in the report it seems that significant decline of adult flies was observed for up to 21 days post treatment compared with the trapped flies in the untreated control. (2) No analysis of inhibition rate was possible during days 2 to 14. On days 21 and 29, the rates were Confidential information respectively. The number of adult flies captured increased to about 50 flies and then decreased with the treatment with pyrethroid. In September, all manure was removed from this farm (day 43). (3) Effective against adult emergence from pupae in laboratory from day 1-29 (Confidential information). The	Confidential information IUCLID 6.7

				decrease of the inhibition rate after day 36 followed by the increase on day 63 was reported to a parasitization by wasps. The number of adult flies captured remains high along the study, with emergence from the floor especially from the fodder yard of the farm. (4) No pupae was obtained during one month after treatment. The number of adult flies was low (below 50). In September, all manure was removed from this farm (day 43). (5) There was a high variation of captured flies during the survey and of dead pupae in this study, which was considered as not conclusive. High parasitization of housefly by wasps was observed when the pupal density of housefly was low.	
Sumilarv 0.5G (Confidential information)	*Musca domestica* (house fly) and *Stomoxys calcitrans* (Stable fly). 98% of flies emerging from pupae sampled from hutches were stable flies.	Field study in calf hutches in the U.S.A. - straw treatment	4 indoor calf hutches; 2 treated and 2 untreated controls. 1 dose rate tested: 16 g/m^2. A retreatment after week 4. Assessment of adult emergence from sampled pupae and straw and numbers of trapped flies for up to 8 weeks. Samples of straw were collected, taken to the lab and seeded with housefly eggs and held until adults emergence.	During the monitoring period of 3-8 weeks after treatment, treatment gave nearly full control of emergence of fly larvae (Confidential information). The number of adult flies collected in emergence traps on 3 occasions during week 3-8 was reduced in treated hutches compared to the untreated control (Confidential information). Emergence of adult house flies (*Musca domestica*) from treated bedding collected during week 3-8 and inoculated in the laboratory with housefly eggs was reduced	Confidential information IUCLID 6.7 Confidential information

				compared to the untreated control (Confidential information). For the first 3 and 4 weeks post treatment a low percentage of hatched flies (*Stomoxys calcitrans*) was recorded in the control (Confidential information). On the 3rd week data on adult stable flies were collected from only one control site (Confidential information) and one treated site (Confidential information). Four (4) weeks after treatment the number of houseflies emerged from the seeded samples were Confidential information.	
Sumilarv 0.5G	Flies including *Musca domestica*(house fly) (natural populations)	Field study in sheep pen in Italy	(1) Treatment of floor with sheep dung inside shed (4 g product/m^2, single treatment) (2) Treatment of floor with sheep dung inside shed (8 g product/m^2, treatment repeated after 78 days (3) Untreated control (4) Confidential information The number of free flying flies was evaluated by sticky ribbons, placed approximatively every 10 m^2, at an height of 2-2.20 m height. The number of catch flies was evaluated after 24 hours. A weekly evaluation has been conducted except if the average weekly captures exceeded 100 adult flies/strip. Approximatively 100 adult flies/strips is considered as a threshold level for comfort of animal and of the farmer.	(1) Significant reduction of free-flying houseflies from day 14 to day 48 (Confidential information). (2) The number of adult houseflies was low at the start of the study but was maintained below 50 adult houseflies / strip until day 43. On 50 and 57 day post treatment adult housefly catches increased (Confidential information). After the second treatment, the number of free-flying houseflies decreased to a tolerable level after 20 days, until 48 days. (3) High number of adults were present and a plateau (Confidential information) was observed from day 14. (4) Three treatment were realised to maintain the population to acceptable levels.	Confidential information IUCLID 6.7 Confidential information

Sumilarv 0.5G	*Musca domestica* (house fly) larvae from laboratory breeding (50 larvae).	Semi field study with inoculation of larvae on manure heap outdoors and on rotting silage silo indoors Italian farm	Treatment of manure heap and rotting silage silo after inoculation of 3rd age larvae coming from laboratory breeding. 1 dose rate tested: 20 g/m^2. (1) Treatment of the accumulated pile of manure heaped up since 1 month. Assessment of adults flying in cages for 30 days. Comparison with a control (half of the area untreated). (2) Treatment of a side of rotting silage silo. Assessment of pupae and adults in laboratory for 28 days. Comparison with a control (half of the area untreated).	(1) Emergence of adults from housefly larvae inoculated on manure heaps was reduced during the monitoring period of 4 weeks (Confidential information). (2) Emergence of adults from housefly larvae inoculated on rotting silage was reduced during the monitoring period of 4 weeks (Confidential information).	Confidential information IUCLID 6.7 Confidential information
Sumilarv 0.5G	*Musca domestica* (house fly)	Laboratory study	Laboratory inhibition studies on emergence of housefly larvae when applied topically and when used to treat the larval medium. (1) Topical application to late 3rd instar. Observation of inhibition activity. (2) Treatment of larval medium with an aqueous or suspension of the compound. Observation of the inhibition activity. (3) Treatment of larvae of housefly (3rd instar of field strain) either by uniform application, by spot treatment (one spot on the surface of the medium), or by mixing the medium at 20 g product/m^2. Observation of the inhibition activity. (4) Treatment of the surface of the medium and observation of inhibition of emergence of of 3rd instar larvae of housefly (field	(1) ID_{50} for emergence of 4-day old CSMA housefly larvae 0.000732 g a.s./larva (topical application); (2) IC_{50} for emergence of 2-day and 4-day old CSMA housefly larvae 0.0048 and 0.0031 g a.s./g medium (treatment of growth medium). (3) 98.0% inhibition of emergence by uniform application, 98.3% by spot application, 97.7% by mixing. (4) 90.2%, 94.3% and 97.5% inhibition of emergence of 3rd instar larvae of housefly after treatment of the surface of the medium with at a rate of 2.5, 5 and 10 g product/m^2.	Confidential information IUCLID 6.7 B5.10/01

			strain) at 2.5, 5 and 10 g product/m^2		
Sumilarv 0.5G	OP-resistant *Musca domestica* (house fly)	Field study in waste treatment facilities.	Inoculation of waste with eggs and larvae (2-day-old and 4-day-old) of house flies. Treatment with Sumilarv 0.5G, 40 g product/m^2. Observation of the number of emerged flies and comparison with a treatment with Diflubenzuron (1 g a.s./m^2) and with a control observation for 36 days.	80% control of emergence of OP-resistant house flies was reached between 16 and 22 days after treatment. At other observation points (9, 13, 26, 33 and 36 days after treatment) the number of emerged flies in the treated waste was not different from that in untreated waste.	
Sumilarv 0.5G	*Musca domestica* (house fly) and false stable fly (*Muscina stabulans*) as dominant fly species	Field trial in poultry houses	Surface treatment at the rate of 20 g/m^2 – single application on manure. Also another test with surface treatment at the rate of 20 g/m^2 – single application on manure + an adulticide space spray.	Control of housefly and false stable fly within 1 week, lasting up to 12 weeks, by combination of Sumilarv 0.5G and Sumithion-NP flowdust (adulticide, aerial spray, applied "several times" - not further specified). Treatment on manure with Sumilarv 0.5G alone (20 g product /m^2) effective, from week 7 to week 11.	
Sumilarv 0.5G (Confidential information)	*Musca domestica* (house fly)	Field study in Japan Field study in pig or cow sheds with manure heaps Japanese farm	(1) Pig shed, 20 g Sumilarv 0.5G/m^2 spread on manure heap, retreatment with 5 g/m^2 on day 40 (2) Cow shed, 50 g Sumilarv 0.5G/m^2 spread on manure heap (3) Cow shed, 10 g Sumilarv 0.5G/m^2 spread on manure heap. Pyrethroid insecticide was applied on day 30. (4) Pig shed, 10 g Sumilarv 0.5G/m^2 spread on manure heap. (5) Pig shed, untreated control (only counts from free flying flies) The number of adult flies captured on fly ribbons and adult emergence in the laboratory of pupae collected	(1) Effective against adult emergence from pupae in laboratory from day 1-29 (≥90% abnormal emergence except day 21: 63%); 11% abnormal emergence 1 day before treatment; no effect on number of free-flying house flies. (2) No data on adult emergence from pupae in laboratory; inconclusive regarding effect on number of free-flying houseflies. (3) Inconclusive regarding adult emergence from pupae in laboratory (pre-test emergence too low, 51% abnormal emergence 1 day before	Confidential information IUCLID 6.7 B5.10/01

			from treated heaps were determined. Evaluation for up to 11 weeks.	treatment); no effect on number of free-flying house flies. (4) Effective against adult emergence from pupae in laboratory from day 1-21 (≥94%), not effective from day 29; 19% abnormal emergence; no consistent effect on the number of flies caught. The degrease in numbers of captured flies on sticky ribbon traps was not clear since houdeflies emerged from untreated places in some sheds. Therefore, it is nessecary to apply the product not only to manure but also to other places in the shed.	
Sumilarv 5WDG (WDG formulation containing 5.0% Pyriproxyfen); Confidential information	*Musca domestica* (house fly)	Field study in closed animal buildings (cowshed, sheepfold or pigsties) in France	Three replicates of closed livestock buildings in which the entire ground surface of the building was covered in manure. For Sumilarv 5 WDG two dose rates were tested: 1 or 2 g product in every 1 litre water/m^2. The spray dilutions were applied to the surface of the manure using a commercial sprayer. Confidential Untreated replicate buildings were also maintained. The number of emerged adult flies was counted using 40x40 cm sticky strips, with one strip for every 50 m^2 ground area. The number of flies on strips were counted -7 and -3 days prior to applications and then 24 hours, and 14, 30, 60 and 90 days	Sumilarv 5WDG applied at the highest dose rate (equivalent to 20 g/m^2 of Sumilarv® 0.5G) gave effective management of flies (>90%) from 1 to 3 months after application. At the lower dose rate control (equivalent to 10 g/m^2 of Sumilarv® 0.5G), was approximately 90% only after 1 month, decreasing thereafter For reference products control was 99%, after 90 90 days, while in the untreated control only 3% and 6% reduction of fly population was recorded.	Confidential information IUCLID 6.7

			after. Only *M. domestica* flies were counted.		
Sumilarv 0.5G (Confidential information	*Musca domestica* (house fly) - Miyakonojo strain of *Musca domestica* (resistant to pyrethroids and to organophosporus compounds)	Simulated field test in Japan	Seeding of the test medium with eggs and larvae After seeding of the test medium (10 kg of swine manure) with 300 eggs, 300 2-day-old and 500 4 -day-old larvae, the test medium was treated 3 hours later. Dose tested: 20 g product/m^2 Another 500 2 -day-old and 500 4 -day-old larvae of the same strain were released into the manure again on the 13^{th} day. Newly emerged adults were collected from the trap (stainless steel screen) and counted every 3 or 4 days for 49 days. The efficacy is expressed as the corrected mortality for the number of flies emerged from an untreated plot. The containers are placed in a hen house under natural conditions.	Percentage of % inhibition of emergence of 94.6% (data corrected by Abbott's formula) (9 adults emerged).	Confidential information IUCLID 6.7

Conclusion on the efficacy of the product
Based on the results of the field study by Confidential infromation which was carried out in Spain in 2016 in cattle farms (animal houses + manure heaps) the product was effective in terms of decreasing adult emergence of both the housefly, *Musca domestica*, and the stable fly, *Stomoxys calcitrans*, when applied either at 10 g/m^2 (3 applications with an interval of 1 month between applications) or at 20 g/m^2 (1 application). The 10 g/m^2 application regime gave sufficient overall control of fly larvae (adult emergence inhibition) at 3 months after the 1st application while sufficient fly larvae control (adult emergence inhibition) was observed 2 months after a single application of the product at 20 g/m^2.

2.2.5.6 Occurrence of resistance and resistance management

Large populations and high selection pressure over relatively long time periods are known to lead to insecticide resistance, especially when only one insecticide or closely chemically related insecticides are used.

Given the global distribution of houseflies and the widespread activity to control them, resistance is known to have developed to several of the major classes of insecticides including group 7C, Pyriproxyfen.

In the simulated field tests by Confidential information Sumilarv 0.5G was shown to control strains of housefly having known resistance to organophosphates as well as cross resistance to both organophosphates and pyrethroids, two of the major chemical classes used to control this and other fly pests. That study indicated that whilst Pyriproxyfen-resistant populations of flies may exist, Sumilarv0.5G can still provide effective control and also is able to contribute to the management of resistance to insecticides that belong to other chemical classes.

According to the Arthropod Pesticide Resistance Database provided by IRAC (http://www.pesticideresistance.org/search.php), some cases of resistance of houseflies on pyriproxyphen have been reported in the literature.
Therefore, the following strategies for avoiding and/or managing the development of resistance are proposed:

- Where an extended period of fly control is required, treatments should be alternated with products with different mode of action.
- Fly infestation in the animal house can be estimated by monitoring methods (e.g. monitoring of (re)-appearance of larvae in the manure or adult fly population with glue strips) prior to chemical treatment.
- The use of the product can be combined with other sanitation measures (e.g. frequent removal of dung) or non-chemical means of control (for example biological control including the use of parasitoids) within an integrated fly control program.

- Levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance, noting that sanitary conditions and proximity of untreated refuges can contribute to the risk of re-infestation.
- Check the efficacy of the product on site : if needed, causes of reduced efficacy must be investigated to ensure that there is no resistance or to identify potential resistance.
- The users should inform if the treatment is ineffective and report straightforward to the registration holder
- The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

2.2.5.7 Known limitations

There are no known abiotic or other extraneous factors which may reasonably be expected to limit the efficacy of the product.

2.2.5.8 Evaluation of the label claims

According to the submitted PAR and SPC, the intended uses (label claims) as applied for by the applicant including target organisms, dose rates and application methods are as follows:

The product is intened to be used indoors by professionals (and trained professionals) for the control of fly larvae in animal housing such as cattle pens, pig houses and poultry houses and in manure heaps.

The product is intended to be applied as a solid treatment. Sumilarv® 0.5G should be applied either at a rate of 20 g product/m^2 (equivalent to 0.1 g a.s./m^2) every 3 months, or with repeated applications of 10 g product/m^2 (equivalent to 0.05 g a.s./m^2) at 1 month intervals. In situations where the movement or addition of manure for example is more frequent it is recommended to use the lower dosage (10 g product/m^2) and re-treat at appropriate monthly intervals.

The product may be scattered by hand (when wearing suitable protective clothing) or applied using a suitable granular applicator.

Trials submitted by the applicant to substantiate label claims:

A number of field trials, laboratory screening tests, and simulated-use studies were provided with the initial submission of the dossier for Sumilarv® 0.5G.

The results of the semi-field study by Confidential information in containers of cow dung, in terms of mean inhibition of housefly adult emergence, are not valid because of the low adult emergence records in the untreated control.

According to the results of the field study by Confidential information, the product was effective in outdoor manure heap at 10 g/m^2 against housefly larvae over a 5 week period in terms of mean inhibition of housefly adult emergence.

In the field and simulated-use studies by Confidential information, the product was applied on dung of cow sheds at 10 or 20 g/m^2 once a week or on heap of pig dung at 10 g/m^2 twice with 3 weeks interval or on heap of cow/pig dung twice at 5 g/m^2 with an interval of 14 days in combination with an adulticide.

According to the results of the field study Confidential information, the product was effective in manure heaps against housefly larvae at 10 g product/m^2 for 3 weeks in terms of inhibition of housefly adult emergence and decline of free flying houseflies. In this study the product was also applied at 10 g product/m^2 along with a pyrethroid (permethrin), at 20 g product/followed by a second treatment at 5 g product/m^2 and at 50 g product/m^2 was spread on manure heap.

The results of the field study by Confidential information were indicative for the efficacy of the product at 16 g/m^2 on straw bedding in calf hutches against housefly larvae for 4 weeks and stable fly larvae for 3 weeks post treatment considering the limited number of tested sites for emerged trapped stable flies and the variability of eclosed adult houseflies from seeded straw in the control. These results can be used only as supportive data for efficacy of the product applied at the higher dose of 20 g/m^2 on straw bedding in calf hutches against housefly larvae for 4 weeks and stable fly larvae for 3 weeks post treatment. The results obtained from treated stable fly pupae were not valid because of the low percentage of adult emerge in the control. Also, the results obtained after the second treatment on 4th week can not be used to support label claims because the product was not applied according to the label claims.

According to the results of the field study by Confidential information the product was effective against housefly population when applied on litter in sheep pens at 4 or 8 g product/m^2 for 6-7 weeks post treatment, considering the number of trapped free flying houseflies in treated and untreated pens. These results can be used as supportive data for efficacy of the product applied at the higher doses of 10 or 20 g/m^2 on litter in sheep pens against housefly larvae for 6-7 weeks post treatment.

According to the results of the semi-field study by Confidential information the product was effective against housefly larvae when applied on manure heap outdoors and rotting silage indoors at 20 g product/m^2 for 4 weeks post treatement.

According to the results of the field trial of the study Confidential information the treatment on manure with the product at 20 g product/m^2 in a poultry farm was effective against housefly population from 7th until 11th week post treatment. The results from laboratory trials of this study are indicative for the larvicidal and adult emergence inhibition effect of the product against houseflies.

According to the results of the field study by Confidential information the product was effective against housefly larvae when applied on manure heaps in pig sheds at 20 g product/m^2 for 4 weeks and at 10 gr product/m^2 for 3 weeks post treatment, in terms of inhibition of housefly adult emergence.

According to the results of field study by Confidential information the product Sumilarv 5WDG (5% pyriproxyphen) was effective against housefly population when applied on manure in closed animal buildings (cowshed, sheepfold or pigsties) at the highest dose rate (equivalent to 20 g/m^2 of Sumilarv 0.5G) for 1 to 3 months, and at the lower dose rate (equivalent to 10 g/m^2 of Sumilarv 0.5G) for 1 month, after application. This study was performed with Sumilarv 5WDG, not with Sumilarv 0.5G. The WDG formulation is applied after dilution in water whereas the claimed formulation (G) is intended to be used by

scattering without dilution. Since the tested formulation is different from the claimed one, this study could be used only as supportive data and not as key study to adequately substantiate the label claims.

According to the results of the simulated-use study by Confidential information the product was effective against housefly larvae when applied on swine manure at 20 g product/m^2, in terms of inhibition of housefly adult emergence.

The eCA considered that the aforementioned efficacy studies that were originally submitted by the applicant did not adequately support efficacy of the product according to the label claims, thus one application at a rate of 20 g of product/m^2 every 3 months, or repeated applications at 10 g product/m^2 at 1 month intervals against fly larvae in animal houses and manure heaps.
New field studies on house flies (*Musca domestica*) and stable flies (*Stomoxys calcitrans*) were requested by the eCA in order for the applicant to support the proposed label claims for uses of Sumilarv® 0.5G. Hence, an additional field study (Confidential information) was submitted by the applicant including efficacy data for up to 3 months after treatment at cattle farm sites treated at application rates of:

- 10 g/m^2 (3 applications with an interval of 1 month between applications) and

- 20 g/m^2 (1 application) with further test sites included as untreated controls. Testing areas within each site included animal housing and manure heaps.

According to the results of the field study by Confidential information the product was sufficiently effective against housefly and stable fly larvae when applied onto manure in cattle pens and manure heaps at 10 g product/m^2 with 3 repeated applications of 1 month interval between applications at 3 months after the first application, or at 20 g/m^2 at 2 months after a single application. The product was effective in terms of decrease in the adult emergence of both the housefly and the stable fly. The results obtained by the trapping of free flying flies are not valid in terms of efficacy evaluation considering the high decrease that was recorded in trapped flies in the untreated control sites and the following justification provided by the applicant "the percentage decrease of free-flying insects in the treated sites is less characteristic for the evaluation of the emergence from the manure samples, due to the reinvasion of the natural population from outside the test site and also because of the difficulties incurred to assess the density of the population using a limited number of sticky fly papers in large premises.".

Taking into account the treatment regime and results in the field study by Confidential information eCA considers that:

a) at 20 g of product/m^2 the product was sufficiently effective against fly larvae at 2 months after a single application and therefore the product should be applied every 2 months, not every 3 months as claimed by the applicant.
b) at 10 g product/m^2 the product was effective against fly larvae with 3 repeated applications with 1 month interval between applications at 3 months after the first application, and this treatment regime should be addressed in the authorized uses in PAR and SPC.

Overall, based on the submitted efficacy studies and after evaluation process in all sections, the eCA concludes into the proposed authorized uses of the product as described in 2.1.4.1 (table 1).

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

The use of Sumilarv® 0.5G can be combined with the application of other products as part of an effective resistance management strategy such as pyrethroids. There are no known interactions between these products.

2.2.6 Risk assessment for human health

Sumilarv® 0.5G was the representative formulation that was evaluated for Annex I inclusion of pypriproxyfen. The product was therefore already evaluated as the 'representative formulation' during the approval of the active substance(s).

In the context of the application for a national authorisation of biocidal products (NA-APP), the risk assessment for human health for the product has been presented considering the scenarios already evaluated during the approval of the active substance and completing the indirect exposure as suggested in the assessment report. The evaluation was submitted in the form of a document IIB and a document IIC, submitted to the Greek authorities on January 2016 and in the form of an updated product assessment report (PAR) template developed in August 2015.
The ECHA Guidance on Biocides Human Health Exposure Methodology (October 2015) is considered.

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Summary table of in vitro studies on skin corrosion / irritation
No *in vitro* data are available – please see below for *in vivo* data.

Summary table of animal studies on skin corrosion / irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings*	**Remarks** *(e.g. major deviations)*	**Reference**
Primary Skin Irritation Study Equivalent to OECD 404 GLP Study Confidential information	Rabbit New Zealand White Male & Female 3/sex/group	Test substance: Sumilarv® 0.5G (Confidential information) Vehicle: Physiological Saline Dose: 0.5 g Duration of exposure: 4 hr	Average score over 24-48-72h: Confidential information All skin effects were completely reversible 72 hours after treatment. Sumilarv® 0.5G was mildly irritating to rabbit skin. (see pyriproxifen CAR, Doc. IIIB)	Confidential information	Confidential information IUCLID 8.2

Summary table of human data on skin corrosion / irritation
No human data is available.

Conclusion used in Risk Assessment – Skin corrosion / irritation	
Value/conclusion	Mildly irritating to rabbit skin.
Justification for the value/conclusion	Very slight to well defined signs of erythema were noted 4.5h after treatment of rabbit skin under occlusive conditions. Slight edema was apparent in one animal and very slight edema was apparent in 3 other rabbits at the same time point; there was no edema in the other 2 animals. The incidence and severity of both erythema and edema had declined by 24 and 48 h after treatment and erythema and edema was not present in any animal 72 h after application of Sumilarv® 0.5G. There was no difference in the effect of Sumilarv® 0.5G on normal or abraded skin.
Classification of the product according to CLP	According to Regulation (EC) 1272/2008 and the Guidance on the Application of CLP Criteria (June 2015), no CLP proposal is required.

Data waiving
No waiving statement is required due to the available *in vivo* data.

Eye irritation

Summary table of in vitro studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Test substance, Doses**	**Relevant information about the study**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
No *in vitro* data is available – please see below for *in vivo* data.					

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility*	**Remarks** *(e.g. major deviations)*	**Reference**
Primary Eye Irritation Study Equivalent to OECD 405 GLP Study	Rabbit New Zealand White, Male & Female Group(A):	Test substance: Sumilarv® 0.5G (Confidential information) Dose: 0.1g Duration of	<u>Group A:</u> Average score over 24-48-72h: Confidential information. Fully reversible effects 72 hours	N/A	Confidential information IUCLID 8.1.2

Summary table of animal studies on serious eye damage and eye irritation					
Confidential information	unwashed eye, 3M & 3F Group(B): washed eye, 2M & 1F.	exposure: Group A: 72 hr Group B: 1 min	after treatment. Sumilarv® 0.5G was mildly irritating to the unwashed rabbit eye. (see pyriproxifen CAR, Doc. IIIB)		

Summary table of human data on serious eye damage and eye irritation				
Type of data/ report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
No human data is available.				

Conclusion used in Risk Assessment – Eye irritation	
Value / conclusion	Mildly irritating to the unwashed rabbit eye.
Justification for the value / conclusion	In the unwashed eye group (group A), redness and chemosis in conjunctiva were found 1 hour after application together with congestion of the iris. By 24 hours after application the incidence of congestion of the iris had reduced, the degree of chemosis of the conjunctiva remained unchanged and the severity of redness of the conjunctiva decreased. These symptoms all disappeared by 72 hours.
Classification of the product according to CLP	According to Regulation (EC) 1272/2008 and the Guidance on the Application of CLP Criteria (June 2015), no CLP proposal is required.

Data waiving
No waiving statement is required due to the available *in vivo* data.

Respiratory tract irritation

Summary table of animal studies on respiratory tract irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levels, Duration of exposure**	**Results** *Clinical signs, histopathology, reversibility*	**Remarks** *(e.g. major deviations)*	**Reference**
No *in vivo* animal data is available – please see below for a waiving statement.					

Summary table of human data on respiratory tract irritation				
Type of data/ report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
No human data is available – please see below for a waiving statement.				

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	N/A
Classification of the product according to CLP and DSD	In the absence of any data, no CLP proposal (according to Regulation (EC) 1272/2008 and Guidance on the Application of CLP Criteria (June 2015) is possible.

Data waiving	
Information requirement	Respiratory tract irritation data not required (ADS in the BPR).
Justification	None of the product components are respiratory irritants based on the available MSDS (see Section 3.6). This is further supported by the fact that Sumilarv® 0.5 G is not a skin or eye irritant.

Skin sensitisation

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, . Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, duration of exposure Route of exposure** *(topical/intradermal, if relevant)*	**Results** *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)*	**Remarks** *(e.g. major deviations)*	**Reference**
Skin sensitisation assessed according to the Buehler method. Conforms to OECD 406 GLP Study Confidential information	Guinea pig Hartley Male 10 / group	Test substance: Sumilarv® 0.5G (Confidential information) Vehicle: Distilled water Dose: 0.5 g Duration of exposure: Applied 3 times a week for 3 weeks Route of exposure: Dermal application	No appreciable skin reaction was observed 24 and 48 hours after either each induction or the challenge. The positive control, dinitrochlorobenzene (DNCB), gave the expected positive response. Under the conditions of the study, Sumilarv® 0.5G was not a sensitiser to the skin of guinea pigs.	Confidential information.	Confidential information IUCLID 8.3.1

Summary table of human data on skin sensitisation				
Type of data/ report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
No human data is available.				

Conclusion used in Risk Assessment – Skin sensitisation	
Value / conclusion	Not sensitising to the Guinea pig skin.
Justification for the value / conclusion	No appreciable skin reaction was observed 24 and 48 hours after either each induction or the challenge. Under the experimental conditions of the Buehler test, Sumilarv® 0.5G was not a sensitiser to the skin of guinea pigs. Although a GPMT or LLNA test are the preferred tests for skin sensitization, since the active substance and the other formulants do not have sensitizing properties, the available data are considered suitable for the evaluation of the skin sensitizing properties of Sumilarv® 0.5G.
Classification of the product according to CLP	According to Regulation (EC) 1272/2008 and the Guidance on the Application of CLP Criteria (June 2015), no CLP proposal is required.

Data waiving
No waiving statement is required due to available *in vivo* data.

Respiratory sensitisation (ADS)

Summary table of animal data on respiratory sensitisation					
Method, Guideline,GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance Dose levels, Duration of exposure**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
No *in vivo* animal data is available – please see below for a waiving statement.					

Summary table of human data on respiratory sensitisation				
Type of data/ report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
No human data is available – please see below for a waiving statement.				

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	N/A
Justification for the value/conclusion	N/A
Classification of the product according to CLP and DSD	In the absence of any data, no CLP proposal (according to Regulation (EC) 1272/2008 and Guidance on the Application of CLP Criteria (June 2015) is possible.

Data waiving	
Information requirement	Respiratory sensitisation data not required (ADS in the BPR).
Justification	None of the product formulants is a skin or respiratory sensitiser based on the available MSDS (see Section 3.6).

Acute toxicity

Acute toxicity by oral route

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levels, Type of administration** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD_{50}**	**Remarks** *(e.g. major deviations)*	**Reference**
Acute Oral Toxicity OECD 401 GLP Study Confidential information	Rat, Sprague-Dawley Male & Female 5M & 5F / group	Test substance: Sumilarv® 0.5G (Confidential information) Dose: 0 and 5000 mg/kg bw Type of admin.: Gavage dosed in 0.5% methylcellulose	There were no deaths or clinical signs of toxicity. There were no significant differences in bodyweight between treated and control animals and there were no treatment related effects on gross pathological findings.	>5000 mg/kg bw	None	Confidential information IUCLID 8.5.1

Summary table of human data on acute oral toxicity				
Type of data/ report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
No human data is available.				

Value used in the Risk Assessment – Acute oral toxicity

Value	>5000 mg/kg bw
Justification for the selected value	There were no deaths or clinical signs of toxicity. There were no significant differences in bodyweight between treated and control animals and there were no treatment related effects or gross pathological findings. The acute oral LD_{50} of pyriproxyfen 0.5% granules was >5000 mg/kg bw.
Classification of the product according to CLP	According to Regulation (EC) 1272/2008 and the Guidance on the Application of CLP Criteria (June 2015), no CLP proposal is required.

Data waiving
No waiving statement is required due to available *in vivo* data.

Acute toxicity by inhalation

Summary table of animal studies on acute inhalation toxicity						
Method, Guideline, GLP status , Reliability	**Species, Strain, Sex, No/group**	**Test substance, form** *(gas, vapour, dust, mist)* **and particle size (MMAD) Actual and nominal concentration, Type of administration** *(nose only / whole body/ head only)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LC_{50}**	**Remarks** *(e.g. major deviations)*	**Reference**
No *in vivo* data available – please see below for a waiving statement.						

Summary table of human data on acute inhalation toxicity				
Type of data/ report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
No human data available.				

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	N/A
Justification for the selected value	N/A

Classification of the product according to CLP	In the absence of any requirement to generate data, a CLP proposal (according to Regulation (EC) 1272/2008 and Guidance on the Application of CLP Criteria (June 2015) is not necessary.

Data waiving	
Information requirement	Inhalation data.
Justification	According to the Guidance on the BPR Volume III Human Health, Part A Information Requirements (Section 8.7.2 Version 1.1, November 2014), an acute inhalation study with the formulation needs to be provided if the formulation is: 1) volatile (vapour pressure >1 x 10-2 Pa at 20°C), 2) a powder containing a significant portion (> 1%) of particles with particle size MMAD <50 micrometers, or 3) is applied in manner which generates aerosols, particles, or droplets in an inhalable size range (MMAD <50 micrometers). Sumilarv® 0.5G is non volatile with a vapour pressure of 1.33 x 10^{-5} Pa. It is a granule formulation, with 0.177-0.274% of particles < 150 micron, it is nearly dust free and has attrition >99.6% before and after storage. Furthermore, all the product formulants are of low acute inhalation toxicity based on the available MSDS (see Section 3.6). Therefore, Sumilarv® 0.5G is also considered of low acute inhalation toxicity and performance of an acute inhalation study is not considered necessary.

Acute toxicity by dermal route

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LD_{50}**	**Remarks** *(e.g. major deviations)*	**Reference**
Acute Dermal Toxicity OECD 402 GLP Study Confidential information	Rat Sprague-Dawley Male & Female 5M & 5F / group	Test substance: Sumilarv® 0.5G (Confidential information) Vehicle: 0.5% methylcellulose Dose: 0 & 2000 mg/kg bw Area covered: 30 cm^2 (occl.)	No deaths or toxic signs were found in either sex receiving the test material and there were no treatment related effects on bodyweight or gross pathology.	>2000 mg/kg bw	None	Confidential information IUCLID 8.5.3

Summary table of human data on acute dermal toxicity				
Type of data/ report, reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
No human data available.				

Value used in the Risk Assessment – Acute dermal toxicity	
Value	> 2000 mg/kg bw
Justification for the selected value	No deaths or toxic signs were found in either sex receiving the test material and there were no treatment related effects on bodyweight or gross pathology. The acute dermal LD_{50} of 0.5% pyriproxyfen granules was >2000 mg/kg.
Classification of the product according to CLP	According to Regulation (EC) 1272/2008 and the Guidance on the Application of CLP Criteria (June 2015), no CLP proposal is required.

Data waiving
No waiving statement is required due to the available *in vivo* data.

Information on dermal absorption

There are no dermal absorption data for pyriproxifen in Sumilarv® 0.5G. An *in vitro* dermal absorption study on human skin with an EC formulation containing 100 g/L pyriproxifen is provided. The exact composition of the EC formulation is not available.
However, the study is considered adequate for the estimation of the dermal absorption of pyriproxifen in Sumilarv® 0.5G based on the following argumentation copied from the CAR of pyriproxifen:

"Based on the physical chemical properties of pyriproxyfen (MW 321, log Pow 4.86), a dermal absorption of 100% should be assumed for risk assessment purposes.
However, Sumilarv® 0.5G is a granule, and dry particulates will be absorbed less readily than liquids. Dry particulates will have to dissolve into the surface moisture before absorption can occur. Considering the low water solubility of pyriproxyfen (0.1 mg/L), the dermal absorption is considered to be limited.
Despite the differences between the granule formulation and the EC formulation, it can be concluded that the dermal of Sumilarv® 0.5G will not be higher than the dermal absorption of the EC formulation. Therefore, for risk assessment purposes a dermal absorption of 13% will be assumed as a worst-case estimate."

Summary table of in vitro studies on dermal absorption					
Method, Guideline, GLP status, Reliability	**Species, Number of skin samples tested per dose, Other relevant information about the study**	**Test substance, Doses**	**Absorption data for each compartment and final absorption value**	**Remarks** *(e.g. major deviations)*	**Reference**
In Vitro Dermal Absorption OECD 428 (2002 draft) GLP Study Confidential information	Human and Rat (Wistar) skin 5 or 6 replicates from at least 3 different subjects/animals	Test substance: - [phenoxyphenyl-^{14}C]Pyriproxyfen - Unlabelled pyriproxyfen - Pyriproxyfen 10EC blank Doses: Conc: 100 g/L Diln 0.015 g/L	Confidential information.	None	Confidential information IUCLID 8.6

Summary table of animal studies on dermal absorption						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Concentration of test substance/ Label, Duration of exposure**	**Absorption data for each compartment and final absorption value**	**Signs of toxicity**	**Remarks** *(e.g. major deviations)*	**Reference**
No *in vivo* animal data available.						

Value(s) used in the Risk Assessment – Dermal absorption			
Substance	Pyriproxyfen	N/A	N/A
Value(s)	Confidential information	N/A	N/A
Justification for the selected value(s)	Results of *in vitro* data generation	N/A	N/A

Data waiving
No waiving statement is required due to the available *in vitro* data.

Available toxicological data relating to non-active substance(s) (i.e. substance(s) of concern)

All available toxicological and environmental information is contained within the Material Safety Data Sheets. The product Sumilarv® 0.5G does not contain any substance of concern (for justification see Confidential Annex).

Available toxicological data relating to a mixture

Not applicable as Sumilarv® 0.5G contains no other Active Substances.

Other
Effects of processing and data regarding residue levels set by EU and international regulatory agencies can be found in the Section titled *'Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)'*.

2.2.6.2 Exposure assessment

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use*	**Professional use**	**Non-professional use**	**Industrial use***	**Professional use**	**General public**	***Via* food**
Inhalation	No	Yes (minimal)	N/A	No	Yes (minimal)	No	N/A
Dermal	No	Yes	N/A	No	Yes	Yes	N/A
Oral	No	No	N/A	No	No	Yes	N/A

*Not relevant in this assessment as the technical material and biocidal product are manufactured outside of the EU.

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1	Application	Primary Exposure – applying manually	Professionals
2	Loading and application	Primary Exposure – loading and applying by hand granule spreader	Professionals
3	Loading and application	Primary Exposure – loading and applying by blower with granule nozzle	Professionals
4	Mixing and loading	Primary Exposure – mixing and loading of crawler mount type power granular feeder	Professionals
5	Application	Primary Exposure –application by crawler mount type power granular feeder	Professionals
6	Post application	Secondary Exposure – laundering contaminated clothing	Bystanders
7	Post application	Secondary Exposure - children (on visits to a farm)	Bystanders

Models and scenarios utilised in the following assessment are those submitted to the Regulatory Authority of The Netherlands during the evaluation and inclusion of the Active Substance (AS) with the exception of the Scenario number 7.

During the preparation and conversion of the PAR from the previous dossier format, the worst case Active Substance (AS) content (0.525% w/v) has been updated and included in all risk assessments.

Industrial exposure

It is considered by the applicant that the exposure associated with manufacturing, handling and/or packaging of actives or products in industry and in producing end-products containing biocidal products is covered by EU and National Legislation associated with worker and/or workplace exposure and protection.
Consequently, no assessment of Industrial exposure is presented.

Professional exposure

Scenario 1

Description of Scenario 1		
Granular dispersion by hand. Manual application of the product will not involve loading and therefore only exposure during application is estimated. Dermal exposure values are given for no clothes without gloves, for no clothes but with gloves, for a single layer of clothes with gloves and for coveralls over a single layer of clothing with gloves. Scenario 17 ("Granular bait dispersed by hand (application)") of PHED seems the most suitable model to estimate exposure during granular dispersion by hand. Detailed calculations are presented in Annex 3.2.		
	Parameters	Value
	Pyriproxyfen content	0.525%
	Dermal absorption	13%
	Inhalation absorption	confidential information.
	Area treated per day	confidential information.
	Amount used per day (assuming max. treated areas and maximum application rate of 20 g product/m², i.e. 0.1 g a.s./m² [worst case])	confidential information.
	Inhalation exposure	confidential information.
Tier 1	Dermal exposure body (no clothing, without gloves)	confidential information.
Tier 2	Dermal exposure body (no clothing, with gloves)	confidential information.
	Dermal exposure body (single layer clothing, with gloves)	confidential information.
	Dermal exposure body (coveralls over a single layer of clothing, with gloves)	confidential information.

Scenario 2

Description of Scenario 2		
Loading and mechanical application by hand granule spreader. Dermal exposure values are given for no clothes without gloves and for a single layer of clothes with and without gloves. Scenario 30 ("Granule/ open pour/ belly grinder (loading and application)") of PHED seems the most suitable model to estimate exposure during granular dispersion by hand granule spreader. Detailed calculations are presented in Annex 3.2.		
	Parameters	Value
	Pyriproxyfen content	0.525%
	Dermal absorption	13%
	Inhalation absorption	100%
	Area treated per day	confidential information.
	Amount used per day (assuming max. treated areas and maximum application rate of 20 g product/m², i.e. 0.1 g a.s./m² (worst case))	confidential information.
	Inhalation exposure	confidential information.
Tier 1	Dermal exposure body (no clothing, without gloves)	confidential information.
Tier 2	Dermal exposure body (single layer clothing, without gloves)	confidential information.
	Dermal exposure body (single layer clothing, with gloves)	confidential information.

Scenario 3

Description of Scenario 3		
Loading and mechanical application by blower with granule nozzle. Dermal exposure values are given for no clothes without gloves, for a single layer of clothes with and without gloves and for coveralls over a single layer of clothing with gloves. Scenario 30 ("Granule/ open pour/ belly grinder (loading and application)") of PHED seems the most suitable model to estimate exposure during granular dispersion by blower with granule nozzle. Detailed calculations are presented in Annex 3.2.		
	Parameters	Value
	Pyriproxyfen content	0.525%
	Dermal absorption	13%
	Inhalation absorption	100%
	Area treated per day	confidential information.
	Amount used per day (assuming max. treated areas and maximum application rate of 20 g product/m², i.e. 0.1 g a.s./m² (worst case))	confidential information.
	Inhalation exposure	confidential information.
Tier 1	Dermal exposure body (no clothing, without gloves)	confidential information.
Tier 2	Dermal exposure body (single layer clothing, without gloves)	confidential information.
	Dermal exposure body (single layer clothing, with gloves)	confidential information.
	Dermal exposure body (coveralls over a single layer of clothing, with gloves)	confidential information.

Scenario 4

Description of Scenario 4		
Mixing and loading of mechanical crawler mount type power granular feeder. The dermal exposure values are given for no clothes without gloves, for a single layer of clothes with and without gloves and for coveralls over a single layer of clothing with gloves. Scenario 2 ("Granular, open mixing and loading") of PHED seems the most suitable model to estimate exposure during mixing and loading of the mechanical crawler mount type power granular feeder. Detailed calculations are presented in Annex 3.2.		
	Parameters	Value
	Pyriproxyfen content	0.525%
	Dermal absorption	13%
	Inhalation absorption	100%
	Area treated per day	confidential information.
	Amount used per day (assuming max. treated areas and maximum application rate of 20 g product/m², i.e. 0.1 g a.s./m² [worst case])	confidential information.
	Inhalation exposure	confidential information.
Tier 1	Dermal exposure body (no clothing, without gloves)	confidential information.
Tier 2	Dermal exposure body (single layer clothing, without gloves)	confidential information.
	Dermal exposure body (single layer clothing, with gloves)	confidential information.
	Dermal exposure body (coveralls over a single layer of clothing, with gloves)	confidential information.

Scenario 5

Description of Scenario 5		
Application by mechanical crawler mount type power granular feeder. The dermal exposure values are given for no clothes and single layer of clothes both without gloves. Scenario 15 ("Solid broadcast spreader application/ open cab, AG uses") of PHED seems the most suitable model to estimate exposure during the application by mechanical crawler mount type power granular feeder. Detailed calculations are presented in Annex 3.2.		
	Parameters	Value
	Pyriproxyfen content	0.525%
	Dermal absorption	13%
	Inhalation absorption	100%
	Area treated per day	confidential information.
	Amount used per day (assuming max. treated areas and maximum application rate of 20 g product/m², i.e. 0.1 g a.s./m² (worst case))	confidential information.
	Inhalation exposure	confidential information.
Tier 1	Dermal exposure body (no clothing, without gloves)	confidential information.
Tier 2	Dermal exposure body (single layer clothing, without gloves)	confidential information.

Calculations for Scenarios 1 - 5

See Annex 3.2 for detailed calculations.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/day)**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**
Scenario 1	1 / No PPE	confidential information.	confidential information.	confidential information.	confidential information.
	2 / Gloves	confidential information.	confidential information.	confidential information.	confidential information.
	2 / Single layer clothing, gloves	confidential information.	confidential information.	confidential information.	confidential information.
	2 / Coveralls over single layer of clothing, gloves	confidential information.	confidential information.	confidential information.	confidential information.
Scenario 2	1 / No PPE	confidential information.	confidential information.	confidential information.	confidential information.
	2 / Single layer clothing	confidential information.	confidential information.	confidential information.	confidential information.
	2 / Single layer clothing, gloves	confidential information.	confidential information.	confidential information.	confidential information.
Scenario 3	1 / No PPE	confidential information.	confidential information.	confidential information.	confidential information.
	2 / Single layer clothing	confidential information.	confidential information.	confidential information.	confidential information.
	2 / Single layer clothing, gloves	confidential information.	confidential information.	confidential information.	confidential information.
	2 / Coveralls over single layer of clothing, gloves	confidential information.	confidential information.	confidential information.	confidential information.
Scenario 4	1 / No PPE	confidential information.	confidential information.	confidential information.	confidential information.
	2 / Single layer clothing	confidential information.	confidential information.	confidential information.	confidential information.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/day)**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**
	2 / Single layer clothing, gloves	confidential information.	confidential information.	confidential information.	confidential information.
	2 / Coveralls over single layer of clothing, gloves	confidential information.	confidential information.	confidential information.	confidential information.
Scenario 5	1 / No PPE	confidential information.	confidential information.	confidential information.	confidential information.
	2 / Single layer clothing	confidential information.	confidential information.	confidential information.	confidential information.

Combined scenarios

Summary table: combined systemic exposure from professional uses					
Scenarios combined	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/day)**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**
Scenarios 4 & 5	1 / No PPE	confidential information.	confidential information.	confidential information.	confidential information.
	2 / Single layer clothing	confidential information.	confidential information.	confidential information.	confidential information.
	2 / Single layer clothing, gloves	confidential information.	confidential information.	confidential information.	confidential information.
	2 / Coveralls over single layer of clothing, gloves	confidential information.	confidential information.	confidential information.	confidential information.

N/A: Not applicable since these options were not considered for both Scenarios 4 and 5.

Indirect exposure

Scenario 6

Description of Scenario 6		
During the solid application of Sumilarv® 0.5G, contamination of clothing following 1 day's work at 2 hours *per* day is performed using the indicative dermal exposure values from each application method. It is assumed that adults will wash contaminated operator clothing at home following one day's work and exposure will be by dermal contact with contaminated clothing when loading it into a washing machine. Detailed calculations are presented in Annex 3.2.		
	Parameters	Value
	Pyriproxyfen content	0.525%
	Area of both hands (palms) *	410 cm^2
	Transfer coefficient **	30%
	Dermal absorption	13%
	Body weight	60 kg
	Area of medium sized coverall	confidential information.
For use with Scenario 1	Dermal exposure (Scenario 1 - Laundering of contaminated clothing)	confidential information.
	Amount of product handled per day	confidential information.
	Residues on coverall	confidential information.
For use with Scenario 1	Dermal exposure (Scenario 1 - Laundering of contaminated coverall)	confidential information.
	Amount of product handled per day	confidential information.
	Residues on coverall	confidential information.
For use with Scenario 2	Dermal exposure (Scenario 2)	confidential information.
	Amount of product handled per day	confidential information.
	Residues on coverall	confidential information.
For use with Scenario 3	Dermal exposure (Scenario 3)	confidential information.
	Amount of product handled per day	confidential information.
	Residues on coverall	confidential information.
For use with Scenarios 4&5	Dermal exposure (Scenarios 4&5)	confidential information.
	Amount of product handled per day	confidential information.
	Residues on coverall	confidential information.

* US EPA Exposure Factors Handbook 2011 as included in the Biocides Human Health Exposure Methodology (Oct., 2015) p15
** TNsG, Part 2, p204

Calculations for Scenario 6

See Annex 3.2 for detailed calculations.

Summary table: systemic indirect exposure of professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/day)**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**
Scenario 6	For use with Scenario 1 Laundering of contaminated clothing	confidential information.	confidential information.	confidential information.	confidential information.
	For use with Scenario 1 Laundering of contaminated coverall	confidential information.	confidential information.	confidential information.	confidential information.
	For use with Scenario 2	confidential information.	confidential information.	confidential information.	confidential information.
	For use with Scenario 3	confidential information.	confidential information.	confidential information.	confidential information.
	For use with Scenarios 4&5	confidential information.	confidential information.	confidential information.	confidential information.

Combined scenarios

To account for a worker that lives alone and therefore has to launder their own work coveralls, the following combined scenarios are considered.

Summary table: combined direct and indirect systemic exposure of professional uses					
Scenarios combined	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/day)**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**
Scenarios 1 & 6	1 / No PPE	confidential information.	confidential information.	confidential information.	confidential information.
	2 / Gloves				
	2 / Single layer clothing, gloves	confidential information.	confidential information.	confidential information.	confidential information.
	2 / Coveralls over single layer of clothing, gloves				
Scenarios 2 & 6	1 / No PPE	confidential information.	confidential information.	confidential information.	confidential information.
	2 / Single layer clothing	confidential information.	confidential information.	confidential information.	confidential information.
	2 / Single layer clothing, gloves	confidential information.	confidential information.	confidential information.	confidential information.
Scenarios 3 & 6	1 / No PPE	confidential information.	confidential information.	confidential information.	confidential information.
	2 / Single layer clothing	confidential information.	confidential information.	confidential information.	confidential information.
	2 / Single layer clothing, gloves	confidential information.	confidential information.	confidential information.	confidential information.
	2 / Coveralls over single layer clothing, gloves	confidential information.	confidential information.	confidential information.	confidential information.

Summary table: combined direct and indirect systemic exposure of professional uses					
Scenarios combined	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/day)**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**
Scenarios 4 & 5 & 6	1 / No PPE	confidential information.	confidential information.	confidential information.	confidential information.
	2 / Single layer clothing, without gloves	confidential information.	confidential information.	confidential information.	confidential information.
	3 / Single layer clothing, with gloves	confidential information.	confidential information.	confidential information.	confidential information.
	4 / Coveralls over single layer clothing, with gloves	confidential information.	confidential information.	confidential information.	confidential information.

Exposure of the general public

Scenario 7

It is considered that there will be no significant indirect exposure following application of the product to animal houses, since in practice adults and children will not enter treated areas. If however adults and children were to enter treated animal houses then any exposure would only be on the undersides of footwear and this will not lead to any significant absorption of the active substance. Such a conclusion was supported by the RMS in the CA report for Pyriproxyfen.

Bystander exposure will also be negligible as the product is a granular formulation and there will be no significant drift of the formulation during application. Furthermore, indirect exposure of persons during cleaning animal houses or handling manure is considered negligible: (a) the manure will be damp, if not wet, and so there will be no risk of inhaling any dust from the granules; and (b) direct dermal contact with granules in manure will be minimal as the person would wear gloves and using a shovel when handling manure.

Indirect exposure to the general public *via* animal housing was discussed at TMIII 2011, where it was commented that farmer's children and possibly school children on visits to a farm could have access to the granules after application of the product. However, the RMS (Ctgb) was of the opinion that as the product will be applied to the manure, most granules will be in the manure and therefore it is not very likely that children/toddlers will be orally exposed to the granules.

Based upon the anticipated concentration of Pyriproxyfen in manure (PEC taken from the Environmental Exposure Section – see Section 3.3), the maximum amount of manure that

could be handed by the toddler before the AEL is reached (*i.e.*, reverse reference calculations) is estimated to be 1.25 kg.

Detailed calculations are presented in Annex 3.2.

Monitoring data

The applicant is not aware of any monitoring data related to the use of Pyriproxyfen as a biocidal product. However, there are data available from its use as a plant protection product in both the EU and the US – please follow the links below:

http://www.pan-europe.info/old/Issues/documents/Food/EFSA%20monitoring%20residues%202010%20Mar%2013.pdf

http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/Pesticides/UCM382443.pdf

It is of course critical to ensure that the different uses are distinguished if utilising the monitoring data for the use of Pyriproxyfen as a biocide.

Dietary exposure

Residue definitions

No residue definition for the biocide use has been set at the EU level and no residues above the current MRLs are expected when Sumilarv® 0.5G is used according to the proposed label. Please refer to the residue definitions set for other sectors below (PPP and veterinary medicines).

List of scenarios

Summary table of main representative dietary exposure scenarios			
Scenario number	**Type of use**	**Description of scenario**	**Subject of exposure**
8	Professional	Livestock Exposure	Beef Cattle
9	Professional	Livestock Exposure	Dairy Cattle
10	Professional	Livestock Exposure	Fattening Pig
11	Professional	Livestock Exposure	Breeding Pig
12	Professional	Livestock Exposure	Broiler Chicken
13	Professional	Livestock Exposure	Laying Hen

Information of non-biocidal use of the active substance

Pyriproxyfen is used as an active substance in plant protection products world-wide. In the EU, Pyriproxyfen was included into Annex I of Directive 91/414 (Commission Directive 2008/69/EC of 1 July 2008) and subsequently Regulation (EC) No. 1107/2009 by Regulation (EU) No 540/2011. Plant protection products containing Pyriproxyfen are used on fruit and vegetables, cotton and ornamental trees against pests like greenhouse whitefly, cotton whitefly, woodlouse and San Jose scale. Pyriproxyfen is a juvenile hormone agonist and functions by suppressing embryogenesis and metamorphosis in various insect species.

Pyriproxyfen is also used as an active substance in veterinary medicines. Veterinary medicinal products containing Pyriproxyfen have been granted a marketing authorisation in the EU by the Committee for Medicinal Products for Veterinary Use in the EU (Directive 2001/82/EC). These products are classed as ectoparasiticides for topical use on dogs and cats against flea and tick infestation.

Pyriproxyfen is a photostable insect growth regulator (IGR). It acts through contact, by mimicking Juvenile Hormone which regulates the moulting of insects from one life stage to the next. Pyriproxyfen stops the flea life cycle by both inducing premature oviposition and also suppressing yolk deposition in flea eggs, leading to the production of infertile eggs. Additionally, Pyriproxyfen blocks the development of juvenile stages (larvae and early (pharate) pupae) into adult emergence, thus preventing infestation within the environment of the treated animal.

Residue definitions

Summary table of other (non-biocidal) uses			
	Sector of use[1]	**Intended use**	**Reference value(s)[2]**
1	PPP	Insecticide Residue definition: *Products of plant origin:* Pyriproxyfen *Products of plant origin:* Pyriproxyfen	EU - Maximum Residue Levels (Reg. (EC) No 396/2005) (MRLs) updated by Reg. (EU) No 737/2014
2	Veterinary use	Ectoparasiticide for topical use on cats and dogs	Not applicable – not used on animals grown for human consumption.

[1] e.g. plant protection products, veterinary use, food or feed additives

[2] e.g. MRLs. Use footnotes for references.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Scenario 8

Description of Scenario 8 – Beef Cattle

According to the Assessment Report (Pyriproxyfen – Product-type 18, Non-confidential Evaluation report established by The Netherlands - version 2 of September 2012), it is not expected that residues in food and feeding stuffs will occur in relevant amounts for the intended uses.

The product is intended to be applied only by professionals with selective application over the manure on the floor, in manure cellars or other fly breeding sites. The proposed use suggests that it is highly unlikely that livestock animals such as cows and pigs will be exposed to the active substance *via* contaminated food and water or through licking of the surface, since those animals will not eat from manure. Furthermore, cows and pigs do not contaminate their lying area under normal breeding conditions.

There are no restrictions on whether the farm animals may remain in the premises or not while treatment is carried out. However, the product is a granular solid, applied by hand or with a hand granule spreader (+crawler mount type power granular feeder for waste treatment facilities), therefore given the physical state, the size of granules and dust, as well as the mode of application, inhalation exposure can be excluded. In addition the active substance is almost totally non-volatile (vapour pressure $< 4.23 \times 10^{-2}$ $Pa.m^3.mol^{-1}$). Nevertheless, an inhalation exposure calculation was carried out to demonstrate the worst case scenario. Given the physical state and the mode of application, there are no restrictions proposed whatsoever relating to the covering of troughs, animal feed and water for the treatment of animal housing: the operator is a professional or a PCO ('Pest Control Operator') and the granules are spread by hand or a granule spreader towards the ground and only onto manure.

As a very conservative approach a quantitative assessment has been presented below using the DRAWG draft proposal guidance document (*Technical Notes for Guidance - Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products endorsed during the 39th CA meeting for release for consultation of stakeholders - CA-Dec10-Doc.6.2.b*).

	Parameters	Value
Tier 1	Application rate (daily)	0.105 g a.s./m^2 = 105 mg a.s./m^2
	Treated area (floor, product is applied on ground only, not walls)	370 m^2
	Number of animals per stable	125
	Body weight of beef cattle	500 kg
	Body surface area in contact with surface (floor)	1.44 m^2
	Saturated vapour concentration (SVC)	0.00169 mg a.s./m^3
	Alveolar ventilation rate	50 m^3/d
	Emission factor for spraying	1 (no emission is expected from granules)

Tier 2	JMPR evaluation report (Pyriproxyfen [2000][5])	Livestock feeding study in cattle. Please refer to Annex 3.2 for the detailed justification.

Calculations for estimating livestock exposure for Scenario 8

Please refer to Annex 3.2 for the detailed calculations.

Further information and considerations on scenario 8

N/A

Conclusion

In conclusion, the refined risk assessment shows that the proposed use of 10g product/m^2 *per* month or 20 g product/m^2 every 2 months should not have an unacceptable risk regarding exposure of residue levels resulting from the use of Sumilarv® 0.5G on cattle.

5 FVO Plant protection paper 157. Pesticide residues in food – 1999, Evaluations 1999 – part I Residues. http://books.google.lv/books?id=pbbzLqq4sCgC&pg=PA717&dq=Pyriproxyfen&hl=en&sa=X&ei=RMA6U7ehA6WS7AaDz4CYCw&ved=0CEAQ6AEwAg#v=onepage&q=Pyriproxyfen&f=false

Scenario 9

Description of Scenario 9 – Dairy Cattle

According to the Assessment Report (Pyriproxyfen – Product-type 18, Non-confidential Evaluation report established by The Netherlands - version 2 of September 2012), it is not expected that residues in food and feeding stuffs will occur in relevant amounts for the intended uses.

The product is intended to be applied only by professionals with selective application over the manure on the floor, in manure cellars or other fly breeding sites. The proposed use suggests that it is highly unlikely that livestock animals such as cows and pigs will be exposed to the active substance *via* contaminated food and water or through licking of the surface, since those animals will not eat from manure. Furthermore, cows and pigs do not contaminate their lying area under normal breeding conditions.

There are no restrictions on whether the farm animals may remain in the premises or not while treatment is carried out. However, the product is a granular solid, applied by hand or with a hand granule spreader (+crawler mount type power granular feeder for waste treatment facilities), therefore given the physical state, the size of granules and dust, as well as the mode of application, inhalation exposure can be excluded. In addition the active substance is almost totally non-volatile (vapour pressure $< 4.23 \times 10^{-2}$ $Pa.m^3.mol^{-1}$). Nevertheless, an inhalation exposure calculation was carried out to demonstrate the worst case scenario. Given the physical state and the mode of application, there are no restrictions proposed whatsoever relating to the covering of troughs, animal feed and water for the treatment of animal housing: the operator is a professional or a PCO ('Pest Control Operator') and the granules are spread by hand or a granule spreader towards the ground and only onto manure.

As a very conservative approach a quantitative assessment has been presented below using the DRAWG draft proposal guidance document (*Technical Notes for Guidance - Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products endorsed during the 39th CA meeting for release for consultation of stakeholders - CA-Dec10-Doc.6.2.b*).

	Parameters	Value
Tier 1	Application rate (daily)	0.105 g a.s./m^2 = 105 mg a.s./m^2
	Treated area (floor, product is applied on ground only, not walls)	1170 m^2
	Number of animals per stable	100
	Body weight of dairy cattle	650 kg
	Body surface area in contact with surface (floor)	1.68 m^2
	Saturated vapour concentration (SVC)	0.00169 mg a.s./m^3
	Alveolar ventilation rate	62 m^3/d
	Emission factor for spraying	1 (no emission is expected from granules)

Tier 2	JMPR evaluation report (Pyriproxyfen [2000][6])	Livestock feeding study in cattle. Please refer to Annex 3.2 for the detailed justification.
Tier 3	N/A	N/A
	N/A	N/A
	N/A	N/A

Calculations for estimating livestock exposure for Scenario 9

Please refer to Annex 3.2 for the detailed calculations.

Further information and considerations on scenario 9

N/A

Conclusion

In conclusion, the refined risk assessment shows that the proposed use of 10g product/m^2 *per* month or 20 g product/m^2 every 2 months should not have an unacceptable risk regarding exposure of residue levels resulting from the use of Sumilarv® 0.5G on cattle.

6 FVO Plant protection paper 157. Pesticide residues in food – 1999, Evaluations 1999 – part I Residues. http://books.google.lv/books?id=pbbzLqq4sCgC&pg=PA717&dq=Pyriproxyfen&hl=en&sa=X&ei=RMA6U7ehA6WS7AaDz4CYCw&ved=0CEAQ6AEwAg#v=onepage&q=Pyriproxyfen&f=false

Scenario 10

Description of Scenario 10 – Fattening Pig

According to the Assessment Report (Pyriproxyfen – Product-type 18, Non-confidential Evaluation report established by The Netherlands - version 2 of September 2012), it is not expected that residues in food and feeding stuffs will occur in relevant amounts for the intended uses.

The product is intended to be applied only by professionals with selective application over the manure on the floor, in manure cellars or other fly breeding sites. The proposed use suggests that it is highly unlikely that livestock animals such as cows and pigs will be exposed to the active substance *via* contaminated food and water or through licking of the surface, since those animals will not eat from manure. Furthermore, cows and pigs do not contaminate their lying area under normal breeding conditions.

There are no restrictions on whether the farm animals may remain in the premises or not while treatment is carried out. However, the product is a granular solid, applied by hand or with a hand granule spreader (+crawler mount type power granular feeder for waste treatment facilities), therefore given the physical state, the size of granules and dust, as well as the mode of application, inhalation exposure can be excluded. In addition the active substance is almost totally non-volatile (vapour pressure $< 4.23 \times 10^{-2}$ $Pa.m^3.mol^{-1}$). Nevertheless, an inhalation exposure calculation was carried out to demonstrate the worst case scenario. Given the physical state and the mode of application, there are no restrictions proposed whatsoever relating to the covering of troughs, animal feed and water for the treatment of animal housing: the operator is a professional or a PCO ('Pest Control Operator') and the granules are spread by hand or a granule spreader towards the ground and only onto manure.

As a very conservative approach a quantitative assessment has been presented below using the DRAWG draft proposal guidance document (*Technical Notes for Guidance - Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products endorsed during the 39th CA meeting for release for consultation of stakeholders - CA-Dec10-Doc.6.2.b*).

	Parameters	Value
Tier 1	Application rate (daily)	0.105 g a.s./m^2 = 105 mg a.s./m^2
	Treated area (floor, product is applied on ground only, not walls)	600 m^2
	Number of animals per stable	400
	Body weight of fattening pig	100 kg
	Body surface area in contact with surface (floor)	0.45 m^2
	Saturated vapour concentration (SVC)	0.00169 mg a.s./m^3
	Alveolar ventilation rate	14 m^3/d
	Emission factor for spraying	1 (no emission is expected from granules)
Tier 2	Body surface area in contact with surface (floor)[7]	0.24 m^2

Tier 3	Pyriproxyfen metabolism in rat and ruminant is considered similar[8]	Extrapolation from ruminant data to pigs is acceptable[9]

Calculations for estimating livestock exposure for Scenario 10

Please refer to Annex 3.2 for the detailed calculations.

Further information and considerations on scenario 10

N/A

Conclusion

In conclusion, the refined risk assessment shows that the proposed use of 20 g product/m^2 every 2 months should not have an unacceptable risk regarding exposure of residue levels resulting from the use of Sumilarv® 0.5G in pig houses.

7 Grommers F. J., et al (1970), Swine – floor contact area as function of body weight and posture. J ANIM SCI 1970, 31:1232-1234, http://www.journalofanimalscience.org/content/31/6/1232.full.pdf

8 Conclusion on pesticide peer review regarding the risk assessment of the active substance Pyriproxyfen. EFSA Scientific Report (2009) 3361-99

9 OECD 509

Scenario 11

Description of Scenario 11 – Breeding Pig

According to the Assessment Report (Pyriproxyfen – Product-type 18, Non-confidential Evaluation report established by The Netherlands - version 2 of September 2012), it is not expected that residues in food and feeding stuffs will occur in relevant amounts for the intended uses.

The product is intended to be applied only by professionals with selective application over the manure on the floor, in manure cellars or other fly breeding sites. The proposed use suggests that it is highly unlikely that livestock animals such as cows and pigs will be exposed to the active substance *via* contaminated food and water or through licking of the surface, since those animals will not eat from manure. Furthermore, cows and pigs do not contaminate their lying area under normal breeding conditions.

There are no restrictions on whether the farm animals may remain in the premises or not while treatment is carried out. However, the product is a granular solid, applied by hand or with a hand granule spreader (+crawler mount type power granular feeder for waste treatment facilities), therefore given the physical state, the size of granules and dust, as well as the mode of application, inhalation exposure can be excluded. In addition the active substance is almost totally non-volatile (vapour pressure $< 4.23 \times 10^{-2}$ $Pa.m^3.mol^{-1}$). Nevertheless, an inhalation exposure calculation was carried out to demonstrate the worst case scenario. Given the physical state and the mode of application, there are no restrictions proposed whatsoever relating to the covering of troughs, animal feed and water for the treatment of animal housing: the operator is a professional or a PCO ('Pest Control Operator') and the granules are spread by hand or a granule spreader towards the ground and only onto manure.

As a very conservative approach a quantitative assessment has been presented below using the DRAWG draft proposal guidance document (*Technical Notes for Guidance - Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products endorsed during the 39th CA meeting for release for consultation of stakeholders - CA-Dec10-Doc.6.2.b*).

	Parameters	Value
Tier 1	Application rate (daily)	0.105 g a.s./m^2 = 105 mg a.s./m^2
	Treated area (floor, product is applied on ground only, not walls)	560 m^2
	Number of animals per stable	132
	Body weight of breding pig	260 kg
	Body surface area in contact with surface (floor)	0.84 m^2
	Saturated vapour concentration (SVC)	0.00169 mg a.s./m^3
	Alveolar ventilation rate	30 m^3/d
	Emission factor for spraying	1 (no emission is expected from granules)
Tier 2	Body surface area in contact with surface (floor)[10]	0.45 m^2

Tier 3	Pyriproxyfen metabolism in rat and ruminant is considered similar[11]	Extrapolation from ruminant data to pigs is acceptable[12]

Calculations for estimating livestock exposure for Scenario 11

Please refer to Annexe 3.2 for the detailed calculations.

Further information and considerations on scenario 11

N/A

Conclusion

In conclusion, the refined risk assessment shows that the proposed use of 20 g product/m^2 every 2 months should not have an unacceptable risk regarding exposure of residue levels resulting from the use of Sumilarv® 0.5G in pig houses.

10 Grommers F. J., et al (1970), Swine – floor contact area as function of body weight and posture. J ANIM SCI 1970, 31:1232-1234, http://www.journalofanimalscience.org/content/31/6/1232.full.pdf

11 Conclusion on pesticide peer review regarding the risk assessment of the active substance Pyriproxyfen. EFSA Scientific Report (2009) 3361-99

12 OECD 509

Scenario 12

Description of Scenario 12 – Broiler Chicken

According to the Assessment Report (Pyriproxyfen – Product-type 18, Non-confidential Evaluation report established by The Netherlands - version 2 of September 2012), it is not expected that residues in food and feeding stuffs will occur in relevant amounts for the intended uses.

The product is intended to be applied only by professionals with selective application over the manure on the floor, in manure cellars or other fly breeding sites. The proposed use suggests that it is highly unlikely that livestock animals such as cows and pigs will be exposed to the active substance *via* contaminated food and water or through licking of the surface, since those animals will not eat from manure. Furthermore, cows and pigs do not contaminate their lying area under normal breeding conditions.

There are no restrictions on whether the farm animals may remain in the premises or not while treatment is carried out. However, the product is a granular solid, applied by hand or with a hand granule spreader (+crawler mount type power granular feeder for waste treatment facilities), therefore given the physical state, the size of granules and dust, as well as the mode of application, inhalation exposure can be excluded. In addition the active substance is almost totally non-volatile (vapour pressure $< 4.23 \times 10^{-2}$ Pa.m^3.mol^{-1}). Nevertheless, an inhalation exposure calculation was carried out to demonstrate the worst case scenario. Given the physical state and the mode of application, there are no restrictions proposed whatsoever relating to the covering of troughs, animal feed and water for the treatment of animal housing: the operator is a professional or a PCO ('Pest Control Operator') and the granules are spread by hand or a granule spreader towards the ground and only onto manure.

As a very conservative approach a quantitative assessment has been presented below using the DRAWG draft proposal guidance document (*Technical Notes for Guidance - Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products endorsed during the 39th CA meeting for release for consultation of stakeholders - CA-Dec10-Doc.6.2.b*).

	Parameters	Value
Tier 1	Application rate (daily)	0.105 g a.s./m^2 = 105 mg a.s./m^2
	Treated area (floor, product is applied on ground only, not walls)	390 m^2
	Number of animals per stable	7000
	Body weight of broiler chicken	1.7 kg
	Body surface area in contact with surface (floor)	Not relevant – poultry do not rub against walls and the product is applied without dilution by hand or with a hand granule spreader (+crawler mount type power granular feeder for waste treatment facilities) on manure.
	Saturated vapour concentration (SVC)	0.00169 mg a.s./m^3

	Alveolar ventilation rate	0.12 m^3/d

Calculations for estimating livestock exposure for Scenario 12

Please refer to Annex 3.2 for the detailed calculations.

Further information and considerations on scenario 12

N/A

Conclusion

In conclusion, the refined risk assessment shows that the proposed use of 10 g product/m^2 *per* month or 20 g product/m^2 every 2 months should not have an unacceptable risk regarding exposure of residue levels resulting from the use of Sumilarv® 0.5G on poultry.

Scenario 13

Description of Scenario 13 – Laying Hen

According to the Assessment Report (Pyriproxyfen – Product-type 18, Non-confidential Evaluation report established by The Netherlands - version 2 of September 2012), it is not expected that residues in food and feeding stuffs will occur in relevant amounts for the intended uses.

The product is intended to be applied only by professionals with selective application over the manure on the floor, in manure cellars or other fly breeding sites. The proposed use suggests that it is highly unlikely that livestock animals such as cows and pigs will be exposed to the active substance *via* contaminated food and water or through licking of the surface, since those animals will not eat from manure. Furthermore, cows and pigs do not contaminate their lying area under normal breeding conditions.

There are no restrictions on whether the farm animals may remain in the premises or not while treatment is carried out. However, the product is a granular solid, applied by hand or with a hand granule spreader (+crawler mount type power granular feeder for waste treatment facilities), therefore given the physical state, the size of granules and dust, as well as the mode of application, inhalation exposure can be excluded. In addition the active substance is almost totally non-volatile (vapour pressure $< 4.23 \times 10^{-2}$ Pa.m^3.mol^{-1}). Nevertheless, an inhalation exposure calculation was carried out to demonstrate the worst case scenario. Given the physical state and the mode of application, there are no restrictions proposed whatsoever relating to the covering of troughs, animal feed and water for the treatment of animal housing: the operator is a professional or a PCO ('Pest Control Operator') and the granules are spread by hand or a granule spreader towards the ground and only onto manure.

As a very conservative approach a quantitative assessment has been presented below using the DRAWG draft proposal guidance document (*Technical Notes for Guidance - Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products endorsed during the 39th CA meeting for release for consultation of stakeholders - CA-Dec10-Doc.6.2.b*).

	Parameters	Value
Tier 1	Application rate (daily)	0.105 g a.s./m^2 = 105 mg a.s./m^2
	Treated area (floor, product is applied on ground only, not walls)	750 m^2
	Number of animals per stable	21000
	Body weight of broiler chicken	1.9 kg
	Body surface area in contact with surface (floor)	Not relevant – poultry do not rub against walls and the product is applied without dilution by hand or with a hand granule spreader (+crawler mount type power granular feeder for waste treatment facilities) on manure.
	0.00169 mg a.s./m^3	0.00169 mg a.s./m^3

	Alveolar ventilation rate	0.12 m^3/d

Calculations for estimating livestock exposure for Scenario 13

Please refer to Annex 3.2 for the detailed calculations.

Further information and considerations on scenario 13

N/A

Conclusion

In conclusion, the refined risk assessment shows that the proposed use of 10 g product/m^2 *per* month or 20 g product/m^2 every 2 months should not have an unacceptable risk regarding exposure of residue levels resulting from the use of Sumilarv® 0.5G on poultry.

Internal dose received by the animal and WCCE*						
DRAWG draft proposal guidance document (Technical Notes for Guidance - Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products endorsed during the 39th CA meeting for release for consultation of stakeholders - CA-Dec10-Doc.6.2.b) used to calculate exposures.						
	Parameters**	Inhalation exposure (mg/kg bw/d)	Dermal exposure (mg/kg bw/d)	Oral exposure (mg/kg bw/d)	Total exposure (mg/kg bw/d)	WCCE (% of ADI)
Scenario 8	See Description of Scenario 8	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
Scenario 9	See Description of Scenario 9)	Confidential information	Confidential information	Confidential information	Confidential information	
Scenario 10	See Description of Scenario 10	Confidential information	Confidential information	Confidential information	Confidential information	
Scenario 11	See Description of Scenario 11	Confidential information	Confidential information	Confidential information	Confidential information	
Scenario 12	See Description of Scenario 12	Confidential information	Confidential information	Confidential information	Confidential information	
Scenario 13	See Description of Scenario 13	Confidential information	Confidential information	Confidential information	Confidential information	

**Worst case consumer exposure: combined estimate of the internal dose with the standard food basket (300 g muscle, 100 g liver, 50 g fat, 50 g kidney plus 1500 g milk, 100 g eggs and 20 g honey); **describe the parameters used to derive the WCCE. Use footnotes for references and justifications.*

The Log $P_{o/w}$ for Pyriproxyfen is 5.37[13] and therefore appropriate transfer factors for substances having Log $P_{o/w}$ values between 5 and 6 have been used[14]. The exposure values from the relevant scenarios representing the worst case have been used. These values have been underlined in the table above.

13 DAR, The Netherlands, 2005

14 Leeman et al. (2007): Transfer of chemicals from feed to animal products: The use of transfer factors in risk assessment. Food additives and contaminants; 24, 1-13.

The resulting theoretical maximum daily intake						
Commodity	P_{95} for the transfer factor	Total exposure (mg/kg feed) or x	Relevant scenario	Estimated content in commodity after oral exposure of x mg/kg feed (µg/kg)	Food basket (kg) Theoretical maximum intake for consumers	Estimated maximum theoretical daily intake for humans using the food basket (µg)
Egg	2.43	Confidential information	Scenario 13	Confidential information	0.1	Confidential information
Milk	0.43	Confidential information	Scenario 9	Confidential information	y1.50	Confidential information
Meat	0.03	Confidential information	Scenario 8	Confidential information	0.30	Confidential information
Fat	17.0	Confidential information	Scenario 8	Confidential information	0.05	Confidential information
Liver	1.50	Confidential information	Scenario 8	Confidential information	0.10	Confidential information
Kidney	1.50	Confidential information	Scenario 11	Confidential information	0.05	Confidential information
					Total:	Confidential information

WCCE calculation			
ADI	Human weight (kg)	TMDI or WCCE	% of ADI
0.1 mg/kg bw/day or 100 µg/kg bw/day	60 kg	Confidential information	Confidential information

The calculations above show an exceedance of the ADI. However, in the JMPR evaluation report on Pyriproxyfen residues (Pyriproxyfen [2000][15]), a number of animal metabolism studies, as well as a livestock feeding study in cattle, were assessed. In this study, dairy cows were dosed with the active substance at 0.13, 0.38 and 1.17 mg / bw/ day for 28 days. In tissues and milk, no parent compound was found above 0.01 mg/kg in any of the lower dose groups. For the highest dose group, Pyriproxyfen and metabolites at quantifiable amounts were found in both fat and cream, but not in any other tissues nor in milk or milk products. In the middle dose feeding group (0.38 mg / bw /day), which covers the estimated exposure for beef cattle, Pyriproxyfen residues were not detected in milk and kidney, but were present in body fat at 0.011-0.025 mg / kg (STMR 0.018 mg / kg). Since the residues are proportional to the dose, with an exposure to 0.30 mg a.s./kg bw/d (equivalent to the exposure for beef cattle), the expected medium residues would be around 0.014 mg/kg.

However, taking into account that the highest contributor for the total exposure was dermal exposure and that this study is a feeding study, which estimates the magnitude of residues in animal tissues, if the dose were taken up orally, not dermally, actual residue levels resulting from the use of Sumilarv® 0.5G would be expected to be below 0.01 mg/kg.

15 FVO Plant protection paper 157. Pesticide residues in food – 1999, Evaluations 1999 – part I Residues. http://books.google.lv/books?id=pbbzLqq4sCgC&pg=PA717&dq=Pyriproxyfen&hl=en&sa=X&ei=RMA6U7ehA6WS7AaDz4CYCw&ved=0CEAQ6AEwAg#v=onepage&q=Pyriproxyfen&f=false

Also, Sumilarv® 0.5G is a granular formulation, and dry particulates will be absorbed less readily than liquids. Dry particulates would have to be dissolved by surface moisture before absorption can occur. Considering the low water solubility of Pyriproxyfen (0.1 mg / L), the dermal absorption is considered to be limited. Moreover, animals would not be exposed to the same amount of active substance every day, as the application is only permitted once per month at 0.05 g a.s./ m^2 or once every 2 months at 0.1 g a.s./m^2.

In addition, Pyriproxyfen is a substance of low acute toxicity in all tested species (rats, mice and dogs) either by oral and dermal exposure, or by inhalation (oral LD_{50}>5000 mg/kg bw; dermal LD_{50} > 2000 mg/kg bw; inhalation LC_{50} > 1.3 mg/L, maximum attainable concentration). Pyriproxyfen does not demonstrate any skin or eye irritating properties, and has no skin sensitising properties as shown in a maximisation test[16].

In conclusion, the refined risk assessment shows that the proposed use of 10g product / m^2 *per* month or 20 g product/m^2 every 2 months should not have an unacceptable risk regarding exposure of residue levels resulting from the use of Sumilarv® 0.5G on cattle.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

No specific studies have been conducted to assess the transfer of Pyriproxyfen resulting from biocidal use. However, according to the Assessment Report (*Pyriproxyfen – Product-type 18, Non-confidential Evaluation report established by The Netherlands - version 2 of September 2012*), it is not expected that residues in food and feeding stuffs will occur in relevant amounts for the intended uses.

Importantly, the product is intended to be applied only by professionals with selective application over the manure on the floor, in manure cellars or other fly breeding sites, therefore primary transfer to food can be completely ruled out. The secondary exposure via animal products was assessed and a conclusion was drawn that no residues above 0.01 m/kg will occur in animal products.

Moreover a robust residue data package on Pyriproxyfen is available from other (non-biocidal) uses.

Effects of processing were investigated during the approval process of Pyriproxyfen as active substance for plant protection products.

In a hydrolysis study with conditions simulating pasteurisation, baking/brewing/boiling and sterilisation Pyriproxyfen was found to be stable as no significant degradation products were identified.

The level of residues in processed products was determined in processing studies on tomato and cotton seed. Residues decreased in tomato juice, canned tomato, pureed tomato and ketchup processed from peeled tomatoes. The majority of the residue was recovered in the tomato peel. In tomatoes processed without peeling, a slight concentration of residues was noted in pureed tomatoes.

16 Conclusion on pesticide peer review regarding the risk assessment of the active substance Pyriproxyfen. EFSA Scientific Report (2009) 3361-99

In crude and refined cotton oil as well as in the pressed cotton cake, residues decreased upon processing[17].

Since the residues resulting from use of the biocidal product Sumilarv® 0.5G are not expected to exceed the current MRL of 0.05* mg/kg in animal products set under EU Regulation 396/2005, no further data investigation of the magnitude of residues in processed products, is necessary.

According to the Pyriproxyfen Competent Authority Assessment Report (The Netherlands, 2012), it is not expected that residues in food and feeding stuffs will occur in relevant amounts for the applied uses of Sumilarv® 0.5G (Product type 18). In the CAR, no ADI or ARfD values were set.

ADI	Not allocated - not necessary	
ARfD	Not allocated - not necessary	

Pyriproxyfen was also included into Annex I of Directive 91/414 (Commission Directive 2008/69/EC of 1 July 2008) and subsequently Regulation (EC) No. 1107/2009 by Regulation (EU) No 540/2011. During the EU peer review process the following toxicological reference values were set:

ADI	0.1 mg/kg bw per day	1 year dog study, safety factor 100
ARfD	Not allocated - not necessary	

According to the calculations shown above and existing studies, significant residues in cow matrices are not expected, therefore MRLs already set in Regulation (EC) No 470/2009 and Regulation (EC) No 396/2005 are not expected to be exceeded.

Pyriproxyfen is also used as an active substance in plant protection products worldwide. The EU review report for the active substance Pyriproxyfen - SANCO/836/08 – Final (11 May 2010) established that any residues arising from the proposed uses, following application consistent with good agricultural practice, have no harmful effects on human or animal health.

For the Annex I inclusion, data on the metabolism of Pyriproxyfen in livestock were submitted and evaluated (two studies in goat and two in hen). Metabolism studies were conducted with a dose of 0.34 -0.38 mg/kg bw/day for ruminants and 0.78 mg/kg bw/day for poultry, which is comparable with the expected exposure from the Sumilarv® 0.5G biocidal product uses for ruminants and higher than the expected exposure for poultry. Residues above the LOQ of 0.05 mg/kg are not expected for poultry and eggs, ruminant and pig tissues.

During the recent MRL application for Pyriproxyfen in stone fruits and tea (EFSA, 2013[18]), a consumer risk assessment was performed using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population. The input data also includes MRLs for products of animal origin (at 0.05 mg/kg for all products of animal origin).

17 Conclusion on pesticide peer review regarding the risk assessment of the active substance Pyriproxyfen. EFSA Scientific Report (2009) 3361-99

18 European Food Safety Authority, 2013. Reasoned opinion on the modification of the existing MRLs for Pyriproxyfen in stone fruits and tea. EFSA Journal 2013;11(12):3489, 26 pp. doi:10.2903/j.efsa.2013.3489

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for up to 8.5 % of the ADI (DE child diet). The contribution of residues in the crops under consideration to the total consumer exposure (in terms of percentage of the ADI) accounted for a maximum of 0.53 % for tea (IE adult diet), 0.09 % for cherries (DE child diet) and peaches and 0.01 % for plums (IE adult diet).

The MRLs for Pyriproxyfen were originally set in Regulation 396/2005, which were recently amended according to Regulation 737/2014.

Matrix	EU MRL for Pyriproxyfen
Products of animal origin – terrestrial animals	0.05*

(*) Below the limit of quantification.

Also, during the JMPR evaluation on the active substance Pyriproxyfen (Pyriproxyfen [2000]) a livestock metabolism study in cows was assessed.

Codex MRLs (CXLs) are set for following animal products:

Matrix	CXL for Pyriproxyfen
Goat, Edible offal of	0.01*
Goat meat (includes fat)	0.01*
Cattle, Edible offal of	0.01*
Cattle meat (includes fat)	0.01*

(*) At or about the limit of determination.

The available studies investigating Pyriproxyfen metabolism in livestock were also evaluated and compared with the proposed uses of Sumilarv® 0.5G. Residues above the LOQ of 0.05 mg/kg are not expected for poultry and eggs, ruminant and pig tissues.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

As assessment of this scenario is considered not to be required as no non-professional uses of Sumilarv® 0.5G exist.

Exposure associated with production, formulation and disposal of the biocidal product

It is considered by the applicant that the exposure associated with manufacturing, handling and/or packaging of actives or products in industry and in producing end-products containing biocidal products is covered by EU and National Legislation associated with worker and/or workplace exposure and protection.

With regards to disposal, waste and residues should be disposed of in accordance with local authority requirements. The product is not allowed to runoff to sewer, waterway or ground. Residues and empty containers should be considered as hazardous waste according to local and national provisions.

It is not considered that there are not any specific exposure scenarios for assessment in excess of those already presented above.

Aggregated exposure

No methodology for the assessment of aggregated exposure is currently developed and therefore this is not considered in this evaluation.

Summary of exposure assessment

Summary of main paths of human exposure assessment:

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/day)**
1	Professionals	1 / No PPE	Confidential information
		2 / Gloves	Confidential information
		2 / Single layer clothing, gloves	Confidential information
		2 / Coveralls over a single layer of clothing, gloves	Confidential information
2	Professionals	1 / No PPE	Confidential information
		2 / Single layer clothing	Confidential information
		2 / Single layer clothing, gloves	Confidential information
3	Professionals	1 / No PPE	Confidential information
		2 / Single layer clothing	Confidential information
		2 / Single layer clothing, gloves	Confidential information
		2 / Coveralls over a single layer of clothing, gloves	Confidential information
4	Professionals	1 / No PPE	Confidential information
		2 / Single layer clothing	Confidential information

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/day)**
		2 / Single layer clothing, gloves	Confidential information
		2 / Coveralls over a single layer of clothing, gloves	Confidential information
5	Professionals	1 / No PPE	Confidential information
		2 / Single layer clothing	Confidential information
4 & 5	Professionals	1 / No PPE	Confidential information
		2 / Single layer clothing	Confidential information
		2 / Single layer clothing, gloves	Confidential information
		2 / Coveralls over single layer of clothing, gloves	Confidential information
6	Bystanders	For use with Scenario 1	Confidential information
		For use with Scenario 1	Confidential information
		For use with Scenario 2	Confidential information
		For use with Scenario 3	Confidential information
		For use with Scenarios 4&5	Confidential information
1 & 6	Professionals	1 / No PPE during scenario 1	Confidential information
		2 / Gloves during scenario 1	Confidential information
		2 / Single layer clothing, gloves during scenario 1	Confidential information
		2 / Coveralls over a single layer of clothing, gloves during scenario 1	Confidential information

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/day)**
2 & 6	Professionals	1 / No PPE during scenario 2	Confidential information
		2 / Single layer clothing during scenario 2	Confidential information
		2 / Single layer clothing, gloves during scenario 2	Confidential information
3 & 6	Professionals	1 / No PPE during scenario 3	Confidential information
		2 / Single layer clothing during scenario 3	Confidential information
		2 / Single layer clothing gloves during scenario 3	Confidential information
		2 / Coveralls over single layer clothing, gloves during scenario 3	Confidential information
4 & 5 & 6	Professionals	1 / No PPE during scenarios 4 & 5	Confidential information
		2 / Single layer clothing during scenarios 4 & 5	Confidential information
		2 / Single layer clothing, gloves during scenarios 4 & 5	Confidential information
		2 / Coveralls over single layer clothing, gloves during scenarios 4 & 5	Confidential information
7	Bystanders	1 / No PPE	N/A Reverse calculation scenario

Summary of main paths of livestock exposure assessment:

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/day)**
8	Beef cattle	1	Confidential information
9	Dairy cattle	1	Confidential information
10	Fattening pig	1	Confidential information
11	Breeding pig	1	Confidential information
12	Broiler chicken	1	Confidential information
13	Laying hen	1	Confidential information

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Below are the relevant reference values to be used for biocidal risk characterisation.

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value [&]
$AEL_{short\text{-}term}$	28 day rat study	29 mg/kg bw/day	100*	40%	0.12 mg/kg bw/day
$AEL_{mid\text{-}term}$	1 year dog study	10 mg/kg bw/day	100*	40%	0.04 mg/kg bw/day
$AEL_{long\text{-}term}$	1 year dog study	10 mg/kg bw/day	100*	40%	0.04 mg/kg bw/day

*10-fold for intraspecies and 10-fold for interspecies differences.

[&] Sumilarv® 0.5G will be applied up to 6 times/year in animal houses and waste treatment facilities. Based on the use frequency and the use season (at least spring until autumn), it cannot be excluded that the exposure period will exceed three months. Therefore, a reference dose for $AEL_{short\text{-}term}$ is not considered relevant for the assessment of risk.

Below are the relevant reference values derived following the evaluation of Pyriproxyfen use in plant protection products.

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
ARfD	Not required^	N/A^	N/A^	N/A^	N/A^
ADI	1 year dog study	10 mg/kg bw/day	100*	None	0.1 mg/kg bw *per* day

^There is no evidence in the toxicological database for Pyriproxyfen of acute effects that require an ARfD to be set. This is in agreement with Regulatory Authority assessments of Pyriproxyfen as both a biocide and a plant protection product.

*10-fold for intraspecies and 10-fold for interspecies differences.

It is noted that in the pyriproxyfen revised final CAR (Oct. 2012) an ADI value was not allocated and it was not considered to be necessary.

For consumer risk assessment an ADI value is set in the PAR. The basis for the ADI is the NOAEL from the 1-year dog study, applying a incertainty factor for inter-/intra-species variation (as with $AEL_{long\text{-}term}$).

Maximum residue limits or equivalent

Residue definitions

MRLs or other relevant reference values	Reference	Relevant commodities	Value
MRL	Reasoned opinion on the modification of the existing MRLs for Pyriproxyfen in stone fruits and tea. EFSA Journal 2013;11(12):3489, 26 pp.	Products of animal origin – terrestrial animals	0.05*
CXL	JMPR evaluation on the active substance Pyriproxyfen (2000)	Edible offal of goat	0.01&
CXL	JMPR evaluation on the active substance Pyriproxyfen (2000)	Goat meat (includes fat)	0.01&
CXL	JMPR evaluation on the active substance Pyriproxyfen (2000)	Edible offal of cattle	0.01&
CXL	JMPR evaluation on the active substance Pyriproxyfen (2000)	Cattle meat (includes fat)	0.01&

*Below the limit of quantification

&At or about the limit of determination

The available studies investigating Pyriproxyfen metabolism in livestock were also evaluated and compared with the proposed uses of Sumilarv® 0.5G. Residues above the LOQ of 0.05 mg/kg are not expected for poultry and eggs, ruminant and pig tissues.

Specific reference value for groundwater

No specific reference value for groundwater is required in accordance with BPR Annex VI point 68. The standard maximum limit of 0.1 µg/L for pesticides in groundwater applies, as laid down by Directive 98/83/EC.

Risk for industrial users

No risk assessment from industrial use is presented, since the technical material and biocidal product are manufactured outside of the EU.

Risk for professional users

Systemic effects

Task/ Scenario	Tier/PPE	Estimated uptake (mg/kg bw/d)	Estimated uptake/AEL* (%)	Acceptable (yes/no)
1	1 / No PPE	Confidential information	Confidential information	No
	2 / Gloves	Confidential information	Confidential information	No
	2 / Single layer clothing, gloves	Confidential information	Confidential information	Yes
	2 / Coveralls over single layer of clothing, gloves	Confidential information	Confidential information	Yes
2	1 / No PPE	Confidential information	Confidential information	No
	2 / Single layer clothing	Confidential information	Confidential information	Yes
	2 / Single layer clothing, gloves	Confidential information	Confidential information	Yes
3	1 / No PPE	Confidential information	Confidential information	No
	2 / Single layer clothing	Confidential information	Confidential information	No
	2 / Single layer clothing, gloves	Confidential information	Confidential information	No
	2 / Coveralls over single layer of clothing, gloves	Confidential information	Confidential information	Yes
4	1 / No PPE	Confidential information	Confidential information	Yes
	2 / Single layer clothing	Confidential information	Confidential information	Yes
	2 / Single layer clothing, gloves	Confidential information	Confidential information	Yes
	2 / Coveralls over single layer of clothing, gloves	Confidential information	Confidential information	Yes
5	1 / No PPE	Confidential information	Confidential information	Yes
	2 / Single layer clothing	Confidential information	Confidential information	Yes

* AEL = 0.04 mg/kg bw/day (see revised final CAR of pyriproxyfen, Oct. 2012).

Combined scenarios

Scenarios combined	Tier	Estimated uptake (mg a.s./kg bw/d)	Estimated uptake/AEL* (%)	Acceptable (yes/no)
4 & 5	1 / No PPE	Confidential information	Confidential information	Yes
	2 / Single layer clothing	Confidential information	Confidential information	Yes
1 & 6	1 / No PPE during scenario 1	Confidential information	Confidential information	No
	2 / Gloves during scenario 1			No
	2 / Single layer clothing, gloves during scenario 1	Confidential information	Confidential information	Yes
	2 / Coveralls over a single layer of clothing, gloves during scenario 1	Confidential information	Confidential information	Yes
2 & 6	1 / No PPE during scenario 2	Confidential information	Confidential information	No
	2 / Single layer clothing during scenario 2	Confidential information	Confidential information	Yes
	2 / Single layer clothing, gloves during scenario 2	Confidential information	Confidential information	Yes
3 & 6	1 / No PPE	Confidential information	Confidential information	No
	2 / Single layer clothing during scenario 3	Confidential information	Confidential information	No
	2 / Single layer clothing gloves during scenario 3	Confidential information	Confidential information	No
	2 / Coveralls over single layer clothing, gloves during scenario 3	Confidential information	Confidential information	Yes
4 & 5 & 6	1 / No PPE	Confidential information	Confidential information	Yes
	2 / Single layer clothing during scenarios 4 & 5	Confidential information	Confidential information	Yes

* AEL = 0.04 mg/kg bw/day (see revised final CAR of pyriproxyfen, Oct. 2012).

Local effects

Sumilarv® 0.5G is not classified as either a skin or eye irritant nor has the potential for skin sensitisation. Consequently, it is considered that under the proposed conditions of use, there will be no local effects. No local effect risk characterisation is required.

Conclusion

For professional users safe uses have been identified for the loading of application equipment and/or application of Sumilarv® 0.5G according to the list of intended uses, when appropriate PPE is considered. The recommended type of PPE for each application scenario is as follows:

- Single layer of clothing and gloves, for manual application by hand (Scenario 1),
- Single layer of clothing, for mechanical application by hand granule spreader (Scenario 2),
- Coveralls over a single layer of clothing and gloves for mechanical application by blower with granule nozzle (Scenario 3),
- No PPE for mechanical application using a crawler mount type power granular feeder (Scenarios 4 & 5).

For the combined exposure of professional users, safe uses have been identified for the loading of application equipment and/or application of Sumilarv® 0.5G, followed by the laundering of contaminated clothing, when appropriate PPE is considered, as above.

Risk for non-professional users (Bystanders)

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
6	For use with Scenario 1 Laundering of contaminated clothing	10	0.04	Confidential information	Confidential information	Yes
6	For use with Scenario 1 Laundering of contaminated coverall	10	0.04	Confidential information	Confidential information	Yes
6	For use with Scenario 2	10	0.04	Confidential information	Confidential information	Yes
6	For use with Scenario 3	10	0.04	Confidential information	Confidential information	Yes
6	For use with Scenario 4&5	10	0.04	Confidential information	Confidential information	Yes

Combined scenarios

No assessment for combined scenarios is required.

Local effects

Sumilarv® 0.5G is not classified as either a skin or eye irritant nor has the potential for skin sensitisation. Consequently, it is considered that under the proposed conditions of use, there will be no local effects. No local effect risk characterisation is required.

Conclusion

It is concluded that an acceptable risk can be determined for the washing of Sumilarv® 0.5G contaminated clothing.

Risk for the general public

Systemic effects

It is considered that there will be no significant indirect exposure following application of the product to animal houses, since in practice adults and children will not enter treated areas. If however adults and children were to enter treated animal houses then any exposure would only be on the undersides of footwear and this will not lead to any significant absorption of the active substance. Such a conclusion was supported by the RMS in the CA report for Pyriproxyfen.

Indirect exposure to the general public *via* animal housing was discussed at TMIII 2011, where it was commented that farmer's children and possibly school children on visits to a farm could have access to the granules after application of the product. However, the RMS (Ctgb) was of the opinion that as the product will be applied to the manure, most granules will be in the manure and therefore it is not very likely that children/toddlers will be orally exposed to the granules.

Based upon the anticipated concentration of Pyriproxyfen in manure (PEC taken from the Environmental Exposure Section – see Section 3.3), the maximum amount of manure that could be handed by the toddler before the AEL is reached (*i.e.*, reverse reference calculations) is estimated to be 1.25 kg. It is unlikely that children/toddlers will be exposed to this amount of manure after application of the product.

Combined scenarios

No assessment for combined scenarios is required.

Local effects

Sumilarv® 0.5G is not classified as either a skin or eye irritant nor has the potential for skin sensitisation. Consequently, it is considered that under the proposed conditions of use, there will be no local effects. No local effect risk characterisation is required.

Conclusion

It can be concluded that no adverse health effects are expected after indirect exposure of the general public to Sumilarv® 0.5G contaminated material when visiting farms.

Risk for consumers via residues in food

According to the Assessment Report (Pyriproxyfen – Product-type 18, Non-confidential Evaluation report established by The Netherlands - version 2 of September 2012), it is not expected that residues in food and feeding stuffs will occur in relevant amounts for the intended uses.

Importantly, the product is intended to be applied only by professionals with selective application over the manure on the floor, in manure cellars or other fly breeding sites. The proposed use suggests that it is highly unlikely that livestock animals such as cows and pigs will be exposed to the active substance *via* contaminated food and water or through licking of surface, since those animals will not eat from manure. Furthermore, cows and pigs do not contaminate their lying area, under normal breeding conditions.

In the case of free-range chickens, it is noted that granules - given their size – may be picked up by birds. However, this was not the case for the assessment of the Sumilarv® 0.5G formulation as the granules are too small to pick up. Particle size analysis evaluated in the Assessment Report by the Netherlands shows that < 2.5% of the particles in Sumilarv® 0.5G have a diameter >590 microns and therefore it is very unlikely that a significant quantity of the particles would be consumed by hens.

In the case of product application in poultry houses (caged chickens), Sumilarv® 0.5G will be applied directly on manure beneath the cages or on the manure stored in the cellar (an under-the-building storage depot). Furthermore, secondary exposure of poultry through eating any contaminated larvae and/or pupae can be excluded, since contaminated larvae and pupae will be in the manure and cannot be reached by poultry.

There are no restrictions on whether the farm animals may remain in the premises or not while treatment is carried out. The product is a solid, granular product applied by hand or with a hand granule spreader (+crawler mount type power granular feeder for waste treatment facilities), therefore given the physical state, the size of granules and dust, as well as the mode of application, inhalation exposure can be excluded. In addition, the active substance is almost totally non-volatile (vapour pressure $< 4.23 \times 10^{-2}$ $Pa.m^3.mol^{-1}$). Nevertheless, an inhalation exposure calculation was carried out to demonstrate the worst case scenario. Given the physical state and the mode of application, there are no restrictions proposed relating to the covering of troughs, animal feed and water for the treatment of animal housing as the operator is a professional or a PCO ('Pest Control Operator') and the granules are spread by hand or a granule spreader towards the ground and only onto manure.

However, as a very conservative approach, a quantitative assessment has been presented, carried out with beef and dairy cattle, fattening and breeding pig, laying hen in battery cages, broiler chicken – free range with grating floor and egg-laying hen in battery cages with forced drying, using the DRAWG draft proposal guidance document (Technical Notes for Guidance - Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products endorsed during the 39th CA meeting for release for consultation of stakeholders - CA-Dec10-Doc.6.2.b).

There is additional data however on the effects of processing, which were investigated during the approval process of Pyriproxyfen as an active substance for plant protection products.

In a hydrolysis study with conditions simulating pasteurisation, baking/brewing/boiling and sterilisation, Pyriproxyfen was found to be stable as no significant degradation products were identified.

The level of residues in processed products was determined in processing studies on tomato and cotton seed. Residues decreased in tomato juice, canned tomato, pureed tomato and ketchup processed from peeled tomatoes. The majority of residues were recovered in the

tomato peel. In tomatoes processed without peeling, a slight concentration of residues was noted in pureed tomatoes.

In crude and refined cotton oil, as well as in the pressed cotton cake, residues decreased upon processing[19].

Since the residues resulting from use of Sumilarv® 0.5G are not expected to exceed the current MRL of 0.05 mg/kg in animal products set under Regulation 396/2005, no further data investigating the magnitude of residues in processed products, is necessary.

Pyriproxyfen is also used as an active substance in plant protection products worldwide. The EU review report for the active substance Pyriproxyfen - SANCO/836/08 – Final (11 May 2010) established that any residues arising from the proposed uses, following application consistent with good agricultural practice, have no harmful effects on human or animal health.

For the Annex I inclusion, metabolism data of Pyriproxyfen in livestock was submitted and evaluated (two studies in goat and two in hen). Metabolism studies were conducted with a dose of 0.34 -0.38 mg/kg bw/day for ruminants and 0.78 mg/kg bw/day for poultry, which is comparable with the expected exposure from the Sumilarv® 0.5G biocidal product uses for ruminants and higher than the expected exposure for poultry. Residues above the LOQ of 0.05 mg/kg are not expected for poultry and eggs, ruminant and pig tissues.

During the recent MRL application for Pyriproxyfen in stone fruits and tea (EFSA, 2013[20]), a consumer risk assessment was performed using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population. The input data also includes MRLs for products of animal origin (at 0.05 mg/kg for all products of animal origin).

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for up to 8.5 % of the ADI (DE child diet). The contribution of residues in the crops under consideration to the total consumer exposure (in percentage of the ADI) accounted for a maximum of 0.53 % for tea (IE adult diet), 0.09 % for cherries (DE child diet) and peaches and 0.01 % for plums (IE adult diet).

The MRLs for Pyriproxyfen were originally set in Regulation 396/2005, which were recently amended according to Regulation 737/2014.

Matrix	EU MRL for Pyriproxyfen
Products of animal origin – terrestrial animals	0.05*

(*) Below the limit of quantification.

Consideration of the available studies investigating Pyriproxyfen metabolism in livestock were also evaluated and compared with the proposed uses of Sumilarv® 0.5G. Residues above the LOQ of 0.05 mg/kg are not expected for poultry and eggs, ruminant and pig tissues.

19 Conclusion on pesticide peer review regarding the risk assessment of the active substance Pyriproxyfen. EFSA Scientific Report (2009) 3361-99

20 European Food Safety Authority, 2013. Reasoned opinion on the modification of the existing MRLs for Pyriproxyfen in stone fruits and tea. EFSA Journal 2013;11(12):3489, 26 pp. doi:10.2903/j.efsa.2013.3489

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

Sumilarv® 0.5G contains only one active substance, Pyriproxyfen. Furthermore, Sumilarv® 0.5G should not be combined with other products. Therefore, no assessment of combined exposure is made.

2.2.7 Risk assessment for animal health

It is considered that there are no risks posed to animals from Sumilarv® 0.5G in terms of immediate or delayed unacceptable effects itself, or as a result of its residues, directly or through drinking water, feed, air, or through other indirect effects.

In addition, Pyriproxyfen is one of 3 active ingredients (in combination with dinotefuran and permethrin) authorised for the control of fleas, ticks, sand flies, mosquitoes and stable flies by the EU Committee for Medicinal Products for Veterinary Use (CVMP) following submission of a suitable data package (http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/medicines/002555/vet_med_000282.jsp&mid=WC0b01ac058001fa1c).

Based upon the risk assessments presented in this dossier and the approval of the use of Pyriproxyfen as a veterinary medicine in dogs, it is considered that there would be no unacceptable risk to the health of inadvertently contaminated animals from accidental exposure to Sumilarv® 0.5G.

2.2.8 Risk assessment for the environment

The use of Sumilarv® 0.5G in animal housings may result in exposure of the various environmental compartments. Application to manure will result in a potential exposure to soil when the manure is spread onto land, and there will be subsequent exposure to surface water systems via runoff or/and drainage. Exposure to a STP is possible through the discharge of waste water from cleaning operations of treated animal pens to sewer systems.

The risk assessment for the environment was conducted according to the Guidance on the Biocidal Products Regulation, Vo IV, Part B Risk Assessment, April 2015, from now on Guidance on BPR and ESD PT18 for animal housings and manure storage systems.

2.2.8.1 Effects assessment on the environment

Atmosphere

The risk to atmosphere from Pyriproxyfen and the metabolites 4'-OH-Pyriproxyfen, PYPAC, and DPH-Pyr is considered extremely low due to the low vapour pressure of the substance, the way the product is formulated and the intended method of application.

Sewage Treatment Plant (STP)

The $PNEC_{microorganisms}$ was given as 10 mg a.s./L and also 0.101 mg a.s./L based on maximum solubility (AR, 2012). $PNEC_{microorganisms}$ 0.101 mg a.s./L is used in this document.

Aquatic compartment

The $PNEC_{aquatic\text{-}continuous}$ for Pyriproxyfen is 0.003 µg/L (AR, 2012). For the relevant metabolites to surface water, DPH-Pyr, 4'-OH-Pyriproxyfen, and PYPAC the $PNEC_{aquatic\text{-}continuous}$ are 5.1 µg/L, 0.27 µg/L, and 30 µg/L, respectively (AR, 2012). These $PNEC_{aquatic\text{-}continuous}$ values are relevant for surface water concentrations following emissions from STPs and for runoff and drainage to surface water following application of treated manures to land.

Sediment

Pyriproxyfen and the metabolite 4'-OH Pyriproxyfen have koc values above 500 L/kg and therefore clearly require sediment effects assessment (as shown in the AR, 2012). The metabolites PYPAC and DPH-Pyr have low koc values (21 and 10 L/kg) and are unlikely to have a risk to sediment (Guidance on BPR, Section 3.5.2) however, for completeness $PNEC_{sediment\text{-}continuous}$ values for these metabolites have been estimated using equilibrium partitioning based on the $PNEC_{aquatic\text{-}continuous}$ value.

The $PNEC_{sediment\text{-}continuous}$ values for Pyriproxyfen and 4'-OH-Pyriproxyfen are 1.40 µg/kg ww and 15 µg/kg ww, respectively (values estimated using equilibrium partitioning (Koc of 21175 L/kg and PNEC water of 0.000003 mg/L) and mentioned in the Doc I, CAR 2012 page 14 and document IIC, CAR 2012, page 16). The $PNEC_{sediment\text{-}continuous}$ values for PYPAC and DPH-Pyr using equilibrium partitioning are 37 µg/kg ww and 5.1 µg/kg ww respectively. These $PNEC_{sediment\text{-}continuous}$ values are considered relevant for emissions from STPs and for runoff and drainage to surface water following application of treated manures to land.

Terrestrial

The toxicity towards birds and mammals is low with LD_{50} values of >1906 and >5000 mg/kg bw, respectively (0% mortality). As detailed in Doc I, AR (2012) the lowest long term NOEC for mammals is 200 mg a.s./kg diet and an assessment factor of 30, the PNECoral is 6.7 mg a.s./kg diet (0.44 mg a.s./kg bw). Based on a 21 weeks NOECreproduction of 572 mg a.s./kg diet and an assessment factor of 30, the PNECoral,birds is 19 mg a.s./kg diet (2.3 mg a.s./kg bw).

The worst case $PNEC_{soil}$ for Pyriproxyfen is 0.0011 mg/kg ww based on equilibrium partitioning (Doc I, CAR 2012) and is used to assess the risk to soil organisms from the application of treated manure to arable land and grassland. It should be noted that terrestrial studies were available for micro-organisms, earthworms and plants, however, the $PNEC_{soil}$ based on corresponding data was not accepted at Annex I inclusion level due to the lack of data on non-target soil insects. The $PNEC_{soil}$ based on equilibrium partitioning is likely to be conservative.

New chronic data on the toxicity of Pyriproxyfen are now available for predatory mite (*Hypoaspis aculeifer*), spring tail (*Folsomia candida*) and earthworm (*Eisenia fetida*) with reproductive NOEC (EC_{10}) values of 50 (88.7), 12.5 (12.7) and 50 (49.3) mg a.s./kg soil dw. Greece as the eCA for Sumilarv 0.5G has evaluated the studies and these are shown in Annex 3.8.

Based on the above, Greece has decided to do the risk assessment with and without taking into concideration these new studies. These studies are summarized below.

Three new (not available in pyriproxyfen CAR, 2012) studies on the effects of pyriproxyfen (technical grade) to soil macro-organisms have been submitted by the applicant. These studies investigate (i) the effects of Pyriproxyfen TG on reproduction and growth of earthworms *Eisenia fetida* (Confidential information), (ii) the effects of Pyriproxyfen TG on reproduction of the Collembola *Folsomia candida* (Confidential information), and (iii) the effects of Pyriproxyfen TG on reproduction of the predatory mite *Hypoaspis aquleifer* (Confidential information). These three chronic toxicity studies have been evaluated by the eCA and the respective summaries are provided in Table 2.2.8.1-1.

The GLP chronic toxicity study on the effects of Pyriproxyfen TG on reproduction and growth of earthworms *Eisenia fetida* was well performed according to the OECD testing guideline 222 and fulfilled the corresponding validity criteria. Seven treatment groups were tested: 5 treatment concentrations, 1 untreated control and 1 solvent control, in an artificial soil with 5% peat. Five concentrations of Pyriproxyfen TG were tested: 6.3, 12.6, 25.2, 50.4 and 100.8 mg test item/ kg soil dry weight, corresponding to nominal concentrations of 6.25, 12.5, 25, 50 and 100 mg active ingredient/ kg soil dry weight. Mortality, behavioural abnormalities and pathological symptoms were recorded 28 days after application. The assessment started with the control treatment, followed by increasing rates of the test. For effects on reproduction, the number of offspring was determined after 56 days. Statistical analysis (Williams t-test, one-sided) of the study results indicated a NOEC of 50 mg active ingredient/ kg soil dry weight based on reproduction for earthworm. A reference item Carbendazim was tested and the EC_{50} value obtained for reproduction was 1.87 mg carbendazim/ kg soil within the required ranges verifying the suitability of the test system.

The GLP chronic toxicity study on the effects of Pyriproxyfen TG on reproduction of the Collembola *Folsomia candida* was well performed according to the OECD testing guideline 232 and fulfilled the corresponding validity criteria. A deviation from the OECD 232 photoperiod requirement (namely 12:12 hrs light:dark) is reported since the light:dark duration was 16:8 hrs in the course of the test. A pH ranging between 5.4 and 5.8 was slightly below the minimum required at the test end. However these slight deviations are considered to have only negligible effect on the study outcome since all the validity criteria were met. Seven treatment groups were tested: 5 treatment concentrations, 1 untreated control and 1 solvent control, in an artificial soil with 5% peat. Five concentrations of Pyriproxyfen TG were tested: 6.3, 12.6, 25.2, 50.4 and 100.8 mg test item/ kg soil dry weight, corresponding to nominal concentrations of 6.25, 12.5, 25, 50 and 100 mg active ingredient/ kg soil dry weight. Mortality, behavioural abnormalities and effects on reproduction were recorded 28 days after application. Statistical analysis (Williams t-test) of the study results indicated a NOEC of 12.5 mg active ingredient/ kg soil dry weight based on reproduction for collembola. A reference item Boric acid was tested and the EC50 value obtained for reproduction was 145 mg Boric acid/ kg soil about the required value of 100 mg boric acid/kg soil verifying the suitability of the test system.

The GLP chronic toxicity study on the effects of Pyriproxyfen TG on reproduction of the predatory mite *Hypoaspis aquleifer* was well performed according to the OECD testing guideline 226 and fulfilled the corresponding validity criteria. Seven treatment groups were tested: 5 treatment concentrations, 1 untreated control and 1 solvent control, in an artificial soil with 5% peat. Five concentrations of Pyriproxyfen TG were tested: 6.3, 12.6, 25.2, 50.4 and 100.8 mg test item/ kg soil dry weight, corresponding to nominal concentrations of 6.25, 12.5, 25, 50 and 100 mg active ingredient/ kg soil dry weight. Mortality, behavioural abnormalities and effects on reproduction were recorded 28 days after application. Statistical analysis (Williams t-test) of the study results indicated a NOEC of 50 mg active ingredient/ kg soil dry weight based on reproduction for predatory mite. A reference item Perfekthion (active ingredient dimethoate) was tested and the EC_{50} value obtained for reproduction was

5.5 mg dimethoate/ kg soil and the LC_{50} value was 4.3 mg dimethoate/ kg soil considered within the required range verifying the suitability of the test system.

Table 2.2.8.1-1: Summary table - Further ecotoxicological studies - terrestrial

Summary table of further ecotoxicological studies								
Method, Guideline, GLP status, Reliability	**Species**	**End point**	**Exposure**		**Results**	**Remarks**	**Reference**	**Annex 3.8 point**
			Design	**Dura-tion**	**(mg a.s./kg dw)**			
OECD 226, GLP Confidential information	*Hypoaspis aculeifer*	Repro NOEC EC_{10}	Artificial soil 5% peat	14 days	50 88.7		Confidential information IUCLID: 9.2.5.002	**Section 7.5.2.1/02**
OECD 232, GLP Confidential information	*Folsomia candida*	Repro NOEC EC_{10}	Artificial soil 5% peat	28 days	12.5 12.7		Confidential information IUCLID: 9.2.5.003	**Section 7.5.2.1/03**
OECD 222, GLP Confidential information	*Eisenia fetida*	Repro NOEC EC_{10}	Artificial soil 5% peat	8 weeks	50 49.3		Confidential information IUCLID: 9.2.2.2.002	**Section 7.5.2.1/01**

These data now provide relevant arthropod data to address the concerns of related to the insecticidal mode of action of Pyriproxyfen and their use will provide a second $PNEC_{soil}$ based on terrestrial data (§9.3.1. of Guidance on the Biocidal Products Regulation, Vo IV, Part A, Information requirements, November 2014). The worst case endpoint from these studies is the reproductive NOEC value of 12.5 mg/kg dw for *F candida*. This endpoint is from a study with 5% organic matter and thus the endpoint needs to be corrected using the following formula (equation 71 of Guidance on BPR):

$NOEC_{(standard)} = NOEC_{(exp)}$ mg/kg x $(Fom_{soil(standard)}/Fom_{soil(exp)}$

Therefore the standardised NOEC for *Folsomia* for a soil with 3.4% organic matter = 12.5 x (0.034/0.05) = 8.5 mg/kg dw (7.4 mg/kg ww).

The soil micro-organism study reported a NOEC value of ≥ 1.5 mg/kg dw (≥ 1.3 mg/kg ww). So if this is used as worst case the PNEC soil could be amended to ≥ 0.03 mg/kg dw (0.026 mg/kg ww) using an AF of 50 as there are long term tests for two trophic levels including the most sensitive species (see Table 23, Guidance on BPR). The study with terrestrial plants was not considered due to its limitations (Pyriproxyfen Doc II A, CAR 2012).

The metabolites 4'-OH-Pyriproxyfen and PYPAC may occur in soil at levels greater than 5% of parent. The PNECsoil values for these metabolites have therefore been estimated based on the $PNEC_{aquatic\text{-}continuous}$ values for 4'-OH-Pyriproxyfen and PYPAC. The $PNEC_{soil}$ values estimated based on equilibrium partitioning are 0.012 and 0.014 mg/kg ww for 4'-OH-Pyriproxyfen and PYPAC respectively.

Pyriproxyfen has been shown to have low acute toxicity to bees both by oral and contact exposure. The 48-hour and 96-hour LD_{50} values for oral and contact toxicity to honey bees was > 100 µg a.s./bee respectively (AR, 2012). According to two more exposure studies, that can be used as supplementary information (Pyriproxyfen Doc III A, CAR 2012), no effects were seen on bee brood when honey bee or bumble bee colonies dosed with sucrose solution (25 and 20 mg/L respectively) in 20 days. In addition, the EFSA review for the PPP use of Pyriproxyfen (2009) noted that in a field study in Germany (dose rate 1 x 75 g a.s./ha), Pyriproxyfen 10% EC did not affect mortality of adults or juvenile stages, overall colony performance or survival and development of eggs and larvae through to adult emergence.

The DAR, VOL3, Annex B7, pp.260) for Pyriproxyfen PPP use, states that Pyriproxyfen is considered non-systemic: 'No significant uptake of Pyriproxyfen or metabolites due to the internal transport in the plant is expected as Pyriproxyfen is a non-systemic insecticide.' As Pyriproxyfen is not a systemic insecticide, it is unlikely that it will be taken up from soil (where manure has been applied) by plants and exposure to bees *via* nectar and pollen is therefore unlikely.

Currently, there is no assessment concept available for how to derive a PNEC value for bees. The combination of no significant exposure and low toxicity indicates that there should be no unacceptable risk to bees from the proposed use of the product.

Bioaccumulation potential

Pyriproxyfen had a worst case measured aquatic BCF of 1495 L/kg ww as radioactivity, corresponding with 600 L/kg ww for the active substance, hence <2000 which means that Pyriproxyfen does not meet the B criterion.

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

Direct exposure of the aquatic environment from the proposed uses of the product is not expected. The formulation is a simple single active formulation and therefore active substance data are used to classify the product. However for completeness, available aquatic toxicity data with with Sumilarv® 0.5G are summarised below.

Further Ecotoxicological studies

Table 2.2.8.1-2: Summary table - Further ecotoxicological studies

Summary table of further ecotoxicological studies							
Method, Guideline, GLP status, Reliability	**Species**	**End point**	**Exposure**		**Results**	**Remarks**	**Reference**
			Design	**Dura-tion**	**LC_{50}/EC_{50} mg product/L (mg a.s./L)**		
Similar to OECD 203 GLP status not specified. Reliability 2.	*Cyprinus carpio* Juvenile, Confidential information	Mortality/acute	Static Confidential information	48 and 96 hours.	832.0 (4.2)	No a.s. analysis.	Confidential information IUCLID: 9.2.1.1. 001
No guideline followed. GLP status not specified. Confidential information	*Daphnia pulex* Confidential information	Immobility	Static Confidential information	3 hours.	>2000 (>10)	Only 3h exposure, no a.s. analysis.	Confidential information IUCLID: 9.2.1.2. 001

Conclusion used in Risk Assessment – Further ecotoxicological studies	
Value/conclusion	The risk assessment and classification of the product use active substance data and the product data shown above are submitted for completeness. The reliable data for fish indicate that there is no increase in toxicity of the formulation in comparison with the active substance alone.
Justification for the value/conclusion	Extrapolation of active substance data is justified since the product contains only a single active substance in a simple formulation (co-formulants are relatively inert compared to the a.s.). In any case the risk assessment and classification for the environment is based on the aquatic chronic data available for the active substance.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

No additional data required.

Supervised trials to assess risks to non-target organisms under field conditions

No additional data required or available.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

No additional data required or available.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

No additional data required or available.

Foreseeable routes of entry into the environment on the basis of the use envisaged

Sumilarv® 0.5G is intended for the control of flies in farm applications by treatment of floors contaminated with manure in animal houses and manure storage systems (indoor use) by the sprinkling of granules. Two application doses are proposed: 10 g product/m^2 every month or 20 g product/m^2 every 2 months. Application of Sumilarv® 0.5G will only be required during the fly season, when flies are problematic. This corresponds to a 6-month period, from April to September.

The use of Sumilarv® 0.5G will result in different exposures to the environment. Application to manure will result in a potential exposure to soil when the manure is spread onto land, and there will be subsequent exposure to surface water systems via runoff or/and drainage. Exposure to a STP is possible through the discharge of waste water (from cleaning operations of the treated animal pens) to sewer systems.

Further studies on fate and behaviour in the environment (ADS)

The data used for the exposure assessment has been taken from the Assessment Report (2012) and has been previously assessed by the eCA (NL). No further studies have been performed for the product since data can be extrapolated from the active substance data. However, as a refinement for STP emisions to surface water a new study was performed on the biodegradability of pyriproxyfen in activated sludge that has not been previously assessed. A summary of this study is presented below. The full Doc IIIA is presented in the Point 3.8 of the present document.

Summary table on further studies on fate and behaviour in the environment							
Method, Guideline, GLP status, Reliability	**Compartment**	**pH**	**Temp [°C]**	**Initial TS concentra-tion, C_0[mg/L]**	**Half-life, DT_{50} [d]**	**Re-marks**	**Re-ference[1]**
OECD Method 314B GLP Confidential information	Activated sludge	7.38	22±2	0.01	0.0529	none	Confidential information IUCLID 10.2

Introduction:

This study was designed to determine the biodegradation of [pyridyl-2,6-14C]pyriproxyfen under aerobic conditions in activated sludge. A 0.01 mg/L solution of [pyridyl-2,6-14C] pyriproxyfen was incubated at 22 ± 2 °C in the dark with biotic and abiotic sludge in a closed system. The test substance [pyridyl-2,6-14C]pyriproxyfen and its associated degradates contained in the activated sludge solutions were quantified by liquid scintillation counting (LSC). The disappearance of parent [pyridyl-2,6-14C]pyriproxyfen and the formation of metabolites was followed using high performance liquid chromatography with radiochemical detection (HPLC/RAM) at regular sampling intervals throughout the study.

Material and methods:

The study was under GLP and followed the OECD 314B on the biodegradation of pyriproxyfen in activated sludge.

Radiolabelled [pyridyl-2,6-14C]pyriproxyfen was used for the main study and non radiolabelled pyriproxyfen used as reference material.

The activated sludge used as the inoculum for this study was obtained from the Wareham Wastewater Treatment Plant, Wareham, Massachusetts, which receives primarily domestic waste. Approximately 8 liters of activated sludge were collected and upon arrival at Smithers Viscient, the sludge was passed through a 2-mm sieve and centrifuged at 1000 rpm for 10 minutes. The solids content was determined (4.74% solids content) and 24 grams (dry weight) was re-suspended in a 3-L aliquot of the secondary effluent at a concentration of 3000 ± 100 mg suspended solids/L. The sludge was mixed and aerated at approximately 50 mL/minute.

Prior to dosing, the pH of the biotic sludge was determined to be 7.38. The pH of the abiotic sludge (sterile/inactivated sludge) was determined to be 6.58 and was adjusted to 7.39 with 1 M sodium hydroxide. Prior to dosing, the dissolved oxygen concentration of the biotic sludge, the abiotic sludge and the reference sludge was determined to be 4.86, 6.06 and 4.91 mg O_2/L, respectively. Test temperature was set at 22 ± 2 °C.

The biodegradation of [pyridyl-2,6-14C]pyriproxyfen was studied at a concentration of approximately 0.01 mg/L and a temperature of 22 ± 2 ºC for 28 days in activated sludge.

Activated sludge samples were analyzed at time zero, and 0.167 (4 hours), 1, 2, 3, 7, 14, 21 and 28 days after dosing to determine primary and ultimate biodegradation.

At each sampling interval, the aqueous sludge samples were extracted and analyzed by liquid scintillation counting (LSC) and high performance liquid chromatography with radiochemical detection (HPLC/RAM) to evaluate primary degradation. Analysis of $^{14}CO_2$ trapping solutions was made to evaluate ultimate biodegradation. Dissolved organic carbon (DOC) measurements were also made to evaluate ultimate biodegradation of the reference substance.

Results and conclusion:

[pyridyl-2,6-14C]Pyriproxyfen underwent both primary and ultimate biodegradation over the course of the 28-day study.

Mass balance of the biotic sludge system ranged from 88.5 to 100.9% of the applied radioactivity (% AR). Mass balance of the abiotic sludge system ranged from 104.3 to 116.6% AR. Ultimate biodegradation (conversion to CO_2) occurred at 63.1 and 1.1% AR in the biotic and abiotic activated sludge test solutions, respectively.

Three regions of radioactivity and a polar region were observed in the HPLC analyses of the biotic sludge in addition to the parent peak and are summarized in the table below. No single peak >10% AR was measured in the region marked as 'others'. No single peak was greater than 8% AR in the polar region of the representative samples (Day 1 and 14) by the HPLC analysis using a Hydro-RP column for the separation of small polar molecules. No major regions of radioactivity were observed in the HPLC analyses of the abiotic sludge in addition to the parent peak.

Confidential information.

The DT_{50} and DT_{90} values were calculated with the non-linear kinetic software, CAKE using the SFO model. The overall primary biodegradation half-life after 28 days in the biotic sludge was calculated to be 0.0529 days. The elimination rate constant, k_e, was 13.1 $days^{-1}$. The DT_{90} value for the biotic system was 0.176 days. No significant degradation occurred in the abiotic sludge. The half-life after 28 days in the abiotic sludge was calculated to be 149 days. The elimination rate constant, ke, was 0.00467 $days^{-1}$.

The DT_{90} value for the abiotic system was determined to be 494 days. The kinetic values are presented below:

Confidential information.

The DOC depletion in the ethylene glycol reference control was 97.6% by Day 1, thus exceeding the "pass" criteria of the test (reaching 70% or greater DOC depletion within 14 days). This rapid degradation of the reference substance confirmed the presence of an acceptable microbial community and confirmed system integrity.

Conclusion used in Risk Assessment – Further studies on fate and behaviour in the environment	
Value/conclusion	DT_{50} of 0.0529 d for pyriproxyfen in sewage sludge
Justification for the value/conclusion	Robust study performed under GLP following the OECD guideline 314B
Data waiving	
Information requirement	Not relevant
Justification	Not relevant

Leaching behaviour (ADS)

No further data is required.

Testing for distribution and dissipation in soil (ADS)

No further data is required.

Testing for distribution and dissipation in water and sediment (ADS)

No further data is required.

Testing for distribution and dissipation in air (ADS)

No further data is required.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Biocidal product not sprayed near to surface waters. No additional information required.

Chronic aquatic toxicity

No additional chronic product toxicity data required or available.

Measured aquatic bioconcentration

No additional data for the product required or available.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

The proposed indoor uses of Sumilarv® 0.5G do not include for use of spray outside or for large scale formation of dust.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 18
Assessed scenarios	**Scenario 1**: Use in animal housing **Scenario 2:** Use in manure heaps
ESD(s) used	Emission Scenario Document number 14 for Product Type 18: Insecticides for stables and manure storage systems
Approach	**Scenario 1:** PEC_{soil} calculation following ESD 14, TGD (2003) and CAR (2012,NL), PEC_{gw} using the porewater calculation method and FOCUS modelling, PEC_{sw} calculation using the Montforts (1999) method, and PEC_{stp} using EUSES v2.1.2 **Scenario 2:** risk envelope from Scenario 1
Distribution in the environment	Calculated based on ESD 14, AR (2012, NL as RMS), and TGD 2003
Groundwater simulation	YES
Confidential Annexes	NO
Remarks	none

Emission estimation

Scenario 1

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1: Animal housing			
Application rate of biocidal product	10 or 20	g/m^2	Applications are made every 30 days or 90 days for the 10 g/m^2 application rate or 20 g/m^2 rate, respectively
Concentration of active substance in the product	0.525	%	
Application timings	30 or 90	d	

Pyriproxyfen concentrations in the environment resulting from the application of Sumilarv® 0.5G to animal housing were calculated following the ESD 14 guidance and the AR from The Netherlands. Basic parameters for animal housing have been taken from the ESD 14. In this section of the document only the worst-case values for predicted environmental concentrations (PECs) are presented. All PECs calculations for the exposure assessment are included in Annex 3.2 of this document. Annex 3.2 includes all equations, input parameters and all PEC values for each animal housing and all compartments.

Scenario 2

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 2: Manure heaps			
Application rate of biocidal product	10 or 20	g/m^2	Applications are made every 30 days or 90 days for the 10 g/m^2 application rate or 20 g/m^2 rate, respectively
Concentration of active substance in the product	0.525	%	
Application timings	30 or 90	d	

The dose of Sumilarv® 0.5G applied to manure is 10 g of product/ m^2 every month or 20 g of product/m^2 every 2 months.

According to the ESD document, a manure heap has a triangular prism form. The surface area of the manure is dependent of the total amount of manure produced and the storage time. When compared to the surface area of an animal housing, the manure heap surface area is significantly smaller. Therefore, the amount of product applied to the surface of the manure heap is significantly lower than the amount that would be applied to the whole animal housing. It should be pointed out that after communication with the applicant, either application in stables or on manure heaps will be made, but not both at the same time.

Also, for the PEC_{soil} calculations, it was assumed that all biocide applied in the animal housing will end up in manure and then in soil when manure is applied to soil. A fraction of 1 has been considered as a worst-case, as was considered in the AR report. However, in the ESD document, following a sprinkling application, a fraction of 0.9 of the total amount of biocide applied in the animal housing will end up in the manure. This fraction of 0.9 assumes there are losses of biocide when the manure is transported into the storage. Since a fraction equal to 1 has been considered, then all biocide will end up in the manure, which would be the case for direct application to a manure heap. Therefore, the calculations that have been made for all animal housing applications are worst-case when compared to applications made directly onto the manure heap. The terrestrial risk assessment should therefore be covered by previous calculations.

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	**Fresh water sedi-ment**	**Sea-water**	**Seawa ter sedi-ment**	**STP**	**Air**	**Soil**	**Groun d-water**	**Biota**
Scenario 1	yes	yes	no	no	yes	no	yes	yes	yes
Scenario 2	yes	yes	no	no	yes	no	yes	yes	yes

Input parameters (only set values) for calculating the fate and distribution in the environment for pyriproxyfen			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	321.5	g/mol	AR (2012)
Melting point	48	°C	AR (2012)
Boiling point	318	°C	AR (2012)
Vapour pressure (at 22.8°C)	$1.33x\ 10^{-5}$	Pa	AR (2012)
Water solubility (at 20°C, pH7)	0.101	mg/L	AR (2012)
Log Octanol/water partition coefficient (pH7)	4.86	Log 10	AR (2012)
Organic carbon/water partition coefficient (Koc)	21175	l/kg	AR (2012)
Henry's Law Constant (at 20-23°C)	$4.23\ x\ 10^{-2}$	Pa/m3/mol	Calculated, AR (2012)
Biodegradability	Not readily biodegradable		AR (2012)
DT_{50} for degradation in sewage sludge	**0.0529**	**d**	**New study endpoint summarised**
DT_{50} for biodegradation in surface water	6.5	d or hr (at 12ºC)	Mean value for whole system (AR, 2012)

Input parameters (only set values) for calculating the fate and distribution in the environment for pyriproxyfen			
Input	**Value**	**Unit**	**Remarks**
DT_{50} for hydrolysis in surface water	stable	(at 50ºC /pH4-pH9)	AR (2012)
DT_{50} for photolysis in surface water	5.0	d	Mean value, AR (2012)
DT_{50} for degradation in soil	8.6	d (at 20ºC)	Corrected for moisture, worst-case geomean (AR, 2012)
DT_{50} for degradation in air	0.26 (Atkinson method)– 0.307 (TGD method)	d	AR (2012)

Calculated fate and distribution in the STP		
Compartment	**Percentage [%]**	**Remarks**
	Scenario 1	
Air	5.05×10^{-3}	Values from EUSES v2.1.2
Water	11	
Sludge	56.1	
Degraded in STP	32.9	

Calculated PEC values

Summary table on worst-case calculated PEC values for pyriproxyfen						
	PEC_{STP}	**PEC_{sw}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[µg/L]	[µg/L]	[mg/kg_{wwt}]	[mg/kg]	[µg/L]	[mg/m^3]
Scenario 1	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
Scenario 2	Risk envelope from Scenario 1					

[1] Discharge from treatment of geese (free range with grating floor), see Table 3.2.2.4-2

[2] Local emmission following sewage treatment, see Table 3.2.2.4-2

[3] Turkey manure application to arable land at P_2O_5 immission limit, see Table 3.2.2.1-6

[4] Turkey manure application to arable land at P_2O_5 immission limit, using the Porewater calculation method, see Table 3.2.2.2-3. Using FOCUS modelling PEC_{gw} is <0.000001 µg/L.

Summary table on worst-case calculated PEC values for PYPAC						
	PEC_{STP}	**PEC_{sw}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[µg/L]	[µg/L]	[mg/kg_{wwt}]	[mg/kg]	[µg/L]	[mg/m^3]
Scenario 1	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
Scenario 2	Risk envelope from Scenario 1					

[1] Turkey manure application to arable land at P_2O_5 immission limit, see Table 3.2.2.3.1-4

[2] Turkey manure application to arable land at P_2O_5 immission limit, see Table 3.2.2.3.1-15

[3] Turkey manure application to arable land at P_2O_5 immission limit, see Table 3.2.2.1.1-5

[4] Turkey manure application to grassland at P_2O_5 immission limit. FOCUS modelling, Piacenza scenario. See Table 3.2.2.1.1-4. Note that PEC_{gw} exceeds 0.1 µg/L in some Northern European scenarios but is <0.1 µg/L in all Southern European scenarios.

Summary table on worst-case calculated PEC values for 4'-OH-Pyr						
	PEC_{STP}	**PEC_{sw}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[µg/L]	[µg/L]	[mg/kg_{wwt}]	[mg/kg]	[µg/L]	[mg/m^3]
Scenario 1	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
Scenario 2	Risk envelope from Scenario 1					

[1] Formation in surface water from local emmission of pyriproxyfen following sewage treatment, see Table 3.2.2.4-2

[2] Turkey manure application to arable land at P_2O_5 immission limit, see Table 3.2.2.1.1-5

[3] Turkey manure application to arable land at P_2O_5 immission limit. using the Porewater calculation method, see Table 3.2.2.2-3. Using FOCUS modelling PEC_{gw} is <0.000001 µg/L

Summary table on worst-case calculated PEC values for DPH-Pyr						
	PEC_{STP}	**PEC_{sw}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[µg/L]	[µg/L]	[mg/kg_{wwt}]	[mg/kg]	[µg/L]	[mg/m^3]
Scenario 1	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
Scenario 2	Risk envelope from Scenario 1					

[1] Formation in surface water from local emmission of pyriproxyfen following sewage treatment, see Table 3.2.2.4-2

Primary and secondary poisoning

Primary poisoning

Primary poisoning is not considered to be relevant if applications are made according to the label instructions in animal housing. The granules are not considered to be attractive since the organic carrier does not have any nutritional value. Qualitative and quantitative assessment of the risk from accidental exposure was considered in the assessment report and it was concluded that exposure to granules was unlikely to cause any risk unless daily feed intake was based on the consumption of granules only. Please see Section 2.2.8.3 for updated risk characterisation of this risk using the revised active substance content of 0.525%.

Secondary poisoning

The risk assessment for secondary poisoning is performed according to the strategy outlined in the Guidance on BPR (Section 3.8).

Secondary poisoning *via* the aquatic food chain

Secondary poisoning via the aquatic food chain is based on the schematic:

aquatic food chain water → aquatic organism → fish → fish-eating birds or mammals

The concentration of contaminant in food (fish) of fish-eating predators ($PEC_{oral,predator}$) is calculated from the PEC for surface water and the biomagnification factor according to the following equation:

$$PEC_{oral,predator} = PEC_{sw} \times BCF_{fish} \times BMF$$

PEC_{sw} in mg/L
Bioconcentration factor: BCF_{fish} in L/kg wet fish

In a worst-case approach, the maximum PEC_{sw} for treated manure is used. This corresponds to 0.00363 µg/L from exposure *via* manure to arable land and 0.14 µg/L from the emission from STP.

The BCF_{fish} for Pyriproxyfen is 581 L/kg. As the BCF for Pyriproxyfen is <2000 the biomagnification factor (BMF) is therefore 1 (see Table 24, section 3.8.3.4 of Guidance on BPR).

The resulting $PEC_{oral,\ predator}$ values are shown in Table 2.2.8.2-1.

Table 2.2.8.2-1 PEC values for secondary poisoning via the aquatic food chain for pyriproxyfen

Exposure scenario	PEC_{sw} (mg/L)	$PEC_{oral,\ predator}$ (mg a.s./$kg_{wet\ fish}$)
Application of manure to arable land	Confidential information	Confidential information
Emission from STP	Confidential information	Confidential information

Secondary poisoning *via* the terrestrial food chain

Biomagnification may also occur via the terrestrial food chain. A similar approach as for the aquatic route can be used. The schematic food chain is:

soil → earthworm → worm-eating birds or mammals

Since birds and mammals consume worms with their gut contents and the gut of earthworms can contain substantial amounts of soil, the exposure of the predators may be affected by the amount of substance in the soil. The $PEC_{oral,\ predator}$ which equates to the concentration in earthworms that may be consumed is calculated according to the following equations from Section 3.8.3.7 of the TGD:

$$PEC_{oral,predator} = \frac{BCF_{earthworm} \times PEC_{porewater} + PEC_{soil} \times F_{gut} \times CONV_{soil}}{1 + F_{gut} \times CONV_{soil}}$$

Where:

Parameter	Value	Reference
F_{gut} (kg dw/kg ww)	0.1	Default value Guidance on BPR, Section 3.8.3.7
$BCF_{earthworm}$ (L/kg ww)	870	CAR Pyriproxyfen, Doc II A
RHO_{soil} (Kg ww/m^3)	1700	Guidance on BPR, Table 5, Section 2.3.4
$CONV_{soil}$ (Kg_{wwt}·Kg_{dwt}^{-1})	1.13	Default value of conversion factor for soil concentration wet-dry weight soil, according to Guidance on BPR, Section 3.8.3.7
$PEC_{porewater}$ (mg·L^{-1})	Confidential information	As a worst case approach
PEC_{soil} (mg·Kg_{wwt}^{-1})	Confidential information	As a worst case approach

PEC_{pw} values have been previously calculated in Annex 3.2. The worst case PEC_{pw} and PEC_{soil} that are presented in the table "Summary table on worst-case calculated PEC values for pyriproxyfen" are used for the calculation of $PEC_{oral,\ predator}$.

The resulting $PEC_{oral,\ predator}$ is shown in Table 2.2.8.2-2 for the worst-case category (16, turkey free range with litter floor).

Table 2.2.8.2-2 Worst-case PEC values for secondary poisoning via the terrestrial food chain for pyriproxyfen

Exposure scenario	PEC_{soil} (mg/kg)	PEC_{pw} (mg/L)	$PEC_{oral,\ predator}$ (mg a.s./$kg_{wet\ earthworm}$)
Category 16 (turkey free range with litter floor)			
Worst-case application of manure to arable land	Confidential information	Confidential information	Confidential information

2.2.8.3 Risk characterisation

For the life cycle stages "production and formulation" of the biocidal product no environmental risk characterisation has been performed as the active substance is produced outside of the EU.

The exposure assessment in Section 2.2.8.2 has been performed for the proposed uses inside animal housing (scenario 1) and on indoor manure heaps (scenario 2). It should be noted that use on indoor manure heaps (scenario 2) is covered by the worst case exposure for animal housing (scenario 1).

Atmospheric compartment

Conclusion:

Due to the low volatility of Pyriproxyfen the emission to air will be very low. Therefore the risk of atmospheric exposure is considered negligible.

Aquatic compartment (including STP and groundwater)

PEC/PNEC for Sewage treatment plant (STP)

PEC/PNEC ratios in the Sewage Treatment Plant (STP) and subsequent release to surface water and sedment, resulting from use in animal housing, are shown below. Only the worst-case scenario (geese free range with grating floor) is included (confidential information, Table 3.2.2.4-2, Annex 3.2). The $PNEC_{microorganisms}$ is 0.101 mg a.s./L.

Table 2.2.8.3-1: Worst-case PEC/PNEC values for STP

Summary table on calculated PEC/PNEC values		
Animal subcategory and manure storage type (number)	**Substance**	**$PEC/PNEC_{STP}$**
Geese free range with grating floor (18) – worst case effluent concentration	Pyriproxyfen	Confidential information

Conclusion:

The worst case PEC/PNEC ratios is <1, so no risk to micro-organisms in STP was identified for discharge of liquid waste following cleaning operations after use in the worst case animal housing (Geese free range with grating floor (18)). It is therefore concluded that an acceptable risk is indicated for all animal house types since the worst case animal house had a PEC/PNEC ratio <1.

PEC/PNEC ratios for surface water

Concentrations of Pyriproxyfen in surface water may result from the application of manure to land and subsequent runoff and/or drainage to nearby surface waters and may be released in effluents from STPs treating waste water from poultry animal housing.

The $PNEC_{aquatic\text{-}continuous}$ for Pyriproxyfen is 0.003 µg/L (AR, 2012). For the relevant metabolites to surface water, DPH-Pyr, 4'-OH-Pyriproxyfen, and PYPAC the $PNEC_{aquatic\text{-}continuous}$ are 5.1 µg/L, 0.27 µg/L and 30 µg/L, respectively (AR, 2012). These $PNEC_{aquatic\text{-}continuous}$ values are relevant for surface water concentrations following emissions from STPs and for runoff and drainage to surface water following application of treated manures to land.

Aquatic PEC/PNEC values as a result of effluent from STP (poultry animal housings)

Pyriproxyfen may be released in effluents from STPs treating waste water from poultry animal housing. PEC/PNEC STP values are therefore relevant for poultry animal house/manure storage category numbers 8, 11, 12, 16, 17, and 18. The worst case PEC_{sw} values for Pyriproxyfen during STP emission period is Confidential information for geese free range with grating floor (18) and best case PEC_{sw} value of Confidential information for laying hen free range with litter floor (11) (see Table 3.2.2.4-2, Annex 3.2). Similarly the PEC_{sw} for the metabolites PYPAC, 4'-OH-Pyriproxyfen and DPH-Pyr are Confidential information, Confidential information and Confidential information for the worst case and Confidential information, Confidential information and Confidential information respectively.

Table 2.2.8.3-2: PEC/PNEC ratios from surface water *via* STP (PECs calculated from EUSES v.2.1.2)

Animal subcategory and manure storage type (number)	Substance	PNEC (µg/L)	$PEC/PNEC_{SW}$ (from STP)
Geese free range with grating floor (18) during emission period – worst case scenario (20 g a.s./m^2 every 2 months)	Pyriproxyfen	0.003	Confidential information
	4'OH-Pyr	0.27	Confidential information
	PYPAC	30	Confidential information
	DPH-Pyr	5.1	Confidential information
Laying hen free range with litter floor (11) – Best-case scenario during emission period (10 g.s./m^2 every month)	Pyriproxyfen	0.003	Confidential information
	4'OH-Pyr	0.27	Confidential information
	PYPAC	30	Confidential information
	DPH-Pyr	5.1	Confidential information

For PEC values see Table 3.2.2.4-2 in Annex 3.2.

Conclusion:

PEC/PNEC ratios following the release of STP effluents to surface water indicates a theoretical risk to aquatic organisms for both the worst-case and best-case scenarios. Therefore, the use of Sumilarv® 0.5G in animal housings (8, 11, 12, 16, 17 and 18) that release waste water *via* STP effluent to surface waters will not be recommended on the product label.

Aquatic PEC/PNEC values as a result of run-off and drainage after manure application to land

Surface water PEC values were estimated using porewater calculation and the Montforts (1999) method. The Porewater PEC values (PEC_{pw}) values were adjusted to take account of dilution by a factor of 10 in the receiving water body as a result of runoff or drainage.

Worst PEC_{sw} values for Pyriproxyfen based on pore water calculation and the Montfords (1999) methods are given in Annex 3.2.2.3 in tables 3.2.2.3-1 to 3.2.2.3-4 following manure use on arable and grassland. The following tables show the PEC/PNEC ratios for surface water.

Table 2.2.8.3-3: Pyriproxyfen PEC/PNEC ratios for surface water *via* pore water ($PNEC_{aquatic}$ 0.003 µg/L) – based on Nitrogen content – Arable Land

Cat-Subcat (number)	Animal subcategory and manure storage type	Arable land - RCRs							
		10 g a.s./m²				20 g a.s./m²			
		1st year app	10 year app	30 days TWA	180 days TWA	1st year app	10 year app	30 days TWA	180 days TWA
1	Dairy cow	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
2	Beef	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
3	Veal Calf	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
4	Sow, individual pens	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
5	sows in groups	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
6	Fattening pig	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
7	Laying hen, battery cages without treatment	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
8	Laying hen, battery cages with aeration	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
9	Laying hen, battery cages with forced drying	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
10	Laying hen, compact battery cages	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

Cat-Subcat (number)	Animal subcategory and manure storage type	Arable land - RCRs							
		10 g a.s./m²				20 g a.s./m²			
		1st year app	10 year app	30 days TWA	180 days TWA	1st year app	10 year app	30 days TWA	180 days TWA
11	Laying hen, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
12	Broiler, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
13	Laying hen, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
14	parent broiler >18 weeks, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
15	parent broiler in rearing, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
16	Turkey, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information			
17	Duck, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

Cat-Subcat (number)	Animal subcategory and manure storage type	Arable land - RCRs							
		10 g a.s./m²				20 g a.s./m²			
		1st year app	10 year app	30 days TWA	180 days TWA	1st year app	10 year app	30 days TWA	180 days TWA
18	Geese, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

Confidential information

Table 2.2.8.3-4: Pyriproxyfen PEC/PNEC ratios for surface water *via* pore water ($PNEC_{aquatic}$ 0.003 µg/L) – based on Nitrogen content – Grassland

Cat-Subcat (number)	Animal subcategory and manure storage type	Grassland - RCRs							
		10 g a.s./m²				20 g a.s./m²			
		1st year app	10 year app	30 days TWA	180 days TWA	1st year app	10 year app	30 days TWA	180 days TWA
1	Dairy cow	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
2	Beef	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
3	Veal Calf	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
4	Sow, individual pens	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
5	sows in groups	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
6	Fattening pig	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
7	Laying hen, battery cages without treatment	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
8	Laying hen, battery cages with aeration	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
9	Laying hen, battery cages with forced drying	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
10	Laying hen, compact battery cages	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

11	Laying hen, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
12	Broiler, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
13	Laying hen, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
14	parent broiler >18 weeks, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
15	parent broiler in rearing, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
16	Turkey, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information			
17	Duck, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
18	Geese, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

Table 2.2.8.3-5: Pyriproxyfen PEC/PNEC ratios from surface water *via* pore water ($PNEC_{aquatic}$ 0.003 µg/L) – based on Phosphorus content – Arable land

Cat-Sub-cat (Nb)	Animal subcategory and manure storage type	Arable land - RCRs							
		10 g a.s./m²				20 g a.s./m²			
		1st year app	10 year app	30 days TWA	180 days TWA	1st year app	10 year app	30 days TWA	180 days TWA
1	Dairy cow	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
2	Beef	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
3	Veal Calf	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
4	Sow, individual pens	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
5	sows in groups	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
6	Fattening pig	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
7	Laying hen, battery cages without treatment	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
8	Laying hen, battery cages with aeration	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
9	Laying hen, battery cages with forced drying	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

10	Laying hen, compact battery cages	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
11	Laying hen, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
12	Broiler, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
13	Laying hen, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
14	parent broiler >18 weeks, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
15	parent broiler in rearing, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
16	Turkey, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information			
17	Duck, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
18	Geese, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

Confidential information

Table 2.2.8.3-6: Pyriproxyfen PEC/PNEC ratios from surface water *via* pore water ($PNEC_{aquatic}$ 0.003 µg/L) – based on Phosphorus content – Grassland

Cat - Sub-cat (Nb)	Animal subcategory and manure storage type	Grassland - RCRs							
		10 g a.s./m²				20 g a.s./m²			
		1st year app	10 year app	30 days TWA	180 days TWA	1st year app	10 year app	30 days TWA	180 days TWA
1	Dairy cow	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
2	Beef	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
3	Veal Calf	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
4	Sow, individual pens	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
5	sows in groups	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
6	Fattening pig	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
7	Laying hen, battery cages without treatment	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
8	Laying hen, battery cages with aeration	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
9	Laying hen, battery cages with forced drying	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
10	Laying hen, compact	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

	battery cages								
11	Laying hen, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
12	Broiler, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
13	Laying hen, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
14	parent broiler >18 weeks, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
15	parent broiler in rearing, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
16	Turkey, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information			
17	Duck, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
18	Geese, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

Confidential information

Conclusion:

The risk assessment for the proposed use of 10 g.a.s/m^2 every 30 days indicates that the exposure of surface water *via* runoff and drainage is acceptable from use of manure from 15 animal subcategory and manure storage types (i.e. 1, 2, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15 and 18). The proposed use on three animal subcategory and manure storage types (3, 16 and 17) indicates an unacceptable risk to surface water from the use of 10 g a.s./m^2 and therefore these uses will not be included on the product label.

The risk assessment indicates that there should be no unacceptable risk *via* runoff and drainage to aquatic organisms from the proposed use of 20 g a.s./m^2 every 90 days for any of the 18 animal subcategory and manure storage types.

Metabolites

The aquatic RCR values have been calculated from the maximum total PEC_{sw} for metabolites 4'-OH-Pyriproxyfen, PYPAC and DPH-Pyr. Total PEC_{sw} is a combination of PEC_{sw} calculated from pore water (PEC_{pw} / 10) and direct metabolite formation in water based on % formation of metabolites. The PEC_{sw} values for the metabolites are shown in Annex 3.2.2.3.1, Tables 3.2.2.3.1-3 to 3.2.2.3.1-22. For the relevant metabolites to surface water, DPH-Pyr, 4'-OH-Pyriproxyfen, and PYPAC the $PNEC_{aquatic\text{-}continuous}$ are 5.1 µg/L, 0.27 µg/L, and 30 µg/L, respectively (AR, 2012).

Only the results from the 10 g a.s./m^2 application for the worst case animal subcategory and manure storage type (16) are shown in the summary tables below as these represent the worst case. Please see Annex 3.7.2 for full details of all the RCR values for all scenarios. The results show there is no risk to the aquatic environment as all metabolite RCRs are <0.01.

Table 2.2.8.3-7: Metabolite aquatic PEC/PNEC ratios (RCR) using PEC_{sw} from pore water and direct formation in surface water – Based on Nitrogen content – Arable land

Animal subcategory and manure storage type (number)	Substance	$PNEC_{aquatic}$	10 g a.s./m^2	
			Maximum Total PEC_{sw} (µg/L)	RCR
Turkey, free range with litter floor (16)	4'-OH-Pyriproxyfen	0.27	Confidential information	Confidential information
	PYPAC	30	Confidential information	Confidential information
	DPH-Pyr[1]	5.1	Confidential information	Confidential information

[1] direct formation only

Table 2.2.8.3-8: Metabolite aquatic PEC/PNEC ratios (RCR) using PEC_{sw} from pore water and direct formation in surface water – Based on Nitrogen content – Grassland

Animal subcategory and manure storage type (number)	Substance	$PNEC_{aquatic}$	10 g a.s./m²	
			Maximum Total PEC_{sw} (µg/L)	RCR
Turkey, free range with litter floor (16)	4'-OH-Pyriproxyfen	0.27	Confidential information	Confidential information
	PYPAC	30	Confidential information	Confidential information
	DPH-Pyr[1]	5.1	Confidential information	Confidential information

[1] direct formation only

Table 2.2.8.3-9 Metabolite aquatic PEC/PNEC ratios (RCR) using PEC_{sw} from pore water and direct formation in surface water – Based on Phosphorus content – Arable land

Animal subcategory and manure storage type (number)	Substance	$PNEC_{aquatic}$	10 g a.s./m²	
			Maximum Total PEC_{sw} (µg/L)	RCR
Turkey, free range with litter floor (16)	4'-OH-Pyriproxyfen	0.27	Confidential information	Confidential information
	PYPAC	30	Confidential information	Confidential information
	DPH-Pyr[1]	5.1	Confidential information	Confidential information

[1] direct formation only

Table 2.2.8.3-10 Metabolite aquatic PEC/PNEC ratios (RCR) using PEC_{sw} from pore water and direct formation in surface water – Based on Phosphorus content – Grassland

Animal subcategory and manure storage type (number)	Substance	$PNEC_{aquatic}$	10 g a.s./m²	
			Maximum Total PEC_{sw} (µg/L)	RCR
Turkey, free range with litter floor (16)	4'-OH-Pyriproxyfen	0.27	Confidential information	Confidential information
	PYPAC	30	Confidential information	Confidential information
	DPH-Pyr[1]	5.1	Confidential information	Confidential information

[1] direct formation only

Conclusion:

All the aquatic RCR values for the metabolites 4'OH-Pyriproxyfen, PYPAC and DPH-Pyr are lower than 1 indicating an acceptable risk from these metabolites to the aquatic environment from any of the proposed animal house uses from exposure *via* runoff or drainage.

PEC/PNEC ratios for sediment

The $PNEC_{sediment\text{-}continuous}$ for Pyriproxyfen and 4'-OH-Pyriproxyfen are 1.4 µg/kg ww and 15 µg/kg ww, respectively (Doc I, CAR 2012). The $PNEC_{sediment\text{-}continuous}$ values for PYPAC and DPH-Pyr using equilibrium partitioning are 37 µg/kg ww and 5.1 µg/kg ww respectively. These $PNEC_{sediment\text{-}continuous}$ values are considered relevant for emissions from STPs and for runoff and drainage to surface water following application of treated manures to land.

Sediment PEC/PNEC values as a result of effluent from STP (poultry animal housings)

Table 2.2.8.3-11: PEC/PNEC ratios for sediment *via* STP (PEC values calculated with EUSES v.2.1.2)

Animal subcategory and manure storage type (number)	Substance	PEC_{Sed} µg/kg ww	$PNEC_{Sed}$ µg/kg ww	$PEC/PNEC_{Sed}$ (from STP)
Geese free range with grating floor (18)	Pyriproxyfen	Confidential information	1.4	Confidential information
	4'OH-Pyr	Confidential information	15	Confidential information
	PYPAC	Confidential information	37	Confidential information
	DPH-Pyr	Confidential information	5.1	Confidential information

For PECs see Table 3.2.2.4-2 in Annex 3.2

Confidential information

Conclusion:

The sediment RCR values for the three metabolites are all significantly less than 1 indicating that there should be no unacceptable risk to sediment organisms from the proposed uses in the proposed 18 animal housing types.

Similar to the aquatic RCR, the sediment RCR value for Pyriproxyfen using worst case PECSed values from EUSES v.2.1.2 is above the trigger of 1. Therefore, the use of Sumilarv® 0.5G in animal housings (8, 11, 12, 16, 17 and 18) that release waste water *via* STP effluent to surface waters will not be recommended on the product label.

Sediment PEC/PNEC values as a result of run-off and drainage after manure application to land

The PEC_{Sed} values for Pyriproxyfen using the Porewater calculation and the Montfort (1999) methods are shown in tables 3.2.2.3-5 to 3.2.2.3-8 in Annex 3.2. The Porewater PEC values ($PEC_{pw)}$ values were adjusted to take account of dilution by a factor of 10 in the receiving water body as a result of runoff or drainage.

Table 2.2.8.3-12: Pyriproxyfen PEC/PNEC ratios for sediment *via* Manure application to soil ($PNEC_{sediment}$ 1.4 µg/L) – based on Nitrogen content – Arable Land

Cat-Sub-cat (Nb)	Animal subcategory and manure storage type	Arable land - RCRs							
		10 g a.s./m²				20 g a.s./m²			
		1st year app	10 year app	30 days TWA	180 days TWA	1st year app	10 year app	30 days TWA	180 days TWA
1	Dairy cow	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
2	Beef	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
3	Veal Calf	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
4	Sow, individual pens	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
5	sows in groups	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
6	Fattening pig	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
7	Laying hen, battery cages without treatment	Confidential infor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

		matio n							
8	Laying hen, battery cages with aeration	Confi denti al infor matio n	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation
9	Laying hen, battery cages with forced drying	Confi denti al infor matio n	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation
10	Laying hen, compact battery cages	Confi denti al infor matio n	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation
11	Laying hen, free range with litter floor	Confi denti al infor matio n	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation
12	Broiler, free range with litter floor	Confi denti al infor matio n	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation
13	Laying hen, free range with grating floor	Confi denti al infor matio n	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation
14	parent broiler >18 weeks, free range with grating floor	Confi denti al infor matio n	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation
15	parent broiler in rearing, free range with grating floor	Confi denti al infor matio n	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation
16	Turkey, free range with litter floor	Confi denti al infor matio n	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confidential information			
17	Duck, free range with litter floor	Confi denti al infor matio n	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation

18	Geese, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

Confidential information

Table 2.2.8.3-13: Pyriproxyfen PEC/PNEC ratios for sediment *via* Manure application to soil ($PNEC_{sediment}$ 1.4 µg/L) – based on Nitrogen content – Grassland

Cat - Sub-cat (Nb)	Animal subcategory and manure storage type	Grassland - RCRs							
		10 g a.s./m²				20 g a.s./m²			
		1st year app	10 year app	30 days TWA	180 days TWA	1st year app	10 year app	30 days TWA	180 days TWA
1	Dairy cow	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
2	Beef	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
3	Veal Calf	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
4	Sow, individual pens	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
5	sows in groups	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
6	Fattening pig	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
7	Laying hen, battery cages without treatment	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
8	Laying hen, battery cages with aeration	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
9	Laying hen, battery cages with forced drying	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
10	Laying hen, compact	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

	battery cages								
11	Laying hen, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
12	Broiler, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
13	Laying hen, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
14	parent broiler >18 weeks, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
15	parent broiler in rearing, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
16	Turkey, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information			
17	Duck, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
18	Geese, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

Confidential information

Table 2.2.8.3-14: Pyriproxyfen PEC/PNEC ratios for sediment *via* Manure application to soil ($PNEC_{sediment}$ 1.4 µg/L) – based on Phosphorus content – Arable land

Cat - Sub-cat (Nb)	Animal subcategory and manure storage type	Arable land - RCRs							
		10 g a.s./m²				20 g a.s./m²			
		1st year app	10 year app	30 days TWA	180 days TWA	1st year app	10 year app	30 days TWA	180 days TWA
1	Dairy cow	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
2	Beef	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
3	Veal Calf	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
4	Sow, individual pens	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
5	sows in groups	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
6	Fattening pig	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
7	Laying hen, battery cages without treatment	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
8	Laying hen, battery cages with aeration	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
9	Laying hen, battery cages with forced drying	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
10	Laying hen, compact	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

	battery cages								
11	Laying hen, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
12	Broiler, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
13	Laying hen, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
14	parent broiler >18 weeks, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
15	parent broiler in rearing, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
16	Turkey, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information			
17	Duck, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
18	Geese, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

Confidential information

Table 2.2.8.3-15: Pyriproxyfen PEC/PNEC ratios for sediment *via* Manure application to soil (PNECsediment 1.4 µg/L) – based on Phosphorus content – Grassland

Cat - Sub-cat (Nb)	Animal subcategory and manure storage type	Grassland - RCRs							
		10 g a.s./m²				20 g a.s./m²			
		1st year app	10 year app	30 days TWA	180 days TWA	1st year app	10 year app	30 days TWA	180 days TWA
1	Dairy cow	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
2	Beef	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
3	Veal Calf	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
4	Sow, individual pens	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
5	sows in groups	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
6	Fattening pig	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
7	Laying hen, battery cages without treatment	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
8	Laying hen, battery cages with aeration	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
9	Laying hen, battery cages with forced drying	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
10	Laying hen, compact	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

	battery cages								
11	Laying hen, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
12	Broiler, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
13	Laying hen, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
14	parent broiler >18 weeks, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
15	parent broiler in rearing, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
16	Turkey, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information			
17	Duck, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
18	Geese, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

Confidential information

Conclusion:

The risk assessment for the proposed use of 10 g.a.s/m^2 every 30 days indicates that the exposure of sediment from runoff and drainage route is acceptable from use of manure from 15 animal subcategory and manure storage types (i.e. 1, 2, 4, 5, 6, 7, 8, 9, 10, 11,12, 13, 14, 15 and 18). The proposed use on three animal subcategory and manure storage types (3, 16 and 17) indicates an unacceptable risk to sediment organisms from the use of 10 g a.s./m2 and therefore these uses will not be included on the product label.

The risk assessment indicates that there should be no unacceptable risk to sediment organisms via runoff and drainage from the proposed use of 20 g a.s./m^2 every 90 days for any of the 18 animal subcategory and manure storage types.

Terrestrial compartment

Risk assessment based on EU agreed endpoints

The worst case $PNEC_{soil}$ for Pyriproxyfen is 0.0011 mg/kg ww based on equilibrium partitioning (Doc I, CAR 2012) and is used to assess the risk to soil organisms from the application of treated manure to arable land and grassland. It should be noted that terrestrial studies were available for micro-organisms, earthworms and plants, however, the $PNEC_{soil}$ based on corresponding data was not accepted at Annex I inclusion level due to the lack of data on non-target soil insects. This $PNEC_{soil}$ based on equilibrium partitioning is conservative. The PEC_{soil} values used for the RCR are in Annex 3.2 in tables 3.2.2.1-3 to 3.2.2.1-6 (10 g a.s./m^2) and Tables 3.2.2.1-8 to 3.2.2.1-11 (20 g a.s/m^2). Please note that for the grassland the PEC_{soil} values following 4 applications are relevant (denoted PIECgrs following 4 applications). These values represent the 4 applications by allowing degradation following each application prior to the next application.

Table 2.2.8.3-16: Tier 1 - PEC/PNEC ratios for soil *via* Manure application ($PNEC_{soil}$ 0.0011 mg/kg ww) – based on Nitrogen content – Arable land

Cat-Sub-cat (Nb)	Animal subcategory and manure storage type	Arable land – RCRs							
		10 g a.s./m^2				20 g a.s./m^2			
		1 year app	10 year app	30d TWA	180d TWA	1 year app	10 year app	30d TWA	180d TWA
1	Dairy cow	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
2	Beef	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
3	Veal Calf	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
4	Sow, individual pens	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
5	sows in groups	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
6	Fattening pig	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
7	Laying hen, battery cages without treatment	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
8	Laying hen, battery cages with aeration	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
9	Laying hen, battery cages with forced drying	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
10	Laying hen, compact battery cages	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
11	Laying hen, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
12	Broiler, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
13	Laying hen, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

14	parent broiler >18 weeks, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
15	parent broiler in rearing, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
16	Turkey, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information			
17	Duck, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
18	Geese, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

Confidential information

Table 2.2.8.3-17: Tier 1 - PEC/PNEC ratios for soil *via* Manure application ($PNEC_{soil}$ 0.0011 mg/kg) – based on Nitrogen content – Grassland

Cat-Sub-cat (Nb)	Animal subcategory and manure storage type	Grassland – RCRs							
		10 g a.s./m^2				20 g a.s./m^2			
		1 year app	10 year app	30d TWA	180 d TWA	1 year app	10 year app	30d TWA	180 d TWA
1	Dairy cow	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
2	Beef	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
3	Veal Calf	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
4	Sow, individual pens	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
5	sows in groups	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

6	Fattening pig	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
7	Laying hen, battery cages without treatment	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
8	Laying hen, battery cages with aeration	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
9	Laying hen, battery cages with forced drying	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
10	Laying hen, compact battery cages	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
11	Laying hen, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
12	Broiler, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
13	Laying hen, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
14	parent broiler >18 weeks, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
15	parent broiler in rearing, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
16	Turkey, free range with litter floor	Confidential	Confidential	Confidential	Confidential	Confidential information			

		information	information	information	information				
17	Duck, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
18	Geese, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

Confidential information

Table 2.2.8.3-18: Tier 1 - PEC/PNEC ratios for soil *via* Manure application ($PNEC_{soil}$ 0.0011 mg/kg) – based on Phosphorus content – Arable land

Cat - Sub-cat (Nb)	Animal subcategory and manure storage type	Arable land – RCRs							
		10 g a.s./m²				20 g a.s./m²			
		1 year app	10 year app	30d TWA	180d TWA	1 year app	10 year app	30d TWA	180d TWA
1	Dairy cow	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
2	Beef	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
3	Veal Calf	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
4	Sow, individual pens	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
5	sows in groups	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
6	Fattening pig	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
7	Laying hen, battery cages	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

	without treatment								
8	Laying hen, battery cages with aeration	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
9	Laying hen, battery cages with forced drying	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
10	Laying hen, compact battery cages	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
11	Laying hen, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
12	Broiler, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
13	Laying hen, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
14	parent broiler >18 weeks, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
15	parent broiler in rearing, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
16	Turkey, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information			
17	Duck, free range	Confidential	Confidential	Confidential	Confidential	Confidential	Confidential	Confidential	Confidential

	with litter floor	information	information	information	information	information	information	information	information
18	Geese, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

Confidential information

Table 2.2.8.3-19: Tier 1 - PEC/PNEC ratios for soil *via* Manure application ($PNEC_{soil}$ 0.0011 mg/kg) – based on Phosphorus content – Grassland

Cat-Subcat (Nb)	Animal subcategory and manure storage type	Grassland – RCRs							
		10 g a.s./m²				20 g a.s./m²			
		1 year app	10 year app	30d TWA	180d TWA	1 year app	10 year app	30d TWA	180d TWA
1	Dairy cow	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
2	Beef	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
3	Veal Calf	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
4	Sow, individual pens	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
5	sows in groups	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
6	Fattening pig	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
7	Laying hen, battery cages without treatment	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
8	Laying hen, battery cages with aeration	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
9	Laying hen, battery cages with forced drying	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

10	Laying hen, compact battery cages	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
11	Laying hen, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
12	Broiler, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
13	Laying hen, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
14	parent broiler >18 weeks, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
15	parent broiler in rearing, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
16	Turkey, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information			
17	Duck, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
18	Geese, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

Confidential information

Conclusion:
Using the tier 1 conservative $PNEC_{soil}$ value of 0.0011 mg/kg ww (equilibrium partitioning method) indicates a theoretical risk to the majority of animal housing categories. The TGD notes that a 30 day Time-Weighted Average (TWA) is relevant for the risk assessment. Using the 30 day TWA PEC_{soil} values indicates that a few animal housing categories show an acceptable risk (including 1,2, 9,10 and 14 depending on the scenario). Additional chronic soil toxicity data are now available which were used to refine the soil risk characterisation.

Refined risk assessment considering new active ingredient data

New chronic data on the toxicity of Pyriproxyfen are now available for predatory mite (*Hypoaspis aculeifer*), spring tail (*Folsomia candida*) and earthworm (*Eisenia fetida*) with reproductive NOEC (EC_{10}) values of 50 (88.7), 12.5 (12.7) and 50 (49.3) mg a.s./kg soil dw. These data now provide relevant arthropod data to address the concerns of related to the insecticidal mode of action of Pyriproxyfen and can be used to provide an updated $PNEC_{soil}$ based on terrestrial data (9.3.1. Guidance on PBR, Vol. IV, Part A: Information Requirements).

The worst case endpoint from these studies is the standardised NOEC for *Folsomia* for a soil with 3.4% organic matter of 8.5 mg/kg dw (7.4 mg/kg ww). The soil micro-organism study reported a NOEC value of ≥ 1.5 mg/kg dw (≥ 1.3 mg/kg ww). So if this is used as worst case the PNEC soil could be amended to ≥ 0.03 mg/kg dw (0.026 mg/kg ww) using an AF of 50 as there are long term tests for two trophic levels including the most sensitive species (see Table 23, Guidance on BPR).

The PEC_{soil} values used for the RCR are in Annex 3.2 in tables 3.2.2.1-3 to 3.2.2.1-6 (10 g a.s./m^2) and Tables 3.2.2.1-8 to 3.2.2.1-11 (20 g a.s/m^2). Please note that for the grassland the PEC_{soil} values following 4 applications are relevant (denoted PIECgrs following 4 applications). These values represent the 4 applications by allowing degradation following each application prior to the next application.

Table 2.2.8.3-20: Tier 2 - PEC/PNEC ratios for soil *via* Manure application ($PNEC_{soil}$ 0.026 mg/kg ww) – based on Nitrogen content – Arable land

Cat-Sub-cat (Nb)	Animal subcategory and manure storage type	Arable land – RCRs							
		10 g a.s./m^2				20 g a.s./m^2			
		1 year app	10 year app	30d TWA	180d TWA	1 year app	10 year app	30d TWA	180d TWA
1	Dairy cow	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
2	Beef	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
3	Veal Calf	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
4	Sow, individual pens	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
5	sows in groups	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
6	Fattening pig	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
7	Laying hen, battery cages without treatment	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
8	Laying hen, battery cages with aeration	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
9	Laying hen, battery cages with forced drying	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
10	Laying hen, compact battery cages	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
11	Laying hen, free range with litter floor	Confidential infor	Confidential	Confidential	Confidential	Confidential infor	Confidential	Confidential infor	Confidential infor

		matio n	inform ation	inform ation	inform ation	matio n	inform ation	matio n	matio n
12	Broiler, free range with litter floor	Confid ential infor matio n	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential infor matio n	Confid ential inform ation	Confid ential infor matio n	Confid ential infor matio n
13	Laying hen, free range with grating floor	Confid ential infor matio n	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential infor matio n	Confid ential inform ation	Confid ential infor matio n	Confid ential infor matio n
14	parent broiler >18 weeks, free range with grating floor	Confid ential infor matio n	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential infor matio n	Confid ential inform ation	Confid ential infor matio n	Confid ential infor matio n
15	parent broiler in rearing, free range with grating floor	Confid ential infor matio n	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential infor matio n	Confid ential inform ation	Confid ential infor matio n	Confid ential infor matio n
16	Turkey, free range with litter floor	Confid ential infor matio n	Confid ential inform ation	Confid ential inform ation	Confid ential infor matio n	Confidential information			
17	Duck, free range with litter floor	Confid ential infor matio n	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential infor matio n	Confid ential inform ation	Confid ential infor matio n	Confid ential infor matio n
18	Geese, free range with litter floor	Confid ential infor matio n	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential infor matio n	Confid ential inform ation	Confid ential infor matio n	Confid ential infor matio n

Table 2.2.8.3-21: Tier 2 - PEC/PNEC ratios from soil *via* Manure application ($PNEC_{soil}$ 0.026 mg/kg ww) – based on Nitrogen content – Grassland

Cat-Sub-cat (Nb)	Animal subcategory and manure storage type	Grassland – RCRs							
		10 g a.s./m²				20 g a.s./m²			
		1 year app	10 year app	30d TWA	180d TWA	1 year app	10 year app	30d TWA	180d TWA
1	Dairy cow	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
2	Beef	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
3	Veal Calf	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
4	Sow, individual pens	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
5	sows in groups	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
6	Fattening pig	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
7	Laying hen, battery cages without treatment	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
8	Laying hen, battery cages with aeration	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
9	Laying hen, battery cages with forced drying	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
10	Laying hen, compact battery cages	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
11	Laying hen, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential infor	Confidential information	Confidential infor	Confidential infor

						matio n		matio n	matio n
12	Broiler, free range with litter floor	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential infor matio n	Confid ential inform ation	Confid ential infor matio n	Confid ential infor matio n
13	Laying hen, free range with grating floor	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential infor matio n	Confid ential inform ation	Confid ential infor matio n	Confid ential infor matio n
14	parent broiler >18 weeks, free range with grating floor	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential infor matio n	Confid ential inform ation	Confid ential infor matio n	Confid ential infor matio n
15	parent broiler in rearing, free range with grating floor	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential infor matio n	Confid ential inform ation	Confid ential infor matio n	Confid ential infor matio n
16	Turkey, free range with litter floor	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confidential information			
17	Duck, free range with litter floor	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential infor matio n	Confid ential inform ation	Confid ential infor matio n	Confid ential infor matio n
18	Geese, free range with litter floor	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential inform ation	Confid ential infor matio n	Confid ential inform ation	Confid ential infor matio n	Confid ential infor matio n

Table 2.2.8.3-22: Tier 2 - PEC/PNEC ratios from soil *via* Manure application ($PNEC_{soil}$ 0.026 mg/kg ww) – based on Phosphorus content – Arable land

Cat-Sub-cat (Nb)	Animal subcategory and manure storage type	Arable land – RCRs							
		10 g a.s./m^2				20 g a.s./m^2			
		1 year app	10 year app	30d TWA	180d TWA	1 year app	10 year app	30d TWA	180d TWA
1	Dairy cow	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
2	Beef	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
3	Veal Calf	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
4	Sow, individual pens	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
5	sows in groups	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
6	Fattening pig	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
7	Laying hen, battery cages without treatment	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
8	Laying hen, battery cages with aeration	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
9	Laying hen, battery cages with forced drying	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
10	Laying hen, compact battery cages	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
11	Laying hen, free range with litter floor	Confidential infor	Confidential infor	Confidential	Confidential	Confidential infor	Confidential	Confidential infor	Confidential

		matio n	matio n	inform ation	inform ation	matio n	inform ation	matio n	inform ation
12	Broiler, free range with litter floor	Confid ential infor matio n	Confid ential infor matio n	Confid ential inform ation	Confid ential inform ation	Confid ential infor matio n	Confid ential inform ation	Confid ential infor matio n	Confid ential inform ation
13	Laying hen, free range with grating floor	Confid ential infor matio n	Confid ential infor matio n	Confid ential inform ation	Confid ential inform ation	Confid ential infor matio n	Confid ential inform ation	Confid ential infor matio n	Confid ential inform ation
14	parent broiler >18 weeks, free range with grating floor	Confid ential infor matio n	Confid ential infor matio n	Confid ential inform ation	Confid ential inform ation	Confid ential infor matio n	Confid ential inform ation	Confid ential infor matio n	Confid ential inform ation
15	parent broiler in rearing, free range with grating floor	Confid ential infor matio n	Confid ential infor matio n	Confid ential inform ation	Confid ential inform ation	Confid ential infor matio n	Confid ential inform ation	Confid ential infor matio n	Confid ential inform ation
16	Turkey, free range with litter floor	Confid ential infor matio n	Confid ential infor matio n	Confid ential inform ation	Confid ential inform ation	Confidential information			
17	Duck, free range with litter floor	Confid ential infor matio n	Confid ential infor matio n	Confid ential inform ation	Confid ential inform ation	Confid ential infor matio n	Confid ential inform ation	Confid ential infor matio n	Confid ential inform ation
18	Geese, free range with litter floor	Confid ential infor matio n	Confid ential infor matio n	Confid ential inform ation	Confid ential inform ation	Confid ential infor matio n	Confid ential inform ation	Confid ential infor matio n	Confid ential inform ation

Table 2.2.8.3-23: Tier 2 - PEC/PNEC ratios from soil *via* Manure application ($PNEC_{soil}$ 0.026 mg/kg ww) – based on Phosphorus content – Grassland

Cat - Sub-cat (Nb)	Animal subcategory and manure storage type	Grassland – RCRs							
		10 g a.s./m^2				20 g a.s./m^2			
		1 year app	10 year app	30d TWA	180d TWA	1 year app	10 year app	30d TWA	180d TWA
1	Dairy cow	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
2	Beef	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
3	Veal Calf	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
4	Sow, individual pens	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
5	sows in groups	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
6	Fattening pig	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
7	Laying hen, battery cages without treatment	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
8	Laying hen, battery cages with aeration	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
9	Laying hen, battery cages with forced drying	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
10	Laying hen, compact battery cages	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

11	Laying hen, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
12	Broiler, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
13	Laying hen, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
14	parent broiler >18 weeks, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
15	parent broiler in rearing, free range with grating floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
16	Turkey, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information			
17	Duck, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information
18	Geese, free range with litter floor	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information	Confidential information

Conclusion:

Using the refined $PNEC_{soil}$ value of 0.026 mg/kg ww based on the available new chronic soil toxicity data indicates that an acceptable risk to non-target soil organisms is expected for all 18 animal subcategories and storage types (RCR all <1).

Metabolites

The metabolites 4'-OH-Pyriproxyfen and PYPAC may occur in soil at levels greater than 5% of parent. The PNECsoil values for these metabolites have therefore been estimated based on the $PNEC_{aquatic\text{-}continuous}$ values for 4'-OH-Pyriproxyfen and PYPAC. The $PNEC_{soil}$ values estimated based on equilibrium partitioning are 0.012 and 0.014 mg/kg ww for 4'-OH-Pyriproxyfen and PYPAC respectively.

The soil RCR values for the metabolites (see Annex 3.7.1 for full set of RCR values) were calculated using the PEC_{soil} values for metabolites 4'-OH-Pyriproxyfen and PYPAC shown in Annex 3.2 Tables 3.2.2.1.1-2 to 3.2.2.1.1-17. There was no risk to soil for any of the metabolite/scenario combinations and all RCRs were <0.08. Only the results from the 10 g a.s./m^2 application rate are shown below as this application rate results in the worst-case values.

Table 2.2.8.3-24: Metabolite PEC/PNEC ratios (RCR) from PEC_{soil} from manure application – Based on Nitrogen content – Arable land

Animal subcategory and manure storage type (number)	Substance	$PNEC_{soil}$	10 g a.s./m^2	
			Maximum Total PEC_{soil} (mg/kg)	RCR
Turkey, free range with litter floor (16)	4'-OH-Pyriproxyfen	0.012	Confidential information	Confidential information
	PYPAC	0.014	Confidential information	Confidential information

Table 2.2.8.3-25: Metabolite PEC/PNEC ratios (RCR) from PEC_{soil} from manure application – Based on Nitrogen content – Grassland

Animal subcategory and manure storage type (number)	Substance	$PNEC_{soil}$	10 g a.s./m^2	
			Maximum Total PEC_{soil} (mg/kg)	RCR
Turkey, free range with litter floor (16)	4'-OH-Pyriproxyfen	0.012	Confidential information	Confidential information
	PYPAC	0.014	Confidential information	Confidential information

Table 2.2.8.3-26: Metabolite PEC/PNEC ratios (RCR) from PEC_{soil} from manure application – Based on Phosphorus content – Arable land

Animal subcategory and manure storage type (number)	Substance	$PNEC_{soil}$	10 g a.s./m²	
			Maximum Total PEC_{soil} (mg/kg)	RCR
Turkey, free range with litter floor (16)	4'-OH-Pyriproxyfen	0.012	Confidential information	Confidential information
	PYPAC	0.014	Confidential information	Confidential information

Table 2.2.8.3-27: Metabolite PEC/PNEC ratios (RCR) from PEC_{soil} from manure application – Based on Phosphorus content – Grassland

Animal subcategory and manure storage type (number)	Substance	$PNEC_{soil}$	10 g a.s./m²	
			Maximum Total PEC_{soil} (mg/kg)	RCR
Turkey, free range with litter floor (16)	4'-OH-Pyriproxyfen	0.012	Confidential information	Confidential information
	PYPAC	0.014	Confidential information	Confidential information

Conclusion:

All metabolites even for the worst case scenarios pass the soil risk assessment (RCR <1).

Bees

Pyriproxyfen has been shown to have low acute toxicity to bees both by oral and contact exposure. The 48-hour and 96-hour LD_{50} values for oral and contact toxicity to honey bees was > 100 µg a.s./bee respectively (AR, 2012). According to two more exposure studies, that can be used as supplementary information (Pyriproxyfen Doc III A), no effects were seen on bee brood when honey bee or bumble bee colonies dosed with sucrose solution (25 and 20 mg/L respectively) in 20 days. In addition, the EFSA review for the PPP use of Pyriproxyfen (2009) noted that in a field study in Germany (dose rate 1 x 75 g a.s./ha), Pyriproxyfen 10% EC did not affect mortality of adults or juvenile stages, overall colony performance or survival and development of eggs and larvae through to adult emergence. It was considered in the EFSA conclusion (2009) that the risk from any plant metabolites was covered by this field study.

The DAR, VOL3, Annex B7, pp.260) for Pyriproxyfen PPP use, states that Pyriproxyfen is considered non-systemic: 'No significant uptake of Pyriproxyfen or metabolites due to the internal transport in the plant is expected as Pyriproxyfen is a non-systemic insecticide.' As Pyriproxyfen is not a systemic insecticide, it is unlikely that it will be taken up from soil (where manure has been applied) by plants and exposure to bees *via* nectar and pollen is therefore unlikely.

Currently, there is no assessment concept available how to derive a PNEC value for bees.

The combination of no significant exposure and low toxicity indicates that there should be no unacceptable risk to bees from the proposed use of the product.

Groundwater

No specific reference value for groundwater is required in accordance with BPR Annex VI point 68. The standard maximum limit of 0.1 µg/L for pesticides in groundwater applies, as laid down by Directive 98/83/EC.

An initial worst-case groundwater assessment as performed using porewater concentrations as a proxy for groundwater, in accordance with point 7.2.1 of the ESD 14 guidance. According to this method, the metabolite PYPAC exceeds 0.1 µg/L in all animal housings. Therefore, a higher tier calculation was performed using the FOCUS model PEARL (v.4.4.4) and the worst-case soil loadings from manure application. The worst-case soil loading was from turkey manure (animal housing group 16) using the maximum permitted by phosphate immission standards. Calculations were performed for all FOCUS scenarios available for grassland and arable land (maize).

In all cases, the 80th percentile average annual concentrations in groundwater for the worst-case application did not exceed <0.000001 µg/L for pyriproxyfen and the metabolite 4'-OH-pyr. For the metabolite PYPAC, concentrations in groundwater exceed the 0.1 µg/L limit for groundwater for the Jokioinen and Hamburg scenarios only. These scenarios are not representative of the conditions or climate found in Southern Europe and are therefore considered not relevant for the Sumilarv® 0.5G applications.

Primary and secondary poisoning

Primary poisoning

Primary poisoning is not considered to be relevant if applications are made according to the label instructions in animal housing. The granules are not considered to be attractive since the organic carrier does not have any nutritional value. Qualitative and quantitative assessment of the risk from accidental exposure was considered in the assessment report and it was concluded that exposure to granules was unlikely to cause any risk unless daily feed intake was based on the consumption of granules only. However the qualitative risk assessment shown in the AR (assuming 0.5% a.s.) has been updated for a.s. content of 0.525% and is shown below.

Exposure as a result of accidental ingestion may occur although it should be noted that the granules are not based on an organic carrier having any nutritional value. Sumilarv 0.5G contains 0.525% Pyriproxyfen and the density of a granule is 2.06 kg/dm^3 As result, a granule contains 10.8 g a.s./dm^3. Using granular diameters of 0.297-0.590 mm and assuming that granules are spheres, each granule has a volume of 0.014-0.11 mm^3. The resulting amount of a.s. in one granule (Gloading) is 0.00015-0.0012 mg. 1 gram of product contains 4,350-34,500 granules. With a maximum application rate of 20 g product/m^2, the number of granules per m^2 is 87,000 to 690,000.

For the first tier risk assessment, it is assumed that a bird or mammal meets its daily feed intake by consumption of granules only. For a small granivorous bird of 25 g (i.e. the house sparrow, *Passer domesticus*), the Food Intake Rate (FIR) is 8.3 g feed/bird.d or 332 g feed/kg bw.d. With granules containing 5.25 g a.s./kg product, the daily intake of

pyriproxyfen is 43.6 mg a.s./bird.d and = 1743 mg a.s./kg bw.d. For a small mammal of 25 g, the Food Intake Rate (FIR) is 5.7 g feed/mammal.d or 230 g feed/kg bw.d. The daily intake of pyriproxyfen is 29.9 mg as/kg bw.d = 1208 mg as/kg bw.d.

Qualitative acute risk assessment

For the qualitative risk assessment the calculated daily intake is directly compared with the acute LD_{50} of >1906 mg a.s./kg bw (0% mortality) for birds and >5000 mg/kg bw (0% mortality) for mammals.The resulting PEC based on a daily feed intake by consumption of granules does not exceed the LD_{50} for either birds and mammals, indicating that risks can be excluded.

Another way to express the risks to birds and mammals is to calculate the number of granules that have to be taken up to cause an effect. For the qualitative risk assessment for a 25 g bird, the LD_{50}-based on > 1906 mg/kg bw.d (0% mortality) is equivalent to > 47.7 mg/bird.d. With a pyriproxyfen content of 0.00015-0.0012 mg a.s./granule, the LD_{50} is reached when 39,750 – 318,000 granules are eaten. For the qualitative risk assessment for a 25 g mammal, the LD_{50}-based on > 5000 mg/kg bw.d (0% mortality) is equivalent to > 125 mg/mammal.d. The LD_{50} value is reached when 104,167 – 833,333 granules are eaten. In principle, this means that an acute effect to birds and mammals can be excluded after accidental consumption of a few granules.

Secondary poisoning

The effects assessment for bioaccumulation and secondary poisoning is performed according to the strategy outlined in the PBR Guidance. The $PEC_{oral,\ predator}$ values have been calculated in the Exposure assessment, section 2.2.8.2, Tables 2.2.8.2-1 and 2.2.8.2-2. A PNECoral value was derived for birds and mammals. Since mammals were more sensitive (lower PNECoral than birds), the risk assessment is based on the PNECoral for mammals.

Aquatic food chain

Secondary poisoning *via* the aquatic food chain is based on the schematic:

aquatic food chain water → aquatic organism → fish → fish-eating birds or mammals

The $PEC_{oral,predator}$ and PEC/PNEC ratios are shown in Table 2.2.8.3-28. The $PNEC_{oral,\ predator}$ is 6.7 mg a.s./kg food used is based on the worst case mammalian data (Doc I, CAR 2012).

Table 2.2.8.3-28: Pyriproxyfen – PEC/PNEC ratios for secondary poisoning *via* the aquatic food chain

Exposure scenario	$PEC_{oral,\ predator}$ (mg a.s./kg$_{wet\ fish}$)	PEC/PNEC
Following application of manure to arable land	Confidential information	Confidential information
Following emission from STP	Confidential information	Confidential information

PEC/PNEC ratios for the worst case use scenario are <1 and thus no secondary poisoning of either birds or mammals is expected. In addition it should be noted that the Guidance on BPR assumes that only 50% of the diet of fish eating birds and mammals comes from the local area and thus realistic PEC/PNEC values would be even lower than shown above.

Terrestrial food chain

Biomagnification may also occur via the terrestrial food chain. The schematic food chain is:

soil → earthworm → worm-eating birds or mammals

The $PEC_{oral,predator}$ and PEC/PNEC ratios are shown in Table 2.2.8.3-29 The $PNEC_{oral,\ predator}$ is 6.7 mg a.s./kg food used is based on the worst case mammalian data (Doc I, CAR 2012). PEC_{pw} values have been previously calculated in Annex 3.2. The worst case PEC_{pw} and PEC_{soil} that are presented in the table "Summary table on worst-case calculated PEC values for pyriproxyfen" are used for the calculation of $PEC_{oral,\ predator}$. The resulting $PEC_{oral,\ predator}$ was 0.030 mg a.s./$kg_{wet\ earthworm}$ (Section 2.2.8.2, Table 2.2.8.2-2).

Table 2.2.8.3-29: Pyriproxyfen –– PEC/PNEC ratios for secondary poisoning *via* the terrestrial food chain

Exposure scenario	$PEC_{oral,\ predator}$ (mg a.s./$kg_{wet\ earthworm}$)	PEC/PNEC
Worst-case application (category 16)	Confidential information	Confidential information

The terrestrial secondary poisoning PEC/PNEC value representing use in the worst case animal housing (16) does not indicate any unacceptable risk of secondary poisoning (RCR <1). In addition the Guidance on BPR suggests that this value may be halved since only half of the diet is expected to be contaminated.

Conclusion:

All animal subcategory and manure storage types show an acceptable risk assessment with regard to secondary poisoning of mammals and birds from earthworm consumption in soil exposed to manure.

PBT, POP and endocrine disruption assessment

As discussed in the AR Pyriproxyfen does not meet the P- and B- criteria but does meet the T criterion. Therefore Pyriproxyfen is neither a PBT nor vPvB substance, nor does it fulfil the POPs criteria.

Pyriproxyfen is not included in the Commission staff working document on implementation of the Community Strategy for Endocrine Disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM (1999) 706)). Although the mode of action of Pyriproxyfen is as "a juvenile hormone mimic and insect growth regulator", there is no evidence of any endocrine disruption potential in the human health, or in ecotoxicological studies presented in the dossier.

Aggregated exposure (combined for relevant emmission sources)

No guidance on aggregated exposure is available at this time. It should be noted that levels of Pyriproxyfen and its metabolites in the environment following use of manure on land are likely to be much lower than the levels from use as a plant protection product. It should also be noted that application of manure and use as a plant protection product will be separated in time.

Overall conclusion on the risk assessment for the environment of the product

Use in animal housing and indoor manure heaps

A summary of the environmental compartment risk assessments for the animal house categories at the proposed application rates of 10 g/m^2 every month and 20 g/m^2 every 2 months are shown in the tables below.

The calculations that have been made for all animal housing applications are expected to be the worst-case when compared to applications made directly onto the manure heap as explained in section 2.2.8.2. The risk assessment for all compartments for the use in indoor manure heaps should therefore be covered by the risk assessment performed for the animal housings. Applications of Sumilarv® 0.5G can be made to indoor manure heaps for the same manures from animal houses categories that pass the full risk assessment (*i.e.* 11 animal house categories for use of the product at 10 g/m^2 per month and 12 animal house categories for the use of the product at 20 g/m^2 every 2 months).

Table 2.2.8.3-30: Summary table for the risk assessment for all animal housings for the application rate of 10 g/m^2 every month

Animal subcategory and manure storage type (category number)	Ground water	Surface water	Sediment	Waste water	Soil	Secondary poisoning-aquatic	Secondary poisoning-terrestrial
Dairy cow (1)	√	√	√	NR	√	√	√
Beef (2)	√	√	√	NR	√	√	√
Veal Calf (3)	√	x	x	NR	√	√	√
Sow in individual pens (4)	√	√	√	NR	√	√	√
Sows in groups (5)	√	√	√	NR	√	√	√
Fattening pig (6)	√	√	√	NR	√	√	√
Laying hen battery cages without treatment (7)	√	√	√	NR	√	√	√
Laying hen battery cages with aeration (8)	√	x	x	x	√	√	√
Laying hen battery cages with forced drying (9)	√	√	√	NR	√	√	√
Laying hen in compact battery cages (10)	√	√	√	NR	√	√	√
Laying hen free range with litter floor (11)	√	x	x	x	√	√	√
Broiler: free range, with litter floor (12)	√	x	x	x	√	√	√

Laying hen free range with grating floor (13)	√	√	√	NR	√	√	√
Parent broiler >18 weeks - free range with grating floor (14)	√	√	√	NR	√	√	√
Parent broiler in rearing free range with grating floor (15)	√	√	√	NR	√	√	√
Turkey free range with litter floor (16)	√	x	x	x	√	√	√
Duck free range with litter floor (17)	√	x	x	x	√	√	√
Geese free range with litter floor (18)	√	x	x	x	√	√	√

Bold animal housings fail risk assessments
NR- not relevant
√ - pass risk assessment
x – fail risk assessment

Table 2.2.8.3-31: **Summary table for the risk assessment for all animal housings for the application rate of 20 g/m^2 every 2 months**

Animal subcategory and manure storage type (category number)	Ground water	Surface water	Sediment	Waste water	Soil	Secondary poisoning-aquatic	Second poisoni terrest
Dairy cow (1)	√	√	√	NR	√	√	√
Beef (2)	√	√	√	NR	√	√	√
Veal Calf (3)	√	√	√	NR	√	√	√
Sow in individual pens (4)	√	√	√	NR	√	√	√
Sows in groups (5)	√	√	√	NR	√	√	√
Fattening pig (6)	√	√	√	NR	√	√	√
Laying hen battery cages without treatment (7)	√	√	√	NR	√	√	√
Laying hen battery cages with aeration (8)	√	x	x	x	√	√	√
Laying hen battery cages with forced drying (9)	√	√	√	NR	√	√	√
Laying hen in compact battery cages (10)	√	√	√	NR	√	√	√
Laying hen free range with litter floor (11)	√	x	x	x	√	√	√
Broiler: free range, with litter floor (12)	√	x	x	x	√	√	√

Laying hen free range with grating floor (13)	√	√	√	NR	√	√	√
Parent broiler >18 weeks - free range with grating floor (14)	√	√	√	NR	√	√	√
Parent broiler in rearing free range with grating floor (15)	√	√	√	NR	√	√	√
Turkey free range with litter floor (16)	√	NR	NR	x	NR	√	√
Duck free range with litter floor (17)	√	x	x	x	√	√	√
Geese free range with litter floor (18)	√	x	x	x	√	√	√

Bold animal housings fail risk assessments
NR- not relevant
√ - pass risk assessment
x – fail risk assessment

As noted in the aquatic risk assessment, for all animal house uses which release waste water to an STP *i.e.* poultry housing (categories 8, 11, 12, 16, 17 and 18), the PEC/PNEC ratios for Pyriproxyfen are greater than 1 and consequently fail the surface water risk assessment. Therefore, uses for these specific animal housings in not claimed. In addition the Pyriproxyfen PEC/PNEC ratio for animal subcategory and manure storage type 3 (veal calf) is greater than 1 for the proposed use rate of 10 g a.s./m^2 every month and this use is also not claimed.

Based on the refined soil risk assessment, using the new chronic soil toxicity data all 18 animal subcategory and manure storage types pass the risk assessment for the uses recommended on the label for Sumilarv® 0.5G.

Regarding non-compartmental specific effects relevant to the food chain, primary poisoning has been considered non relevant if the label is followed. An acceptable risk assessment in terms of secondary poisoning of mammals and birds *via* the aquatic or terrestrial food chain has been determined for the proposed uses of Sumilarv® 0.5G.

Overall based on the risk assessments shown in the tables above use of Sumilarv® 0.5G at 10 g a.s./m^2 every month can be proposed for 11 animal subcategory and manure storage types (i.e. 1, 2, 4, 5, 6, 7, 9, 10, 13, 14, and 15). Whilst the use at 20 g a.s./m^2 every 2 months can be proposed for 12 animal subcategory and manure storage types (i.e. 1, 2, 3, 4, 5, 6, 7, 9, 10, 13, 14, and 15).

Pyriproxyfen does not meet the P- and B- criteria but does meet the T criterion. Therefore Pyriproxyfen is neither a PBT nor vPvB substance nor does it fulfil the POPs criteria. Regarding the endocrine disruption assessment no evidence of any endocrine disruption potential in the human health, or in ecotoxicological studies presented in the dossier has been found.

2.2.9 Measures to protect man, animals and the environment

Field of use

In view of the potential risks for professional use Personal Protection Equipment (PPE) should be prescribed in order to reduce exposure to guarantee a safe use of Sumilarv® 0.5G.

Table 2.2.9-1 Minimum Personal Protection Equipment proposed to reduce dermal exposure

Type of application	PPE to reduce dermal exposure
Manual application by hand (no equipment)	A single layer of clothing and protective gloves will provide sufficient protection for the professional user when manually applying the product by hand.
Manual application by hand granule spreader	A single layer of clothing will provide sufficient protection for the professional user when applying the product by hand granule spreader.
Manual application by blower with granule nozzle	Coveralls over a single layer of clothing and protective gloves will provide sufficient protection for the professional user when applying the product by blower with granule nozzle.
Manual application by crawler mount type power granular feeder	No specific PPE are necessary for this scenario.

However, in order to reduce the exposure to an acceptable level and to cover all potential exposures, it is proposed that the professional user wear protective impermeable gloves, apron or protective clothing in case of contact, goggles and dust mask/respirator in dusty areas. Please refer to the PPE as described in Section 8 of the Safety Data Sheet.

In addition, during application of Sumilarv® 0.5G in animal housing, professional users should not contaminate foodstuffs, eating utensils or food contact surfaces.

Please refer to relevant section for safe uses based on all aspects of the risk characterisation.

Additional measures mentioned in the proposed SDS:

Avoid release of Sumilarv® 0.5G into the environment.

The product shall not be applied in animal housings and manure heaps at the same time.

Sumilarv® 0.5G at 10 g a.s./m^2 every month should not be used in the following animal subcategories and storage types:

- Veal Calf (3)
- Laying hen, battery cages with aeration (8)
- Laying hen, free range with litter floor (11)
- Broiler, free range with litter floor (12)
- Turkey, free range with litter floor (16)
- Duck, free range with litter floor (17)

- Geese, free range with litter floor (18)

Sumilarv® 0.5G at 20 g a.s./m^2 every 3 months should not be used in the following animal subcategories and storage types:

- Laying hen, battery cages with aeration (8)
- Laying hen, free range with litter floor (11)
- Broiler, free range with litter floor (12)
- Turkey, free range with litter floor (16)
- Duck, free range with litter floor (17)
- Geese, free range with litter floor (18)

Handling and storage:

- **Precautions for safe handling:** Read and follow the manufacturer's recommendations. Observe good chemical hygiene practices. Do not eat, drink or smoke when using the product. Provide good ventilation. Protect against direct sunlight.
- **Conditions for safe storage, including any incompatibilities:** Do not store near heat sources or expose to high temperatures.

Reactivity and chemical stability**:**

- **Reactivity**: There are no known reactivity hazards associated with this product.
- **Chemical stability**: Stable under normal temperature conditions and recommended use.
- **Possibility of hazardous reactions**: Not applicable.
- **Conditions to avoid**: Avoid exposure to high temperatures or direct sunlight.
- **Incompatible materials**: Materials to avoid: No specific or groups of materials are likely to react to produce a hazardous situation.
- **Hazardous decomposition products**: In case of fire, toxic gases (CO, CO2, NOx) may be formed.

First aid measures:

- **Inhalation**: Remove victim immediately from source of exposure.
- **Ingestion**: Rinse mouth thoroughly. Get medical attention.
- **Skin contact**: Wash the skin immediately with soap and water.
- **Eye contact:** Not relevant.

Most important symptoms and effects, both acute and delayed:

- **Inhalation**: No specific symptoms noted.
- **Ingestion**: May cause discomfort if swallowed.
- **Skin contact**: No specific symptoms noted.
- **Eye contact**: No specific symptoms noted.

No recommendation is given, but first aid may still be required in case of accidental exposure, inhalation or ingestion of this chemical. If in doubt, GET MEDICAL ATTENTION PROMPTLY.

Accidental release measures:

- **Personal precautions, protective equipment and emergency procedures**: Wear protective clothing as described in Section 8 of this safety data sheet.
- **Environmental precautions**: Do not allow to enter drains, sewers or watercourses.
- **Methods and material for containment and cleaning up**: Dam and absorb spillages with sand, earth or other non-combustible material. Collect spillage in containers, seal securely and deliver for disposal in accordance with local/regional/national/international regulations. Do not contaminate water sources or sewer systems.

Disposal considerations:

Waste treatment methods: Dispose of waste and residues in accordance with local authority requirements. Do not allow runoff to sewers, waterways or ground. Residues and empty containers should be taken care of as hazardous waste according to local and national provisions.

Firefighting measures:

- **Extinguishing media**: Extinguish with carbon dioxide or dry powder. Larger fires: Water.
- **Special hazards arising from the substance or mixture**: Hazardous combustion products: in case of fire, toxic gases (CO, CO2, NOx) may be formed.
- **Unusual Fire & Explosion Hazards**: No unusual fire or explosion hazards noted.
- **Advice for firefighters**:

- Special Fire Fighting Procedures: No specific firefighting procedure given. Keep run-off water out of sewers and water sources. Dike for water control.
- Protective equipment for fire-fighters: Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

2.2.10 Assessment of a combination of biocidal products

Sumilarv® 0.5G contains only one active substance, Pyriproxyfen. Furthermore, Sumilarv® 0.5G should not be combined with other products. Therefore, no assessment of combined exposure is made.

2.2.11 Comparative assessment

Not relevant. Pyriproxyfen is not in the draft list of the candidate for substitution according to the Article 10 of the Regulation (EC) No. 528/2012 (nor in the draft list of candidate for substitution for plant protection product according to Article 80(7) of Regulation (EC) No 1107/2009).

3 ANNEXES[21]

3.1 List of studies for the biocidal product

List of data submitted by the applicant and relied on:

21 When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

3.2 Output tables from exposure assessment tools

3.2.1 Output tables from exposure assessment tools – human risk assessment

3.3 Confidential information.New information on the active substance

Four new studies have been provided related to the active substance, one related to the biodegradability of pyriproxyfen in activated sludge and three new chronic data on the toxicity of Pyriproxyfen for predatory mite (*Hypoaspis aculeifer*), spring tail (*Folsomia candida*) and earthworm (*Eisenia fetida*).

3.4 Residue behaviour

Please refer to the Estimating Livestock Exposure to Active Substances used in Biocidal Products presented in the scenarios 8 to 13 in the annex 3.1.1

3.5 Summaries of the efficacy studies

Please refer to Table 2.2.5-1

3.6 Confidential annex

See attached file.

3.7 Other

3.7.1 PEC/PNEC ratios for metabolites

Confidential information.

3.8 Additional studies

Confidential information.