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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

Clean Kill®

Product type 18

Active substance: Permethrin

Case Number in R4BP: BC-GL023431-52

Evaluating Competent Authority: Italy

Date: July 2020

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1 CONCLUSION

Following to the comments received by several cMSs during the MRP process, where the original trade name of the product BIO KILL® was questioned as misleading, a different trade name is adopted by the applicant: CLEAN KILL®.

Clean Kill® is a ready-to-use EW (emulsion, oil in water) containing 0.25% w/w permethrin, i.e. 0.269% w/w technical material, to be applied indoor by non-professional users.
The product was originally intended by the applicant for targeted spot application and for application in crack & crevice, by spraying via trigger sprayer.
The targeted spot application was no longer supported for authorization at the resolution step of the formal referral, which was initiated by several cMSs after the bilateral discussion of the MRP process. Only one use remained supported for authorization: **'Targeted spot application in crack & crevice'** on porous/non-porous surfaces by spraying via trigger sprayer with fixed capillary tube, to kill crawling insects (cockroaches, ants, silverfish, earwigs) and spiders. The use of Clean Kill® is restricted to areas that are not wet cleaned and completely protected from water, like garages, cellars, attics, cavities, warehouses, electrical service rooms, boiler rooms.

Physical-chemical data were evaluated and deemed acceptable for the appropriate use and storage of the product. The accelerated and long-term storage stability studies support the applicant's shelf-life claim of **2 years**.
On the basis of the available data/information, Clean Kill® does not pose any physical hazards.

An analytical method which allows the determination of cis- and trans-permethrin in the product is available in the dossier. The method is fully validated and acceptable. However, **a validated analytical method for the determination of each enantiomer of cis- and trans-permethrin is also necessary and should be submitted at product renewal**.

Applied indoor at a dose of **50 mL product/m²** (corresponding to 36 sprays/m², for a maximum treated area of 2 m^2 per house and application), Clean Kill® showed:
- a sufficient effectiveness with a fast knockdown and a complete mortality as targeted spot application in crack and crevice;
- a residual efficacy lasting 4 weeks after treatment on both porous and non-porous materials.

Data were considered sufficient at this stage, although all cMS agreed that there is a gap in the guidance, interpretable in different ways by the MSs in regard to the more fitting design of the SU test to evaluate efficacy in crack and crevice. At the resolution step of the formal referral, it was concluded that, **at renewal stage, an efficacy study specifically designed to represent the application in crack&crevice on porous/non porous surfaces should be submitted**.

For the purpose of the human health risk assessment, permethrin only was considered. One substance of concern was identified in Clean Kill®, which does not require additional risk assessment. As regards both primary and secondary exposure, risks were acceptable.
In consideration of the use pattern of this product under PT18, food and feed contamination is not expected. Therefore, no dietary risk assessment was carried out. The

following RMM is proposed: "Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks".

As regards the environment, the risk assessment was performed considering permethrin and its metabolites DCVA and PBA; no substances of concern were identified in Clean Kill® for the environment.
During the bilateral discussion of the MRP process, several cMSs did not accept the Applicant's proposal to refine the exposure assessment setting the Fce equal to 0%. The additional exposure refinements proposed by the applicant were not accepted, either, and a formal referral was initiated by some cMSs.
During the dispute resolution step, only one use remained supported for authorization: 'Targeted spot application in crack & crevice' on porous/non-porous surfaces by spraying via trigger sprayer with fixed capillary tube, to kill crawling insects (cockroaches, ants, silverfish, earwigs) and spiders, restricted to areas that are not wet cleaned and completely protected from water, like garages, cellars, attics, cavities, warehouses, electrical service rooms, boiler rooms.
The following RMMs were also agreed: 'Do not apply to areas susceptible to wet cleaning' and 'Do not use the product in kitchens and bathrooms'. The RMMs for this specific product should not create a precedent for other cases. This also applies to the use restriction to uninhabitated areas and the examples given in the wording "completely protected from water, like garages, cellars, attics, cavities, warehouses, electrical service rooms, boiler rooms".
Based on these RMMs and considering that the application by trigger sprayer with fixed capillary tube allows the correct application of the product in the crack/crevice, in the exposure evaluation the fraction to treated surfaces and to floor have been set to zero and only emissions to the applicator clothing have been considered. RCR values below 1 for surface water and sediment indicate the risk is controlled also for the aquatic compartment. The approach and calculations for the PEC values were accepted specifically for Clean Kill®, as a compromise, since currently there is no harmonized guidance available for how to quantify the use for capillary tubes. Thus, the approach used for this specific product should not create a precedent for other cases.
In light of the above, as far as permethrin and its metabolites DCVA and PBA are concerned, no unacceptable risks were identified for microorganisms of STP, surface water & sediment, and soil. Permethrin concentration in groundwater proved to be lower than the trigger value set by DWD. No unacceptable risks of secondary poisoning via the food chain were identified, for permethrin and its metabolites, either.

In conclusion, Clean Kill® can be authorized in compliance with article 19(1) of Regulation (EU) No 528/2012, according to the instructions for use and risk mitigation measures stated in the SPC.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country**
Clean Kill®	Italy

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Jesmond Holding AG
	Address	Baarerstrasse 8 CH 6300 Zug Switzerland
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer of the product

Name of manufacturer	DIACHEM S.p.A.
Address of manufacturer	Via Tonale, 15 - 24061 Albano Sant'Alessandro (BG)
Location of manufacturing sites	Via Mozzanica 9/11 24043 Caravaggio (BG), Italy

Name of manufacturer	Vassos Chr. Vasiliou (Imports&Exports) Ltd
Address of manufacturer	167B Kantaras Street 2046 Strovolos - Cyprus
Location of manufacturing sites	167B Kantaras Street P.O.Box 24987 2044 Strovolos - Cyprus

Name of manufacturer	Multi G Férrokemia
Address of manufacturer	Ipoly u. 16 1133 Budapest - Hungary
Location of manufacturing sites	Pannónia u. 57/a 1133 Budapest Hungary

Name of manufacturer	F. Lima S.A.
Address of manufacturer	Urbanização Alto dos Moinhos Rua João Chagas, 12-B Esq. 1500-493 Lisboa - Portugal

Location of manufacturing sites	Largo do Movimento das Forcas Armadas no. 1, Alfragide 2610-123 Amadora Portugal

Name of manufacturer	ZELNOVA ZELTIA
Address of manufacturer	Polígono Industrial Torneiros s/n 36400 Porriño (Pontevedra) - Spain
Location of manufacturing sites	Polígono Industrial Torneiros s/n 36400 Porriño (Pontevedra) Spain

Name of manufacturer	ILIRIJA d.d., Plant Lendava
Address of manufacturer	Tržaška cesta 40, 1001 Ljubljana - Slovenia
Location of manufacturing sites	Industrijska cesta, Petišovci 9220 Lendava Slovenia

Name of manufacturer	PROVEN ORAPI
Address of manufacturer	679 rue du Docteur Lefebvre 06672 VILLENEUVE LOUBET - France
Location of manufacturing sites	679, Avenue du Docteur Lefebvre 06270 Villeneuve Loubet France

Name of manufacturer	Agrobiotrading LTD
Address of manufacturer	Jerusalem str. 1, Mladost 1 1784 Sofia - Bulgarien
Location of manufacturing sites	Tzariza Ioana str. No 4 4400 Pazardjik-Bulgaria

Name of manufacturer	Steinfels Swiss Division der Coop Genossenschaft
Address of manufacturer	St. Gallerstrasse 180 CH-8404 Winterthur - Switzerland
Location of manufacturing sites	St. Gallerstrasse 180 Postfach 53 8411 Winterthur Switzerland

Name of manufacturer	BIOSERVICES INTERNATIONAL
Address of manufacturer	Jagershoek 13 8570 Vichte - Belgium
Location of manufacturing sites	Jagershoek 13 8570 Vichte Belgium

Name of manufacturer	BERNER LTD
Address of manufacturer	Berner Oy Hitsaajankatu 24, 00810 Helsinki - Finland
Location of manufacturing sites	Eteläranta 4B/ P.O. BOX 15 00131 Helsinki Finland

Name of manufacturer	BIOVETA, a.s.
Address of manufacturer	Komenského 212/12 683 23 Ivanovice na Hané Czech Republic
Location of manufacturing sites	Komenského 212/12 683 23 Ivanovice na Hané Czech Republic

2.1.1.4 Manufacturer of the active substance

Active substance	Permethrin
Name of manufacturer	XXXXXXXXXXX
Address of manufacturer	XXXXXX
Location of manufacturing sites	XXXXXXXXXXXXXX

2.1.2 Product composition and formulation

The full composition of the product according to Annex III Title 1 is 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 on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☑

2.1.2.1 Identity of the active substance

Main constituent	
ISO name	permethrin
IUPAC or EC name	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
EC number	258-067-9
CAS number	52645-53-1
Index number in Annex VI of CLP	613-058-00-2
Minimum purity / content	XXXXXXXXXXXXX

2.1.2.2 Candidate for substitution

Substances that fulfil at least two out of the three PBT criteria are candidates for substitution, as identified in the provisions of Article 10 of Regulation (EU) No 528/2012. With regard to PBT assessment, permethrin already fulfilled the T criterion. The P criterion was finally clarified at ENV-WGIII2019, with the conclusion that permethrin is considered to be very persistent. Moreover, bioaccumulation issues have been brought up for discussion at the ECHA PBT EG, and are currently under further evaluation by eCA IE.
However, no conclusions have been published on the ECHA's website for permethrin, yet. No updated AR & LoEPs taking into account the new data/information are available, either. No further action is, therefore, considered necessary for this product at this stage.

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 (% w/w)
Permethrin	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	52645-53-1	258-067-9	XXXXXXXXXXXXX
2-ethylhexan-1-ol	2-ethylhexan-1-ol	Surfactant	104-76-7	203-234-3	XXXXXXXXXX

[*] XXXXXXXXXXXX

The complete composition of the biocidal product is considered as confidential information. Please, refer to the separate Confidential Annex to this PAR.

2.1.2.4 Information on technical equivalence

No technical equivalence assessment is necessary, since the active substance in Clean Kill® is from a reference source in respect of which the initial risk assessment was performed.

2.1.2.5 Information on the substances of concern

According to the criteria given in *Guidance on BPR: Vol III Human Health Parts B+C* as well as Guidance on *BPR: Vol IV Environment Part B+C Version*, the biocidal product Clean Kill® does not contain any substances of concern, except one (2-ethylhexan-1-ol, with EU OEL = 5.4 mg/m^3).
Further details are reported in the separate Confidential Annex to this PAR.

2.1.2.6 Type of formulation

EW (emulsion, oil in water)

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Aquatic Acute 1 Aquatic Chronic 1
Hazard statement	H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects.
Labelling	
Signal words	Warning
GHS Pictograms	GHS09
Hazard statements	H410: Very toxic to aquatic life with long lasting effects.
Precautionary statements	P103: Read label before use. P273: Avoid release to the environment. P391: Collect spillage. P501: Dispose of contents/container in accordance with local / regional / national / international regulations.
Supplemental Hazard statement Code(s)	EUH208 - Contains permethrin. May produce an allergic reaction.
Note	The a.s. is classified as Skin Sens. 1. Nonetheless, it is present at a concentration below the concentration limit of 1% w/w that would trigger the classification for Clean Kill® as Skin Sens. 1 according to CLP regulation. However, the above Supplemental Hazard statement is proposed on the product label.

2.1.4 Authorised uses

Table 1. Use # 1 –Targeted spot application in crack and crevice by non-professionals

Product Type	18
Where relevant, an exact description of the authorised use	Clean Kill® is a RTU liquid formulation used by non-professionals via spots in cracks and crevices on porous/non-porous surfaces. Clean Kill® is used only in areas that are not wet cleaned and completely protected from water (like garages, cellars, attics, cavities, warehouses, electrical service rooms, boiler rooms), to kill crawling insects (cockroaches, ants, silverfish, earwigs) and spiders. Clean Kill® is efficacious in few hours and has 4-week residual activity. Efficacy can be lower on porous surfaces.
Target organism (including development stage)	*Blattella germanica* (German cockroach) *Periplaneta americana* (American cockroach) *Lasius niger* (common black ant) *Lepisma saccharina* (silverfish) *Forficula auricularia* (earwig) *Tegenaria domestica* (barn funnel weaver - spider) Developmental stage: adults
Field of use	Indoor The use is restricted to areas that are not wet cleaned and completely protected from water, like garages, cellars, attics, cavities, warehouses, electrical service rooms, boiler rooms. The product is applied via spots in cracks and crevices which are present on porous/non-porous surfaces and can be of harbourage for crawling insects (cockroaches, ants, silverfish, earwigs) and spiders.
Application method(s)	Spraying (manual application by trigger sprayer with fixed capillary tube)
Application rate(s) and frequency	Apply directly into the crack/crevice. Minimum distance between two pump strokes: 20 cm. Application rate: 36 pump strokes/m^2 (equivalent to 50 mL product/m^2) Max 72 pump strokes/house and application. Max 2 applications/year. Wait 4 weeks before the second application!
Category(ies) of users	Non-professionals
Pack sizes and packaging material	300 mL bottle (PET Octal GP01), trigger sprayer in PP with fixed capillary tube in LDPE and some parts in PE (diptube). Child resistant closure.

2.1.4.1 Use-specific instructions for use

See general directions for use.

2.1.4.2 Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.1.5 General directions for use

2.1.5.1 Instructions for use

Product should be used in accordance with label recommendations. Always read the label or leaflet before use and follow all the instructions provided. Clean Kill® kills crawling insects (cockroaches, ants, silverfish, earwigs), and spiders in few hours and remains efficacious for 4 weeks. The use of Clean Kill® is restricted to areas that are not wet cleaned and completely protected from water, like garages, cellars, attics, cavities, warehouses, electrical service rooms, boiler rooms. The product is applied via spots in cracks and crevices which are present on porous/non-porous surfaces and can be of harbourage for crawling insects (cockroaches, ants, silverfish, earwigs) and spiders. Efficacy can be lower on porous surfaces. Apply directly into the crack/crevice. Minimum distance between two pump strokes: 20 cm. Application rate: 36 pump strokes/m^2 (equivalent to 50 mL product/m^2). Max 72 pump strokes/house and application. Max 2 applications/year. Wait 4 weeks before the second application! Do not attempt to remove the capillary tube. Shake well before use. Avoid the application of the product on very dirty or greasy areas. Wash hands after applying the product, and before eating or drinking. Do not apply other insecticides or insect repellents in areas treated with Clean Kill®. Because resistance is well known to be a potential problem, strategies to avoid resistance are normal practice.

• In case of continuous infestation, to avoid the occurance of resistance, alternate products containing active substances with a different mode of action, (to remove resistant individuals from the population).
• If the infestation persists despite following the instructions of the label/leaflet, contact a pest control professional.
• If the treatment is ineffective the users should report straightaway to the authorization holder.

2.1.5.2 Risk mitigation measures

Do not apply to areas susceptible to wet cleaning.
Do not use in kitchens or bathrooms.
Apply only in areas inaccessible to children and pets.
Keep children and pets away during treatment.
Do not apply in presence of cats and keep cats away from treated surfaces due to high sensitivity to permethrin toxicity.
Remove or cover terrariums, aquariums and animal cages before application. Turn off aquarium air-filter while spraying.
Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks.
Avoid contact with treated surfaces.

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

Direct or indirect effects
Pyrethroids, like permethrin, may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

First aid instructions
If inhaled:
Remove affected person to fresh air and apply artificial respiration, if required. Seek medical advice if specific symptomatic reactions are observed.
If swallowed:
Immediately call a poison control centre or doctor for treatment advice. Do not give any liquid to the person. DO NOT induce vomiting. If vomiting occurs spontaneously, keep head below hips to prevent aspiration. Do not give anything by mouth to an unconscious person.
If on skin or hair:
Remove contaminated clothing and wash with soap and running water. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control centre or doctor for treatment advice if irritation persists.
If in eyes:
Remove contact lenses, if present. Hold eyelids apart and flush eye continuously with running water for 15 – 20 minutes. Call a poison control centre or doctor for treatment advice or if irritation persists.

In the event of a leak or spillage:
Shut off the source of the leak if it is safe to do so.

Immediate actions:
Contain the product to avoid environmental contamination.
Recover product where possible.

Clean up-actions: Absorb spillage in earth, sand or sawdust or other inert material. Place in appropriate metal or plastic containers. Seal the containers and label them. Remove the contaminated material to a safe location for subsequent disposal. If contamination of drainage systems or watercourses is unavoidable, immediately inform the appropriate authorities.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets …) nor down the drains. Dispose of unused product, its packaging (…) and all other waste, in accordance with local regulations.

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

Shelf-life: two years.

2.1.6 Other information

None.

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)
Bottle with trigger sprayer and fixed capillary tube (child resistant closure)	300 mL	PET Octal GP01	Trigger spray in PP with fixed capillary tube in LDPE and some parts in PE (diptube)	Non-professionals	Yes
Bottle with trigger sprayer (child resistant closure)	500 mL	PET Octal GP01	Trigger spray in PP with adjustable nozzle and some parts in PE (diptube)	Non-professionals	Yes
Bottle with cap (re-fill of the bottle with the trigger sprayer)	500 mL	HDPE	Cap in HDPE	Non-professionals	Yes

NOTE: The 500 mL containers originally proposed by the applicant (bottle and re-fill bottle, in grey in the table above) are not covered by this authorization, in order to avoid overdosing. The container size is now limited to 300 mL, in line with the application rate and frequency of the authorized use (Targeted spot application in crack&crevice by non-professionals), to prevent any misuse. The packaging design only allows the application of the product by the trigger sprayer with the capillary tube (non-removable).

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

In relation to the product application, the following data on product are submitted:
- Physical state, color and odor
- pH value
- Density
- Storage stability test and reactivity towards container material

- Storage stability test – long term storage at ambient temperature
- Emulsifiability, re-emulsifiability and emulsion stability
- Particle size
- Pourability / rinseability
- Surface tension
- Viscosity
- Flammable liquids
- Corrosive to metals
- Auto-ignition temperatures of products (liquids and gases)
- Methods for detection and identification
- Efficacy against target organisms.

It shall be noted that the tested batches and the study reports refer to the trade name as originally proposed by the applicant, i.e. Bio Kill®.

2.1.8.2 Access to documentation

The applicant submits a Letter of Access (LoA) granted by the manufacturer of the active substance Tagros Chemicals India Ltd, that covers the studies owned by Tagros Chemicals India Ltd and other information that have been used for including permethrin in the Union list of approved active substances under the Biocidal Products Regulation. With such LoA, Tagros Chemicals India Ltd authorizes the applicant to use, refer to and rely on its data in order to apply for the authorization of the product. It shall be noted that the LoA refers to the trade name as originally proposed by the applicant, i.e. Bio Kill®.

2.2 Assessment of the biocidal product

2.2.1 Intended uses as applied for by the applicant

Clean Kill® is a ready-to-use emulsion in water (EW) containing 0.25% w/w of permethrin (pure). The product can be applied for the control of a wide range of flying and crawling insects and is intended for 'In and around building' use. Clean Kill® is proposed for the control of flying insects (flies and mosquitoes) and crawling insects (cockroaches, ants, silverfish, bed bugs, earwig), mites and spiders.

Use # 1 – Targeted spot application by non-professionals

Product Type	18
Where relevant, an exact description of the authorised use	Clean Kill® is a RTU liquid formulation used by non-professionals for targeted spot application.
Target organism (including development stage)	Flying insects (flies and mosquitoes) and crawling insects (cockroaches, ants, silverfish, bed bugs, earwig), mites and spiders.
Field of use	Indoor
Application method(s)	Trigger spray
Application rate(s) and frequency	Apply the product by spraying from a distance of 30 cm (one spray every 20 cm). 25 sprays cover 1 m^2 of surface. A number of 9 applications per year shall not be exceeded.
Category(ies) of users	Non-professionals
Pack sizes and packaging material	Please see the relevant section.

Use # 2 – Crack and crevice application by non-professionals

Product Type	18
Where relevant, an exact description of the authorised use	Clean Kill® is a RTU liquid formulation that is used by non-professionals for crack and crevice application.
Target organism (including development stage)	Flying insects (flies and mosquitoes) and crawling insects (cockroaches, ants, silverfish, bed bugs, earwig), mites and spiders.
Field of use	Indoor
Application method(s)	Trigger spray
Application rate(s) and frequency	Apply the product by spraying from a distance of 30 cm into crack/crevice. Depending on the length of the crack/crevice, apply the product as once spray every 20 cm. 25 sprays cover 1 m^2 of surface. A number of 9 applications per year shall not be exceeded.
Category(ies) of users	Non-professionals
Pack sizes and packaging material	Please see the relevant section.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	AS in the test substance (% w/w, pure a.s.)	Results	Refer.
Appearance	OPPTS 830.6303; OPPTS 830.6302; OPPTS 830.6304	XXXXXXXX X	Whitish liquid with a color code of 5PB 9/0.5 according to the Munsell Book of Colors (hue of 5PB, a chroma of 9 and a value or lightness of 0.5). The odour of the test item was identified as 'neutral'	Accelerated storage stability of Bio Kill. Jesmond Holding AG. July 2016. Report No. GAT-22-07.16. IUCLID TOC_3.1
Acidity/ alkalinity (pH value)	CIPAC MT 75.3	XXXXXXXX XXX	pH (neat formulation) = 5.40 @ 23.4 °C (n=2) In consideration of the pH value, no acidity/alkalinity data are required	Accelerated storage stability of Bio Kill. Jesmond Holding AG. July 2016. Report No. GAT-22-07.16. IUCLID TOC_3.2
Density	OECD 109 (Oscillating tube densitymeter, suitable for liquids with dynamic viscosity <5 Pa s)	XXXXXXXX XXX	D_4^{20} =1.0083 (n=2)	Accelerated storage stability of Bio Kill. Jesmond Holding AG. July 2016. Report No. GAT-22-07.16. IUCLID TOC_3.3
Storage stability test – **accelerated storage**	CIPAC 46.3 (2 weeks at 54 ± 2 °C)	XXXXXXXX XXXXXXXX X	The accelerated storage stability test has been performed using 0.375 L PET Octal GP01 trigger sprayer bottles (commercial packaging	Accelerated storage stability of Bio Kill. Jesmond Holding AG.

Property	Guideline and Method	AS in the test substance (% w/w, pure a.s.)	Results	Refer.
	Appearance: OPPTS 830.6303; OPPTS 830.6302; OPPTS 830.6304 *Weight loss:* gravimetric *pH:* CIPAC MT 75.3 *Rel. density:* OECD 109 *Pourability:* CIPAC MT 148 *Content of permethrin:* HPLC-UV method as in sec. 2.2.4 *Emulsion stability and re-emulsification:* CIPAC MT 186 (direct measure, without dilution) *Particle size distibution:* CIPAC MT 187 *Valve clogging:* FAO		originally intended by the applicant) **T_0** ▪ Appearance: liquid, whitish (5PB 9/0.5), with a 'neutral odour ▪ Weight loss: -- ▪ pH: 5.40 ▪ Relative density: 1.0083 ▪ Pourability: R = 0.55% (<5%) R'=0.18% (<0.25%) ▪ Content of permethrin: 0.26% w/w ▪ Emulsion stability: homogenous and uniform, without having an oil or cream phase or solid matter during the 24.5 hours observation ▪ Particle size distribution (oil droplets in the EW): D(v,0.5) = 2.69 µm ▪ Valve clogging: no clogging **$T_{2\ weeks@54°C}$** ▪ Appearance: the test item remained liquid, whitish (5PB 9/0.5), with a 'neutral odour ▪ Weight loss: -0.62% ▪ pH: 5.39 ▪ Relative density: 1.0082 ▪ Pourability: ▪ R = 0.12%; R'=0% ▪ Content of permethrin: 0.25% w/w -> Δc_{AS}= -3.8% ▪ Emulsion stability: the test item remained homogenous and uniform, without having an oil or cream phase or solid matter during the 24.5 hours observation ▪ Particle size distribution (oil droplets in the EW): D(v,0.5) = 2.71 µm ▪ Valve clogging: no clogging	July 2016. Report No. GAT-22-07.16. IUCLID TOC_3.4.1.1
Storage stability test –	*Appearance:* OPPTS	XXXXXXXX XXXX	The long-term storage stability study has been performed	SHELF-LIFE STABILITY

Property	Guideline and Method	AS in the test substance (% w/w, pure a.s.)	Results	Refer.
long term storage at ambient temperature	830.6303; OPPTS 830.6302; OPPTS 830.6304 *Weight loss:* gravimetric *pH:* CIPAC MT 75.3 *Relative density:* OECD 109 *Pourability:* CIPAC MT 148 *Content of permethrin:* HPLC-UV method as in sec. 2.2.4 *Particle size distibution:* CIPAC MT 187 *Spray and stream character:* FEA 644 *Spray rate:* FEA 643 *Valve clogging:* FAO		using a 0.375 L PET Octal GP01 trigger sprayer bottle (commercial packaging originally intended by the applicant) **T_0** ▪ Appearance: white opaque liquid ▪ Weight loss: - ▪ pH: 7.32 ▪ Relative density: 0.996 ▪ Pourability: R = 0.12%; R'=0.09% ▪ Content of permethrin: 0.255% w/w ▪ Droplet size distibution: D(v,0.5) = 83.5 µm ▪ Spray and stream character: Like spray ▪ Spray rate: 1.36 g product per stroke ($RSD\%_{n=10}$: 1.1%) ▪ Valve clogging: no clogging **$T_{6\ months}$** ▪ Appearance: no variation from initial ▪ Weight loss: 0.48% ▪ pH: 6.89 ▪ Relative density: 0.997 ▪ Pourability: R = 0.13%; R'=0.13% ▪ Content of permethrin: 0.246% w/w -> Δc_{AS}= -3.5% ▪ Droplet size distibution: D(v,0.5) = not determined ▪ Spray and stream character: not determined ▪ Spray rate: 1.37 g product per stroke ($RSD\%_{n=10}$: 9.5%) ▪ Valve clogging: no clogging **$T_{12\ months}$** ▪ Appearance: no variation from initial ▪ Weight loss: 0.94% ▪ pH: 7.29 ▪ Relative density: 0.998	STUDY AT 25°C/60%RH FOR 24 MONTHS ON THE TEST ITEM "BIO KILL 0.25% PERMETHRIN EW". Eurofins Biolab S.r.l. 2016/271AM. 2019-07-15. IUCLID TOC_3.4.1.2

Property	Guideline and Method	AS in the test substance (% w/w, pure a.s.)	Results	Refer.
			▪ Pourability: R = 0.20%; R'=0.13% ▪ Content of permethrin: 0.244% w/w -> Δc_{AS}= -4.3% ▪ Droplet size distibution: D(v,0.5) = not determined ▪ Spray and stream character: not determined ▪ Spray rate: 1.28 g product per stroke product per stroke (RSD%$_{n=10}$: 4.0%) ▪ Valve clogging: no clogging **$T_{18\ months}$** ▪ Appearance: no variation from initial ▪ Weight loss: 1.36% ▪ pH: 6.98 ▪ Relative density: 0.997 ▪ Pourability: R = 0.07%; R'=0.08% ▪ Content of permethrin: 0.236% w/w ->Δc_{AS}= -7.5% ▪ Particle size distibution: D(v,0.5) = not determined ▪ Spray and stream character: not determined ▪ Spray rate: 1.37 g product per stroke (RSD%$_{n=10}$: 1.3%) ▪ Valve clogging: no clogging **$T_{24\ months}$** ▪ Appearance: no variation from initial ▪ Weight loss: 1.87% ▪ pH: 6.58 ▪ Relative density: 0.998 ▪ Pourability: R = 0.10%; R'=0.13% ▪ Content of permethrin: 0.231% w/w ->Δc_{AS}= -9.4% ▪ Droplet size distibution: D(v,0.5) = 78.9 µm ▪ Spray and stream character: Like spray ▪ Spray rate: 1.29 g product per stroke	

Property	Guideline and Method	AS in the test substance (% w/w, pure a.s.)	Results	Refer.
			(RSD%$_{n=10}$: 5.2%) ▪ Valve clogging: no clogging As for the spray pattern, please also refer to the conclusions below this table.	
Storage stability test – **low temperature stability test for liquids**	CIPAC 39.3	XXXXXXXX XXXXXX	100 mL of product were introduced in a centrifuge tube and a permethrin crystal was added after 1 day at 0 ± 2 °C. After additional 7 days at 0 ± 2 °C, no crystal growth (solid matter) was observed. No phase separation was observed, either	Accelerated storage stability of Bio Kill. Jesmond Holding AG. July 2016. Report No. GAT-22-07.16 IUCLID TOC_3.4.1.3
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Justification for the non-submisssion of data	-	Data waiving, since the characteristics of packaging (PET Octal GP01 bottle) protect the product from light. In addition, permethrin is not sensitive to light	IUCLID TOC_3.4.2
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	As above	-	*Temperature* The results from the accelerated stability & low temperature stability tests show that temperature does not negatively affect the content of the a.s. nor the technical characteristics of the biocidal product. *Humidity* Data waiving, since (i) the product is water based (ii) packaging (PET Octal GP01 bottle) protects the product form humidity	IUCLID TOC_3.4.2
Effects on content of the active	OPPTS 830.6320	XXXXXXXX XXXXXXXX XXXXXXXX	The packaging remained stable after accelerated storage and the long-term storage stability	IUCLID TOC_3.4.2

Property	Guideline and Method	AS in the test substance (% w/w, pure a.s.)	Results	Refer.
substance and technical characteristics of the biocidal product - **reactivity towards container material**		X	tests: no seepage or cracking of the bottles and closures was observed; no change of the bottle shape and color was observed, either. The trigger sprayer remained fir-for-purpose, too (no clogging, also during intermittent use)	
Wettability	As above	-	Data waiving, since the product (RTU EW) is not a solid preparations which is to be dispersed in water	IUCLID TOC_3.5.1
Suspensibility, spontaneity and dispersion stability	As above	-	Data waiving, since this assessment depends on the formulation type (nature) of the biocidal product. Not required for the product, which is a RTU EW	IUCLID TOC_3.5.2
Wet sieve analysis and dry sieve test	As above	-	Data waiving, since the product (RTU EW) is not a wettable powders, suspension concentrates, water dispersible granules, aqueous capsule suspensions, dispersible concentrates, suspo-emulsions, water soluble granules and water soluble application; therefore this test is not powders. Dry sieve test is designed to determine the size distribution of dustable powders and granules for direct application to allow acceptable applicable for this product, either	IUCLID TOC_3.5.3
Emulsifiability, re-emulsifiability and emulsion stability	CIPAC MT 36.3	XXXXXXXX XXXXXX	The product proved to be homogenous and uniform, without having an oil or cream phase or solid matter during the 24.5 hours observation	Accelerated storage stability of Bio Kill. Jesmond Holding AG. July 2016. Report No. GAT-22-07.16.

Property	Guideline and Method	AS in the test substance (% w/w, pure a.s.)	Results	Refer.
				IUCLID TOC_3.5.4
Disintegration time	Justification for the non-submisssion of data	-	Data waiving, since the product (RTU EW) is not a tablet	IUCLID TOC_3.5.5
Particle size	CIPAC MT 187 (laser diffraction) Pre-treatment: homogenisation for 30 seconds and subsequent standing for 10 min to remove air bubbles	XXXXXXXX XXXX	Particle size distribution (oil droplets in the EW): D (v, 0.1) = 1.28 µm D (v, 0.5) = 2.69 µm D (v, 0.9) = 5.20 µm D [4,3] = 4.00 µm	Accelerated storage stability of Bio Kill. Jesmond Holding AG. July 2016. Report No. GAT-22-07.16. IUCLID TOC_3.5.6
	CIPAC MT 187 (laser diffraction)	XXXXXXXX XXXXXXX	Droplet size distribution (sprayed product): D (v, 0.1) = 43.6 µm D (v, 0.5) = 83.5 µm D (v, 0.9) = 176.1 µm D [4,3] = 99.0 µm %V<10 µm = 0.1%	SHELF-LIFE STABILITY STUDY AT 25°C/60%RH FOR 24 MONTHS ON THE TEST ITEM "BIO KILL 0.25% PERMETHRIN EW". Eurofins Biolab S.r.l. 2016/271AM. 2019-07-15. IUCLID TOC_3.5.6
Persistent foaming	CIPAC MT 47.2	XXXXXXXX XXXXXX	No persistent foam was observed (0 mL after 10 s/1 min/3 min/12 min)	Accelerated storage stability of Bio Kill. Jesmond Holding AG. July 2016. Report No. GAT-22-07.16.

Property	Guideline and Method	AS in the test substance (% w/w, pure a.s.)	Results	Refer.
				IUCLID TOC_3.5.7
Pourability / rinseability	CIPAC MT 148	XXXXXXXX XXXXXXXX XXX	Pourability [%]: 0.55% (<5%) Rinsed residue [%]: 0.18% (<0.25%)	Accelerated storage stability of Bio Kill. Jesmond Holding AG. July 2016. Report No. GAT-22-07.16. IUCLID TOC_3.5.8
Burning rate — smoke generators	Justification for the non-submisssion of data	-	Data waiving, since the product (RTU EW) is not applied as a smoke.	IUCLID TOC_3.5.9
Burning completeness — smoke generators	As above	-	Data waiving since the product (RTU EW) is not applied as a smoke	IUCLID TOC_3.5.10
Composition of smoke — smoke generators	As above	-	Data waiving since the product (RTU EW) is not applied as a smoke	IUCLID TOC_3.5.11
Spraying pattern — aerosols	As above	-	Data waiving since the product (RTU EW) is not an aerosol	IUCLID TOC_3.5.12
Physical compatibility	As above	-	Data waiving, since the product is not to be co-applied with other substances, mixtures or biocidal/non-biocidal products. In any case, no possible physical incompatibility with any products is known	IUCLID TOC_3.6
Chemical compatibility	As above	-	Data waiving, since the product is not to be co-applied with other substances, mixtures or biocidal/non-biocidal products. In any case, no possible chemical incompatibility with any products is known	IUCLID TOC_3.6
Degree of	As above	-	Data waiving, since the product	IUCLID

Property	Guideline and Method	AS in the test substance (% w/w, pure a.s.)	Results	Refer.
dissolution and dilution stability			is not used in a water soluble bag or tablets. The dilution stability is not determined, either, since the product is a ready-to-use EW	TOC_3.7
Surface tension	EU Method A.5 (plate method)	XXXXXXXX XXX	Surface tension of the neat formulation at 20°C: 28.7 ± 0.0 mN/m (n=2) Surface tension of the 1% w/v dilution at 20°C: 48.7 ± 0.8 mN/m (n=2) *NB: since the product is a RTU liquid product, the determination of the surface tension of the 1% w/v dilution is actually not required. However, data were available in the dossier and maintained in the PAR.*	'BIO KILL Classic' - Determination of specified physical properties. Oxford Analytical Ltd. Study Number: OA02627. September 22, 2015. IUCLID TOC_3.8
Viscosity	CIPAC MT 192 (rotational viscometer: cone with a diameter of 60 mm and an angle of 1°. Analysis at shear stresses of τ = 1 Pa and τ = 10 Pa and for the shear stress τ at the shear rate of γ = 100 s^{-1})	XXXXXXXX XXXXXXXX XXXXXXXX XX	The dynamic viscosity at τ_{1Pa} proved to be 66.20 and 45.13 mPa s at 20 and 40°C, respectively (n=2). The dynamic viscosity at τ_{10Pa} proved to be 8.64 and 7.50 mPa s at 20 and 40°C, respectively (n=2). Shear stress τ (at γ = 100 s^{-1}): 1.80 and 1.53 Pa at 20 and 40°C, respectively (n=2).	Accelerated storage stability of Bio Kill. Jesmond Holding AG. July 2016. Report No. GAT-22-07.16. IUCLID TOC_3.9

NOTE: In the long-term storage stability study, the pH of the neat formulation at T0 proved to be ca. 2-fold higher than expected. A justification for this apparent inconsistency was requested by the refMS-IT. According to the applicant, the only explanation is that the pH was measured, by mistake, not on the neat formulation but after the dilution of the product.
The applicant also submitted a CoA recently done, which confirmed that the pH of the neat formulation is of the same magnitude as indicated in the accelerated storage stability test. In particular, pH data were presented for 5 different batches manufactured from 01/10/2019 to 14/10/2019. All results proved to be in the range 5.8-5.9 (neat formulation).

Conclusion on the physical, chemical and technical properties of the product

Clean Kill® is a ready-to-use EW (emulsion, oil in water) containing 0.25% w/w of permethrin as pure active substance, corresponding to 0.269% w/w as technical material. The product is to be used by manual application by trigger sprayer with fixed capillary tube, as eventually agreed at resolution step of the formal referral initiated by some cMSs. The authorized packaging design allows the correct application of the product in cracks/crevices.

Clean Kill® is an odourless whitish liquid (color code of 5PB 9/0.5 according to the Munsell Book of Colors). The pH of the neat formulation is 5.4 at 23.4°C, therefore no acidity data are required. D_4^{20} was determined to be 1.0083.

The following technical characteristics were addressed in accordance with the FAO manual for EW formulations:
- pourability (to demonstrate that the user can make use of the maximum amount of the preparation and that an excessive amount of the material does not remain in the container);
- emulsion stability and re-emulsification (to determine whether a preparation forms and maintains a stable emulsion);
- persistent foam (to determine the amount of foam likely to be present in the application equipment).

In addition, the particle size distribution of the oil droplets in the EW was addressed by CIPAC MT 187.
The spray pattern, the droplet size distribution of the sprayed product and the spray rate were also investigated. Data were obtained on the product in the original packaging intended by the applicant (375 mL PET Octal GP01 bottle with trigger sprayer).
As regards the spray pattern, recorded on 200 x 250 mm Indigo Cobalt Chloride water sensitive paper from a 30 cm distance, only photos were made available in the original study report (SHELF-LIFE STABILITY STUDY AT 25°C/60%RH FOR 24 MONTHS ON THE TEST ITEM "BIO KILL 0.25% PERMETHRIN EW". Eurofins Biolab S.r.l. 2016/271AM. 2019-07-15. IUCLID TOC_3.4.1.2). Following the request for additional data/information by the refMS-IT, the Applicant claimed a spray diameter of ca. 15 cm, based on an *in-house* test. The provided information is consistent with the evidence as available in the dossier and can be accepted.
Owing to the formulation type (EW) and its use pattern (ready-to-use formulation), no further testing is deemed necessary for technical characteristics.
Satisfactory results were obtained, which ensure Clean Kill® is homogeneous when applied through the appropriate application equipment. Data on the relevant technical characteristics of the product were provided also after accelerated storage (2 weeks at 54°C) and/or after long-term storage (6, 12, 18 and 24 months at 25°C/60% RH).

Several storage stability tests were performed on the product. Both accelerated and long-term storage stability studies were carried out on Clean Kill® in its original packaging (375 mL PET Octal GP01 bottle with trigger sprayer). No significant change in the packaging was observed. Results can be extrapolated to the 300-mL pack size, now the only pack size covered by the authorization.

- Accelerated storage stability test: the product in its original packaging was kept at 54°C for 2 weeks. The variation of the a.s. content (-3.48%) proved to be acceptable; no significant change in appearance, pH, density and several relevant characteristics of the product was observed, either.
- Long-term storage stability study: both intermediate and final results have been made

available during the evaluation of the product.
After **2-yr storage** at 25±2°C and 60±5% RH , the a.s. content proved to decrease by 9.4%. No significant change in appearance, density and several key parameters of the product was observed. It shall be noted that no pH data on the neat formulation were provided after 2-yr storage. No data on the emultion stability after 2-yr storage were provided, either. However, satisfactory data on the formulation pH and emulsion stability were presented after accelerated storage, which can be considered sufficient evidence to support the applicant's shelf-life claim of 2 years.
The droplet size distribution before and after 2-yr storage was investigated by applying laser diffraction (CIPAC MT 187). The product was sprayed by the commercial trigger sprayer bottle (5 actuations for each analysis, 1-2 s between each actuation). Measurements were made placing the trigger sprayer 20 cm far from and at the same height as the Spraytech laser beam. The main parameters, namely D(v,0.5) and %V<10 µm, did not vary significantly upon storage.
Evidence was provided that the preparation may be satisfactorily applied. Intermediate data demonstrating the satisfactory operation of the trigger sprayer prior to and after storage have been provided by the applicant in the storage stability study, included the spray pattern, the amount of spray delivered with each operation and observations on the nozzle for blockages. Since the biocidal product is not applied in one single operation, the intermittent use of the sprayer during the storage was also addressed.

- Low temperature stability: a test was conducted, CIPAC MT 39.3. No separation of solid/oily matter was observed after.

Testing on the effect of light is not necessary for Clean Kill®, since opaque packaging ensures protection from direct sunlight. Moreover, the a.s. is not sensitive to light. The effect of humidity is not to be investigated, either, being Clean Kill® an aqueous formulation.
Taking into account all the available storage stability data, in conclusion results support the applicant's shelf-life claim of **2 years**.

Clean Kill® is not intended to be used in combination with other products. Clean Kill® proved to be a surface-active fluid with a low viscosity, consistently with the product composition and the formulation type (EW).

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	AS in the test substance (% w/w, pure a.s.)	Results	Refer.
Explosives	Justification for the non-submission of data	-	Explosive properties are associated with the presence of certain chemical groups in a molecule which can react to produce very rapid increases in temperature or pressure. The screening procedure is aimed at identifying the presence of such reactive groups and the potential for rapid energy release. The biocidal product is not expected to possess explosive properties since the a.s. was concluded to be	IUCLID TOC_4.1

Property	Guideline and Method	AS in the test substance (% w/w, pure a.s.)	Results	Refer.
			'not explosive' and there are no chemical groups associated with explosive properties in any of the co-formulants, either	
Flammable gases	As above	-	Data waiving since the product (RTU EW) is not a gas	IUCLID TOC_4.2
Flammable aerosols	As above	-	Data waiving since the product (RTU EW) is not an aerosol	IUCLID TOC_4.3
Oxidising gases	As above	-	Data waiving since the product (RTU EW) is not a gas	IUCLID TOC_4.4
Gases under pressure	As above	-	Data waiving since the product (RTU EW) is not a gas under pressure.	IUCLID TOC_4.5
Flammable liquids	Method EC A9 (Pensky-Martens closed cup)	XXXXXXXXX XXXXX	No flashpoint up to 85°C (n=2)	'Bio Kill - (Permethrin 0.25% EW)' Determination of specified physico-chemical properties. Study Number: OA03301. Oxford Analytical Ltd. 03/07/2019 IUCLID section 4.6
Flammable solids	Justification for the non-submission of data	-	Data waiving since the product (RTU EW) is not solid	IUCLID TOC_4.7
Self-reactive substances and mixtures	As above	-	Data waiving since the a.s. is not classified as 'explosive' or 'self-reactive substance' and there are no chemical groups associated with explosive or self-reactive properties in any of the co-formulants, either	IUCLID TOC_4.8
Pyrophoric liquids	As above	-	Data waiving since the experience in manufacture and handling shows that the product does not ignite	IUCLID TOC_4.9

Property	Guideline and Method	AS in the test substance (% w/w, pure a.s.)	Results	Refer.
			spontaneously on coming into contact with air at normal temperatures, i.e. the product is known to be stable at room temperature for prolonged periods of time (days)	
Pyrophoric solids	As above	-	Data waiving since the product (RTU EW) is not solid	IUCLID TOC_4.10
Self-heating substances and mixtures	As above	-	Data waiving. In general, the phenomenon of self-heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids	IUCLID TOC_4.11
Substances and mixtures which in contact with water emit flammable gases	As above	-	Data waiving since the product is known not react with water (water-based product, with a high water content)	IUCLID TOC_4.12
Oxidising liquids	As above		Data waiving since some of the ingredients of the product contain oxygen and chlorine , but they are chemically bonded only to carbon or hydrogen	IUCLID TOC_4.13
Oxidising solids	As above	-	Data waiving since the product (RTU EW) is not solid.	IUCLID TOC_4.14
Organic peroxides	As above	-	Data waiving since the product does not contain organic peroxides.	IUCLID TOC_4.15
Corrosive to metals	UN Test C.1 (UN Manual of Tests and Criteria: Part III, 37.4: Test methods for corrosion to metals)	XXXXXXXXX XXXXXXXX	Corrosion Properties were investigated at 55±1 °C. <u>Steel specimens</u>: Fully suspended in the formulation; mass loss <0.1% Half suspended in the formulation / Half exposure to the gas phase mass loss <0.1% Fully suspended in the gas phase mass loss <0.1% Recorded results for the steel specimens in contact with the formulation were well within the 13.5% specified minimum limit of the mass loss for 7 days exposure	'Bio Kill - (Permethrin 0.25% EW)' Determination of specified physico-chemical properties. Oxford Analytical Ltd. Report no. OA03313. 25 July 2019.

Property	Guideline and Method	AS in the test substance (% w/w, pure a.s.)	Results	Refer.
			time at 55 ± 1°C. Result: Negative <u>Aluminium specimens</u>: Fully suspended in the formulation; mass loss <0.01% Half suspended in the formulation / Half exposure to the gas phase mass loss <0.01% Fully suspended in the gas phase mass loss <0.01% Recorded results for the aluminium specimens in contact with the formulation were well within the 13.5% specified minimum limit of the mass loss for 7 days exposure time at 55±1 °C. Result: Negative A signed statement was also submitted by the laboratory in charge of the study, declaring that no localized pitting was observed for any of the investigated specimens.	IUCLID TOC_4.16
Auto-ignition temperatures of products (liquids and gases)	Method EC A15 Using ASTM-E659-78 Apparatus: GC OVEN Atmospheric Pressure: 1003 mb	XXXXXXXXXXXXXXXXXX	No flame at 400°C using 100 µL (n=2) Observation time: 10 min	'Bio Kill - (Permethrin 0.25% EW)' Determination of specified physico-chemical properties. Study Number: OA03301. Oxford Analytical Ltd. 03/07/2019 IUCLID TOC_4.17.1
Relative self-ignition temperature for solids	Justification for the non-submission of data	-	Data waiving since the product (RTU EW) is not solid	IUCLID TOC_4.17.2

Property	Guideline and Method	AS in the test substance (% w/w, pure a.s.)	Results	Refer.
Dust explosion hazard	As above	-	Data waiving since the product (RTU EW) is not a powder and does not contain (nor is able to produce) dust	IUCLID TOC_4.17.3

Conclusion on the physical hazards and respective characteristics of the product

The a.s. is not classified as 'explosive', 'oxidising' or 'self-reactive'. As for the co-formulants, there are no chemical groups associated with explosive, oxidising or self-reactive properties. It can be anticipated that Clean Kill® has neither explosive nor oxidising properties and is not expected to be self-reactive, either.

Clean Kill® is not a flammable liquid (flash-point determined, following the IT-CA's request, by Pensky-Martens closed cup: > 85°C). Experience in production and handling shows that Clean Kill® (water-based RTU EW, with a high water content) does not ignite spontaneously on coming into contact with air at normal temperatures. Experience in handling and use shows that the product does not react with water, either. Testing according to ASTM - E659-78 (Auto-ignition temperatures of liquids and gases) was performed, following the IT-CA's request; no auto-ignition was observed up to 400°C.

Clean Kill® should not be considered for classification in the hazard classes of organic peroxide. Due to the formulation type (EW), dust formation is not expected; so the dust explosion hazard class is not applicable, either.

A corrosion test was requested by the IT-CA to address the hazard class 'Corrosive to metals'. Data obtained under UN C.1 Test (UN Test in Part III of the UN Manual of Tests and Criteria, section 37.4) showed that the product is not 'Corrosive to metals'. A signed statement was also submitted by the laboratory in charge of the study, declaring that no localized pitting was observed for any of the investigated specimens.

On the basis of the available data/information, Clean Kill® does not pose any physical hazards. Therefore, no need for a risk characterisation for physical hazards is envisaged.

2.2.4 Methods for detection and identification

XXXXXXXXXXXXXXXX

Scope and outline

This method is used for the quantitative determination of the active ingredient permethrin in the product at a concentration of 2.5 g/L. (corresponding to 0.25% w/w). Analysis is carried out using Reverse Phase - High Performance Liquid Chromatography (RP-HPLC) and an external calibration with a permethrin Pestanal® analytical standard (ASTD).
Quantitative analysis was performed using dicyclohexyl phthalate as the internal standard (ISTD). For the quantification of permethrin, the sum of the two isomers (cis- and trans-permethrin) was calculated for both the calibration and the test item solutions.
A ratio of the two isomers in the test items can be established as percentage, by dividing the cis- and trans- isomer by the sum of isomers.

Procedure

Preparation of internal standard solution
A solution of dicyclohexyl phthalate at a concentration of 0.1 to 1 g/L in acetonitrile with 0.1 vol-% formic acid was prepared and homogenized using an ultrasonic bath.

Preparation of calibration solution
About 20 mg of the analytical standard (ASTD) permethrin is weighed accurately, dissolved in 20 mL internal standard solution (ISTD) and homogenized in an ultrasonic bath for 10 min (calibration stock solution). 900 µL solution are added to an autosampler vial and 100 µL of the calibration stock solution are added, resulting in a concentration of 0.1 mg/mL (working concentration). The procedure for the calibration is performed in triplicate.

Preparation of test item solution
Approx. 800 mg ofthe product are weighed accurately in a 30 or 50 mL bottle and 20 mL ISTD solution are added. The solution is homogenized in an ultrasonic bath for 15 min, filtered through a 0.2 µm syringe filter and filled into a vial.

Specificity

The specificity was investigated using the calibration solution and the test item. Additionally, acetonitrile and a formulation blank as separate dilutions with acetonitrile were injected to check for interferences at the retention time of the two isomers of the active ingredient. Chromatograms were submitted, to prove there are no interference peaks at the retention times of trans-permethrin and cis-permethrin (ca. 5.2 min and 5.6 min, respectively).

Linearity

The linearity was performed using five concentrations of the analytical standard between 0.05 and 1 mg/mL for permethrin, corresponding to an approximate range of 50% to 1000% of the working concentration (i.e. 0.125% w/w to 2.5% w/w in the product).

Precision

The precision of permethrin in the product was investigated by analyzing five independent samples of the test item five times.

Accuracy

Two approaches were used:

I) In the first place, the accuracy for permethrin was determined by spiking the samples used for investigating the method precision with known amounts of permethrin analytical standard solutions, corresponding to five fortification levels between 57% and 178% of the working concentrations for permethrin (0.1 mg/mL), i.e. from 0.14% w/w to 0.44% w/w in the product.
II) Additionally, the matrix (placebo), was spiked with the product at five fortification levels between 0% and 100% of the nominal a.s. content. 20 mL ISTD solution were added and homogenized for HPLC analysis.

Limit of quantification (LOQ) and limit of detection (LOD)

The limit of quantification (LOQ) and limit of detection (LOD) do not need to be reported for the active ingredient determination in a formulated product, according to SANCO 3030/99 rev. 4.

Reference

Determination of permethrin in Bio Kill by Hogh Performance Liquid Chromatography (HPLC). Jesmond Holding AG. May 2016. Report No. GAT-15-05.16 [new layout of Report No. GAT-0513-PMT07-HPLC (2013)].

Conclusion on the methods for detection and identificationof the product
A method by RP-HPLC with UV detection at 230 nm on a Zorbax SB-Aq, Rapid Resolution HT, 50 x 3.0 mm, 1.8 µm pore size column for the determination of permethrin in the product has been developed and validated according to SANCO/3030/99 rev. 4. The test item is dissolved in the internal standard solution, then sonicated for 15 minutes and filtered prior to analysis. Permethrin content proved to be 0.256% w/w in the investigated test item (Bio Kill®, batch: AB01 080915), with the following (average) permethrin ratio: 26.07% for cis-permethrin 73.93% for trans-permethrin The method is: - sufficiently specific, as showed by example chromatograms from the analysis of permethrin standard in solution with dicyclohexyl phthalate (IS), acetonitrile, formulation blank (placebo), and product sample; - linear (R^2>0.999996) over the range 0.125–2.5% w/w, corresponding to ca. 50-1000% of the nominal a.s. content in the product; - accurate*, with mean recovery rates in the acceptable range 95-105% at spiking levels ranging fom 0.14 to 0.44% w/w (corresponding to ca. 57% and 178%, respectively, of the nominal a.s. content); - precise, being the $\%RSD_{n=5}$= 0.806% below the limit of 3.3% given by the modified Horwitz equation. **Please, note the conclusion on the accuracy of the method takes into account only the results according to approach I). The additional results obtained according to approach II) are reported in the table above just for completeness.* The analytical method described above allows the determination of cis- and trans-permethrin in the product. The method is fully validated and acceptable. However, as requested in the permethrin AR (PT18) and for the purpose of market control, **a validated analytical method for the determination of each enantiomer of cis- and trans-permethrin in Clean Kill® is also necessary and should be submitted at product renewal.**

Residue analysis

Acceptable analytical methods for permethrin residues in soil, air and water (as summarized below) are available in the CAR of permethrin drafted by the IE (eCA) under PT18.

Analytical Methods for Residues in soil
Soil samples of were extracted in a microwave extractor with a mixture of acetonitrile/water and ammonium formate. The sample was cleaned up by centrifugation. Identification and quantitation of the test item was done using HPLC MS/MS detection in the Multiple Reaction Monitoring mode. The method was validated using a silt loam soil (Höfchen) and a sandy loam soil (Laacher Hof).
LOQ = 5.0 µg/kg in soil (permethrin) (Bayer/Sumitomo)

Analytical Methods for Residues in air
Air is sucked through XAD adsorption tubes at about 1.5 L/min for 6 hours (total air sampling volume about 0.5 m^3). Subsequently, the adsorption material is extracted with acetone.
The extract is diluted with methanol/water (1/2 v/v) and analysed by HPLC/MS/MS, monitoring two parent-daughter ion transitions.
LOQ = 5 µg/m^3 air (Bayer/Sumitomo)

Air is sucked through adsorption tubes at about 1.8 L/min for 6 hours at 35°C. Subsequently, the adsorption material is extracted with acetone. The extract was analysed for permethrin using GC/ECD. GC-MS/MS was used as a confirmatory method (three ions with an m/z > 100).
LOQ = 0.0001 mg/m^3 air (Tagros)

Analytical Methods for Residues in water
Acidified water samples are diluted with acetonitrile and analysed by HPLC-MS/MS using positive ionisation mode without further cleanup. Concentrations were quantified using external matrix-matched standard solutions LOQ = 0.05 µg/L for drinking and surface water, permethrin only. (Bayer/Sumitomo)

No analytical method for permethrin residues in body fluids and tissues is required, since permethrin is not classified as Acute toxicity (cat. 1 - 3), CMR (cat. 1) or STOT 579 (cat. 1).

No analytical method for permethrin residues in food and feedstuff is required, in consideration of the use pattern of the product under PT 18.

No analytical methods for residues are necessary for any co-formulants. None are classified as Acute toxicity (cat. 1 - 3), CMR (cat. 1) or STOT (cat. 1). As for co-formulants classified hazardous for the environment, none are present at concentrations which lead to the classification of the product. In conclusion, no co-formulant needs to be monitored.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Clean Kill® is a ready-to-use EW product, containing 0.25% w/w permethrin (as pure active substance), corresponding to 0.269% w/w (as technical grade active substance; min. purity: 93%), used as insecticide by general public (non-professionals). The product is intended for indoor use by non-professional users, for targeted spot application in crack and crevice on porous and non-porous surfaces by spraying via trigger sprayer with fixed capillary tube, to kill crawling insects (cockroaches, ants, silverfish, earwigs) and spiders.

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

Clean Kill® is proposed for killing:

Crawling insects:

Blattella germanica (German cockroach)

Periplaneta americana (American cockroach)

Lasius niger (common black ant)

Lepisma saccharina (silverfish)

Forficula auricularia (earwig)

Spiders

Tegenaria domestica (barn funnel weaver - spider)

2.2.5.3 Effects on target organisms, including unacceptable suffering

Clean Kill® is an insecticide with knockdown and residual activity. It acts by ingestion and contact by the target organism.

2.2.5.4 Mode of action, including time delay

Permethrin is a type I axonic poison, which exerts its effects by means of hyperexcitation of both the peripheral and central nervous systems of target insects. Its effects are characterised by progressive fine whole body tremor, exaggerated start response, uncoordinated muscle twitching and hyperexcitability. Permethrin also induces hepatic microsomal enzymes.
Pyrethroids act on the insect nervous system by slowing action potential decay and thereby initiating repetitive discharges in motor and sensory axons. Electrophysiological studies have suggested that these phenomena result from modification of the gating kinetics of neuronal, voltage-sensitive Na channels. Single channel studies have been conducted which have shown that pyrethroids slow the kinetics of opening and closing of Na channels.
Pyrethroids show high potency and selectivity for insects over mammals. The negative temperature dependence of pyrethroid action is partly responsible for the low mammalian toxicity of these compounds. Type 1 pyrethroids produce a distinct poisoning syndrome characterised by progressive fine whole body tremor, exaggerated start response, uncoordinated muscle twitching and hyperexcitability. The effects are generated largely by effects in the central nervous system. Permethrin also induces hepatic microsomal enzymes.

It should also be noted that permethrin may also exhibit a mild contact repellent effect in conjunction with the insecticidal effect. This contact repellence effect is also common to other pyrethroid insecticides (such as deltamethrin, cypermethrin, esfenvalerate and lamda-cyhalothrin) and is known as the "hot-foot effect" and may be relevant for some arthropods. The repellent effect is dose related and for insecticidal products the repellent effect of permethrin is considered as a side effect, since the toxic response of the insect is a delayed kill (insecticidal) effect.
No information was provided or available on the efficacy of the different permethrin isomers.

2.2.5.5 Efficacy data

Four studies were performed on the biocidal product Clean Kill® (originally named as Bio Kill®); all details of these studies are reported below.

Study n° 1: Laboratory testing of a dose range of an insecticidal speciality intended to control various pests (non key study)

Experimental data on the efficacy of the biocidal product against target organism(s)	
Function	Insecticide
Field of use envisaged	Indoor
Test substance	Bio Kill® Classic (permethrin 0.25% w/w as pure a.s.) - Lot AB01 080915
Test organism(s)	Model of FLYING INSECTS: *Musca domestica* (common house fly) Model of CRAWLING INSECTS: *Blattella germanica* (German cockroach) Model of SPIDERS: *Tegenaria domestica* (barn funnel weaver - house spider) The insects used for the test were from strains bred in TEC, and spiders were from wild infestations.
Test method	The purpose of this study was to assess several doses of an insecticidal active substance against various pests. The trial was done by exposing the insects on porous and non-porous surfaces sprayed with different dosages of the product. The procedure was adapted from the French registration standard methodology C.E.B. N°135 in the Appendix of approved methodologies for Biocides registration, in the Manual for the Authorization of Pesticides - EU part – Biocides - Chapter 7 Efficacy - version 1.1; January 2013, i.e. CA-Dec12-Doc.6.2.a-Final.
Test system / concentrations applied / exposure time	Ceramic (non-porous) and concrete (porous) tiles of 15 cm x 15 cm were treated with the product and the insects exposed for 1 hour. Knockdown was recorded at regular time intervals (1 – to- 8 hrs, 24, 48 and 72 hrs), both for Day0 and 4 weeks after treatment. *Flies:* 50 mixed sex adults 2 to 4 days old of *Musca domestica* from a laboratory colony breeding since 1986 (origin of the strain: Wellcome). The breeding conditions are following the requirements of the French standard NF T 72-320. Density of the target organisms: 50 x 3 replicates. No anaesthesia was used, the insects were retrieved from the breeding extemporane using a soft "mouth vacuum cleaner". *Cockroaches:* *Blattella germanica* from a French strain (I.N.A Paris-Grignon – strain INA-TEC 1991). Colony breeding is done according to Fre nch method C.E.B N° 159, and susceptibility to the main insecticide groups is checked annually. Breeding conditions: in a controlled climatic conditions chamber kept at 22+/-1°C, 70+/-10% HR, light 16h dark 8h

	700 lux (but the boxes are covered by a black cardboard to avoid too direct light source). The cockroaches are bred in plastic metacrylate boxes of 35 cm x 25 cm x 20 cm containing a shelter (pile of egg cardboards), a food source (dog petfood biscuit) and a water source (cotton wick in a test tube filled with water). The food and water source are changed twice a week. Density of the target organisms: 25 x 3 replicates. - 10 males aged 2 to 15 days - 10 virgin females aged 2 to 15 days - 5 second stage juveniles. *Spiders:* *Tegenaria domestica* The spiders were not from laboratory colony breeding but from wild infestations. They were collected with the help of a PCO and brought to the laboratory for anesthesia using CO_2 during the time to expose for the assay. The spiders were found in Bayonne (64 - France). CO_2 anaesthesia was used before the trial / recovery time before the trial = 2 h. Due to the difficulty to find this kind of arthropod, only 5 insects were exposed to the treatment per each replicate. 3 replicates were conducted. *Controls:* The batches of target species constituting controls were placed on the surfaces treated with water. The control batches were intended to check the quality of the batches used for the tests and unintentional effects introduced by handling and experimental conditions. If applicable, mortality observed on the control batches allowed the mortality observed on batches subject to the treatment to be corrected and thus validated the overall test. The climatic conditions of the trial were: temperature 25 °C +/- 2 °C; relative humidity of 65 +/- 5 %; light/dark 8h/16h 700 lux. For each target organism, a single negative control was carried out with water alone at 35 ml/m^2. *Product* 3 concentrations of the bp were tested: - 12 mL/m^2 - 25 mL/m^2 - 35 mL/m^2 - (untreated control) water alone 35 mL/m^2 *Application of the treatments:* The treatments were done by using a one-use hand-held sprayer and Good Pratice procedure was used to apply the intended dosage +/-5%. The droplets were thin enough to wet the surfaces without leaking and without excessive vaporization in the air. The materials were treated flat and the actual treated area was 10 times the area of the materials. The treated tiles were randomly assigned among the total treated area and not handled before complete drying. The untreated materials were treated with water. 3 replicates were conducted by factor (3 doses of the test product + untreated).
Test results: effects	The untreated control gave enough low death rates (< 5%) to validate the trial *Day0:* 100% mortality for all species on both porous and non- porous material was observed at 24hrs with the dosage of 25 and 35 mL/m^2. For *M. domestica*, 100% mortality was reached after 4 hours with 25 mL/m^2 and

	after 1 hour with 35 mL/m^2. *4 weeks after treatment:* after 24 hours 100% of mortality was observed for all species on both porous and non- porous material with the dosage of 35 mL/m^2. For *M. domestica*, 100% mortality was reached after 4 hours with the dose 25 mL/m^2, and 1 hour with the dose 35 mL/m^2.
Reference	JESMOND Holding AG. LABORATORY TESTING OF A DOSE RANGE OF AN INSECTICIDAL SPECIALITY INTENDED TO CONTROL VARIOUS PESTS. MARCH 2016. Report n° 1998a2-BKC/0915R.

*Study n° 2: Laboratory measurement of the effectiveness of an insecticide speciality intended for the destruction of crawling and flying insects and spiders in household environment (**key study**)*

Experimental data on the efficacy of the biocidal product against target organism(s)	
Function	Insecticide
Field of use envisaged	Indoor
Test substance	Bio Kill® Classic RTU (permethrin 0.25% w/w as pure a.s.) – Lot WR02 110314
Test organism(s)	FLYING INSECTS: *Musca domestica* (common house fly) – nymphs + eggs *Aedes aegypti* (mosquito) *Culex pipiens* (mosquito) *Anopheles gambiae* (tropical mosquito) *Tineola bisselliella* (clothes moth) CRAWLING INSECTS/MITES: *Blattella germanica* (German cockroach) *Periplaneta americana* (American cockroach) *Lasius niger* (common black ant) *Lepisma saccharina* (silverfish) *Cimex lectularius* (bed bug) *Forficula auricularia* (earwig) *Dermatophagoides pteronyssinus* (house dust mite) SPIDERS: *Tegenaria domestica* (barn funnel weaver - house spider)
Test method	In accordance with the following guidelines: Residual Spray test: ▪ C.E.B. method No. 135 / 159 (1st edition: April 1987 Revised: March 2007): "Method for studying the effectiveness of insecticide and/or acaricide preparations intended for surface treatment of premises used for storage, industrial transformation and marketing of animal or plant based products". Direct Spray test: ▪ adapted from the standard ASTM E 654-96 (Reapproved 2009): "Standard test method for effectiveness of aerosol and pressurized spray Insecticides against cockroaches" - Addendum of approved methods in the Draft guidance document to replace part of Appendices to chapter 7 (page 187 to 200) of the TNsG on Product evaluation – Pt18 & 19. CA-Sept10-Doc.6.2b
Test system / concentrations applied / exposure time	*RESIDUAL SPRAY TEST* *Characteristics of the materials to be tested*

	The test focussed on 4 materials: ▪ Representing absorbent materials ○ bare concrete blocks (minimum 5 cm thick, having an average cement weight of 500 kg/m^3) ○ untreated wood (raw pine wood) ○ carpet (100% polyamide, 1420 g/m^2, height of the fibres = 4.5 mm) ▪ Representing non-absorbent materials: ○ ceramic tiles (non porous side) *Dimensions and preparation of the panels* The typical surfaces selected measured 15 cm x 15 cm that were placed inside a 60 m^2 chamber. The tiles were covered by the cover of a PETRI dish of a 14 cm diameter for each species. *Experimental product and dose* BIO KILL® Permethrin 0.25% w/w (as pure a.s.) Dosage: 50 mL/m^2 *Exposure time*: 1 hour. *Number of insects tested*: 25 of each species per replicate, except for house spiders *Tegenaria domestica* that were 5 per replicate. All were adults, except for *D. pteronyssinus* (Mixed population adult + larvae) and *T. bisselliella* (3rd instar nymphs). *Number of replicates*: 4 *Test points*: - 2 hours after bp application (assess of instantaneous effect) – T0 - 4 weeks after bp application (residual effect) – T4 *Practical conditions for application of the preparations* The treatments are done by using a pressurized sprayer (2 bars).The droplets were thin enough to wet the surfaces without leaking and without excessive vaporization in the air. The quantity of the spray actually applied was measured by weighing. The typical surfaces were treated flat and the total surface actually treated was 1 m^2; surfaces were distributed randomly within the area treated excluding the edges. The typical surfaces were not handled before they were completely dry, i.e. until dry residue was obtained. The control typical surfaces did not receive insecticide. They were treated with water to take into account the release of products constituting the materials. *Principle* Each experimental unit was constituted of the typical surface and the insects. The day of treatment (2 hours after in order for the surfaces to be dry), a no choice efficacy test was performed. The persistence was measured by performing the same efficacy test after 4 weeks of storage of the panels. The actual temperature and hygrometry during the tests (exposure) were from 25.5 °C to 26.2 °C, 69 % to 73% RH, light 700 lux, smooth ventilation 1 m^3/h. The experimenter recorded the mortality of the insects at regular time intervals, depending on the speed of action, in order to know the short-term kinetics of the effect. After a total exposure time of 1 hour, the insects were removed from the typical surfaces by gentle suction using an adapted vacuum cleaner and transferred to untreated inert surfaces

	with a nutritious substratum and water available. This was placed under climatic breeding conditions. *DIRECT SPRAY TEST* *Treatment room:* closed room of 60 m^3. In the center of the floor a glass ring was placed in which insects were held with a paper filter on the bottom to avoid insects being flood by the treatment. *Number of insects tested*: 25 of each species per replicate, except for house spiders *Tegenaria domestica* that were only 4 per replicate. All are adults, except for *D. pteronyssinus* (Mixed population adult + larvae) and *T. bisselliella* (nymphs 3rd instar). *Number of replicates*: 4 *Test points*: 30 seconds, 1, 1.5, 2, 5, 15, 30 minutes, 1 hour, 24 hours. *Application method*: the bp was applied by using a one-use laboratory sprayers delivering 0.5 +/-0.01 mL from a 30 cm distance. The ring is removed and contemporary the product is sprayed and a chronometer is activated, monitoring every 30 seconds to check the number of dead/alive insects. After 30', all insects were collected into Petri boxes for a 24 hrs assessment.
Test results: effects	Residual Spray Test: The mortality of the untreated control series was 0-5% (Abbot transformation not required). At T0, KT100 was 30' for all species except *P. americana* and *T. domesticca* (1 hour). At T4 (weeks), KT100 was 45' for all species except *P. americana* and *T. domestica* (1 hour). Treatment led to total, final mortality (no recovery after 24 hours) up to 4 weeks after treatment of the supporting media. The product was effective on all types of pests. The product gave faster results on non porous materials, which is an expected result. Direct Spray test: The mortality of the untreated control series was 0- 5% (Abbot transformation not required). Treatment led to fast knockdown (30 seconds – 1 minute) on all target organisms and the efficacy was complete (100% mortality after 24 hours = no recovery).
Reference	Jesmond Holding AG. LABORATORY MEASUREMENT OF THE EFFECTIVENESS OF AN INSECTICIDE SPECIALITY INTENDED FOR THE DESTRUCTION OF CRAWLING AND FLYING INSECTS AND SPIDERS IN HOUSEHOLD ENVIRONMENT. 2015. Report No. 1909a-BKC/0315R.

*Study n° 3: Simulated use trial on the efficacy of a residual insecticide against various pests (**key study**)*

Experimental data on the efficacy of the biocidal product against target organism(s)	
Function	Insecticide
Field of use envisaged	Indoor
Test substance	BIO KILL® CLASSIC RTU - Permethrin 0.25% (2.5 g/L) - Lot WR02

	110314
Test organism(s)	FLYING INSECTS: *Musca domestica* (common house fly) *Aedes aegypti* (mosquito) *Culex pipiens* (mosquito) *Anopheles gambiae* (tropical mosquito) *Tineola bisselliella* (clothes moth) CRAWLING INSECTS: *Blattella germanica* (German cockroach) *Periplaneta americana* (American cockroach) *Lasius niger* (common black ant) *Lepisma saccharina* (silverfish) *Cimex lectularius* (bed bug) *Forficula auricularia* (earwig) *Dermatophagoides pteronyssinus* (house dust mite) SPIDERS: *Tegenaria domestica* (barn funnel weaver - house spider)
Test method	TEC methodology in accordance with: The study procedure is a TEC methodology according to the following guidelines: CA-Dec12-Doc.6.2.a-Final / Manual for the Authorization of Pesticides - EU part – Biocides - Chapter 7 Efficacy - version 1.1; January 2013 Agreement procedures for Officially Recognized Trials according to the European directive 91/414/CE - replaced by 1107/2009 (French ministry of agriculture)
Test system / concentrations applied / exposure time	*Test chamber* The test was conducted in four 15 m^3 (6 m^2 floor) test chambers (i.e. the 4 replicates) in compliance with the standard BSI 4172 Part1&2 concerning the hand-held pressurized insecticide testing (1993). The test chambers were maintained at a temperature of 26°C±1°C and a relative humidity of 70%±5% during the period of testing. A smooth ventilation (< 10 m^3/h) was activated during the assay. Light: 700 lux 12 hours + 12 hours darkness. The test chamber materials are washable and unporous material on the walls/ceiling and on the floor (respectively epoxy-painted steel and ceramic tiles). To simulate what happens in premises, some polystyrene blocks and cardboards were set into the test chamber to be harbourages, and a water + food source: - water source (six 25 cm long water vials with a cotton wick) - food source (4 locations on the floor, under harborages, 2 Petri dishes with petfood biscuit. The insects were able to reach water and food sources without being in contact with the insecticide. The target organisms had a lot of places to hide: harborages, cracks and crevices. Only the half of the area was treated = the target organisms had the choice not to be in contact with the product. *Number of insects tested*: 25 of each species per replicate, except for house spiders *Tegenaria domestica* that were only 5 per replicate. All were adults, except for *D. pteronyssinus* (Mixed population adult + larvae) and *T. bisselliella* (3rd instar nymphs). *Number of replicates*: 4 *Application of the treatments* The application was done using a professional sprayer GLORIA 8L with an anti-drop nozzle. The water mixture was vigorously shaken between each

	treatment. The sprayer is part of the Good Experiment Practice devices and used according to the accuracy procedure to apply the intended dose of product +/-5%. The rate was 50 mL/m². The treated area was half of the test chamber, i.e. 3 m². The pathway to the food/water sources were not treated. Efficacy assessments The purpose of the trial was to assess the efficacy: - After treatment - 4 weeks after treatment As the counts of insects was destroying the elements in the treated chamber (to find insects hidden in cracks and harborages), this was not doable to keep the same setting for both assessments Day0 and Day0+4weeks. Then, 2 trials were conducted, one with a count after 7 days and another one with a second release of insects 4 weeks after treatment and a count after 4 weeks + 7 days. An experimenter was entering the test chamber to count dead insects 7 days after treatment (trial at application). The target organisms (dead or alive) were retrieved and the test chamber was kept in controlled conditions for a new release of arthropods 4 weeks after treatment. 4 weeks and 7 days after treatment, the experimenter is entering the test chamber and count dead/alive organisms. The same assessments or death rates were conducted in the untreated control batches. The results are given by a mortality percentage and compared to the mortality recorded in the untreated trial.
Test results: effects	*Treated individuals:* 7 days after treatment: 100% of mortality for all species tested 4 weeks + 7 days after treatment: 100% of mortality for all species tested *Control individuals:* 0-6% of mortality for all species both 7 days after treatment and 4 weeks + 7 days after treatment. Residual efficacy: 4 weeks. The untreated control mortality data were lower enough to validate the trial (< 10%). The product has proved a very good control of the insects with a complete kill. The efficacy remains good 4 weeks after treatment.
Reference	Jesmond Holding AG. SIMULATED USE TRIAL ON THE EFFICACY OF A RESIDUAL INSECTICIDE AGAINST VARIOUS PESTS. 2015. Report 1909-b3/0315R.

Study n° 4: Simulated use trial on the efficacy of a residual insecticide against various pests (non key study)

Experimental data on the efficacy of the biocidal product against target organism(s)	
Function	Insecticide
Field of use envisaged	Indoor
Test substance	BIO KILL® CLASSIC RTU - Permethrin 0.25% (2.5 g/L) - Lot 1901232706
Test organism(s)	FLYING INSECTS: *Musca domestica* (common house fly) *Aedes aegypti* (mosquito) *Culex pipiens* (mosquito) *Anopheles gambiae* (tropical mosquito)

	CRAWLING INSECTS: *Blattella germanica* (German cockroach) *Periplaneta americana* (American cockroach) *Lasius niger* (common black ant) *Lepisma saccharina* (silverfish) *Cimex lectularius* (bed bug) *Forficula auricularia* (earwig) *Tineola bisselliella* (clothes moth) *Dermatophagoides pteronyssinus* (house dust mite) SPIDERS: *Tegenaria domestica* (barn funnel weaver - house spider)
Test method	TEC methodology in accordance with: The study procedure is a TEC methodology according to the following guidelines: CA-Dec12-Doc.6.2.a-Final / Manual for the Authorization of Pesticides - EU part – Biocides - Chapter 7 Efficacy - version 3; April 2018 Agreement procedures for Officially Recognized Trials according to the European directive 91/414/CE - replaced by 1107/2009 (French ministry of agriculture).
Test system / concentrations applied / exposure time	Test chamber The test was conducted in four 15 m^3 (6 m^2 floor) test chambers in compliance with the standard BSI 4172 Part1&2 concerning the hand-held pressurized insecticide testing (1993). The test chambers were maintained at a temperature of 26°C ± 1°C and a relative humidity of 70% ± 5% during the period of testing. A smooth ventilation (< 10 m^3/h) was activated during the assay. Light: 700 lux 12 hours + 12 hours darkness. The test chamber materials are washable and unporous material on the walls/ceiling and on the floor (respectively epoxy-painted steel and ceramic tiles). To simulate what happens in premises, some polystyrene blocks and cardboards were set into the test chamber to be harbourages, and a water + food source: ▪ water source (six 25 cm long water vials with a cotton wick) ▪ food source (4 locations on the floor, under harborages, 2 Petri dishes with petfood biscuit). The insects were able to reach water and food sources without being in contact with the insecticide. Target organisms For each mode of treatment and repetition, batches were used as follows: 25 of each species, except for house spiders *Tegenaria domestica*, which were very difficult to find and for whom only 5 were used per replicate (+ corresponding untreated controls). All organisms used in this test were adults, except for *D. pteronyssinus* (Mixed population adult + larvae) and *T. bisselliella* (3rd instar nymphs). Control batches: The batches of target species constituting controls were placed in identical conditions to those of batches exposed to the test product. The control batches were intended to check the quality of the batches used for the tests and unintentional effects introduced by handling and experimental conditions. If applicable, mortality observed on the control batches allowed the mortality observed on batches subject to the treatment to be corrected and thus validated the overall test. The insects were released 2 hours after treatment (to let enough time for the product to dry).

	Application of the treatments The application was done using a professional sprayer GLORIA 8L with an anti-drop nozzle. The water mixture was vigorously shaken between each treatment. The sprayer is part of the Good Experiment Practice devices and used according to the accuracy procedure to apply the intended dose of product ± 5%. The rate was 35 mL/m². The treated area was half of the test chamber, i.e. 3 m². The pathway to the food/water sources were not treated. Efficacy assessments and provided results The purpose of the trial was to assess the efficacy: ▪ After treatment ▪ 4 weeks after treatment. As the counts of insects was destroying the elements in the treated chamber (to find insects hidden in cracks and harborages), this was not doable to keep the same setting for both assessments Day0 and Day0+4weeks. Then, 2 trials were conducted, one with a count after 24 hours and another one with a second release of insects 4 weeks after treatment and a count after 4 weeks + 24 hours. An experimenter was entering the test chamber to count dead insects 7 days after treatment (trial at application). The target organisms (dead or alive) were retrieved and the test chamber was kept in controlled conditions of 2.1. for a new release of arthropods 4 weeks after treatment. 4 weeks and 24 hours after treatment, the experimenter is entering the test chamber and count dead/alive organisms. The same assessments or death rates were conducted in the untreated control batches. The results are given by a mortality percentage and compared to the mortality recorded in the untreated trial. Replicates, Standard, Untreated Controls, Experimental design The number of replicates done was 5. No standard was included in the experimental design. Untreated control: the same procedure was used but without any treatment in order to compare the evolution of the populations of the insects in the two situations, treated and untreated. Experimental design: [experimental product + untreated control] x 5 replicates x 2 dates of assessments.
Test results: effects	*Treated individuals:* At day 0 and at +4weeks after treatment: 100% of mortality for all species tested *Control individuals:* 0-2% of mortality for all species at day 0 and 0-3% of mortality 4 weeks after treatment. Residual efficacy: 4 weeks. The untreated control mortality data were lower enough to validate the trial (< 10%). The product has proved a very good control of the insects with a complete kill. The efficacy remains good 4 weeks after treatment.
Reference	Jesmond Holding AG. SIMULATED USE TRIAL ON THE EFFICACY OF A RESIDUAL INSECTICIDE AGAINST VARIOUS PESTS. 2019. Report 2519/1119R.

Conclusion on the efficacy of the product

The product Clean Kill® was originally intended by the applicant for targeted spot treatment and targeted spot application in crack&crevice against flying and crawling insects, dust mites and spiders.
A complete data package, according to the BPR guidance, was provided with a lab study (Study n. 2) and a simulated use test setting (Study n. 3) at the concentration of 50 mL product/m^2, with satisfactory results.
Two additional studies were also provided: a dose finding lab study (Study n. 1) on three representative species (*M. domestica*, *B. germanica* and *T. domestica*) to show that also lower concentrations of the product were efficacious (i.e. 35 mL product/m^2), and a simulated use trial (Study n. 4), carried out with the 35 mL product/m^2 dose against all the claimed target organisms.
At the resolution step of the formal referral initiated by several cMSs after the bilateral discussion of the MRP process, only one use remained for authorization: the targeted spot application in crack & crevice, by spraying via trigger sprayer with fixed capillary tube. For such application, flying insect could no longer be considered a feasible target, and the complete spectrum of related species was removed from the intended uses.
Some cMSs remarked that the SU test did not completely fit the description of a simulated use test to verify efficacy in crack and crevices. However, it was agreed that this was due to the fact that the BPR guidance available at the time of dossier submission did not provide enough information for a more fitting design. The refMs considered that, given the availability of harborages and hiding spots in the SU test arena and the possibility for target organisms to crawl away from the treated areas, together with the packaging of the product (equipped with a non-removable capillary tube to dispense the product inside narrow spaces), it could be concluded that efficacy for targeted spot application in crack&crevice to kill crawling insects and spiders on both porous and non porous surfaces, was sufficiently proven at 50 mL product/m^2 dose. For the 35 mL product/m^2 dose, only three species were tested on both porous and non porous surfaces, which would limit the claim for this lower dose to non porous surfaces only.

To summarize, under these conditions, with the samples of products supplied, the target organisms and the methodology considered, the product Clean Kill®, applied indoor as ready-to-use product at a dose of 50 mL product/m^2, showed:

- a sufficient effectiveness, with a fast knockdown and a 100% mortality within 24 hours, and
- a residual efficacy lasting 4 weeks on porous and non-porous surfaces against the following pests:

CRAWLING INSECTS:
Blattella germanica (German cockroach)
Periplaneta americana (American cockroach)
Lasius niger (common black ant)
Lepisma saccharina (silverfish)
Forficula auricularia (earwig)

SPIDERS:
Tegenaria domestica (barn funnel weaver - spider)

Tineola bisseliella, although tested, was not included among the intended targets as indicated by the applicant, as a different set up of the simulated test would have been

necessary. The same observation is valid for *Cimex lectularius* (bedbug), as bedbugs do not leave their harbourage without a host which attracts them.
House dust mites were considered no longer appropriate targets for the authorized use.

It shall be noted that the above conclusion, that sufficient data are available to support the efficacy on porous and non-porous surfaces with the application rate 50 mL product/m^2, is the result of the expert judgment and is applicable to this particular case only. **A new simulated use efficacy study should be submitted at product renewal, when the updated guidance is available.**

<u>NOTE</u>: 50 mL product/m^2 = 50.4 g product /m^2 (product density: 1.0083 g/mL). According to the information provided by the Applicant under Sec. 2.2.2, one spray delivers typically 1.3-1.4 g of product (i.e. 3 mg a.s./spray).
As a result, 50.4 g product/m^2 correspond to 36 sprays/m^2, equivalent to 1 spray every ca. 20 cm for targeted spot application in crack & crevice, as indicated under the 'Authorized uses' section.

2.2.5.6 Occurrence of resistance and resistance management

Resistance to permethrin has been documented in wide varieties of insects. These species include pear psylla (Preem D.J. et al 1990), fall army worm (Smith, J.E. 1991), German cockroach (Atkinson, T.H.et al 1991; Limoee M. et al. 2011; R. Miyajia et al. 2017), spotted tentiform leafminer (Marshall, D.B. and D.J. Pree. 1986), house fly (Shen, J and F.W.Plapp. 1990), Stable fly (Cilek, J.E and G.I. Greena, 1994), headlice (Rupes, V. et al. 1995; Mumcuoglu, K.Y.et al, 1995; Burgess, I.F. et al 1995), tobacco budworm (Wolfenbarger, A. and J.vargas-Camplis 1997), *C. felis* in Australia, Europe and United States (MK Rust et al. 2015), and *I. ricinus* in Italy (Mangia et al. 2018).
The level of resistance is less than tenfold in some of the species but high levels of resistance have been observed in cockroaches (45-fold) (Atkinson, T.H.et al 1991), lice (up to 385 fold) (Rupes, V. et al. 1995), and budworm (1400 fold) (Wolfenbarger, A. and J.vargas-Camplis. 1997).

Mechanism of resistance may vary from organism to organism. In the Colorado potato beetle, it is suggested that resistance is due to low levels of Permethrin hydrolysis. In the fungus gnat, resistance to permethrin is attributed to changes in monooxidase activity in the resistant population. In H. virescens, altered functioning of the Na+ channels, and a subsequent elevation of the action potential threshold is thought to cause the resistance. Resistance to pyrethroids has developed rapidly (among head lice) since permethrin was introduced in 1991.

In general, pyrethroid resistance has been attributed to reduced neural sensitivity, enhanced metabolism, and reduced penetration ratio in many insects. A substantial degree of resistance remaining after synergism suggests the presence of other resistance mechanisms. Cross-resistance to pyrethroids and the susceptibility to carbaryl suggested that a common site of pyrethroid action exists.

Application of permethrin synergists such as Piperonyl butoxide (PBO) or Triphenyl phosphate (TPP) to permethrin resistant head lice suggests that monooxygenases (cytochrome P-450s) and the esterase enzyme systems were responsible for some pyrethroid resistance. A lack of synergism of D-phenothrin resistance by Piperonyl butoxide suggests that a non-oxidative mechanism, such as nerve insensitivity is also present in resistant lice.

It is extremely important to generate a pest management strategy in order to combat the onset of resistance. Assumptions of such a plan include the absence of cross-resistance and lack of similarity in biochemical mechanisms in head lice. The use of synergists for the inhibition of detoxifying enzymes represent not only an alternative to improve control, but a tool for elucidating resistance mechanisms.
The principles of strategies for managing the development of resistance are similar for permethrin as they are for other synthetic pyrethroids: where possible, application treatments should be recommended to be combined with non-chemical measures products should always be used in accordance with label recommendations complete elimination of insect pests should be attempted in infested areas applications should always be made against the most susceptible stages in the pest life cycle where an extended period of control is required, treatments should be alternated with products with different modes of action levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance.

2.2.5.7 Known limitations

Unintended effects
The active substance in Clean Kill®, permethrin, may exhibit a mild contact repellent effect in conjunction with the insecticidal effect. This contact repellence effect is also common to other pyrethroid insecticides (such as deltamethrin, cypermethrin, esfenvalerate and lambda-cyhalothrin) and is known as the "hot-foot effect" and may be relevant for some arthropods. The repellent effect is dose related and for insecticidal products the repellent effect of permethrin is considered as an unintended side effect, since the toxic response of the insect is a delayed kill (insecticidal) effect.

Known limitations on efficacy of the biocidal product
According to the efficacy trials and to permethrin properties, no limitations of Clean Kill® are known.

2.2.5.8 Evaluation of the label claims

The efficacy data provided are considered sufficient to support the claim against the following target organisms, when the product is used indoor by manual application, via trigger sprayer with fixed capillary tube for targeted spot application in crack and crevice, on both porous and non-porous surfaces:
Crawling insects: cockroaches (*Blattella germanica, Periplaneta americana*), ants (*Lasius niger*), silverfish (*Lepisma saccharina*), earwigs (*Forficula auricularia*).
Spiders: (*Tegenaria domestica*).

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

Clean Kill® is not intended to be authorised for use with other biocidal products.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

General information

Clean Kill® is a ready-to-use EW product, containing 0.25% w/w permethrin (as pure active substance), corresponding to 0.269% w/w (as technical grade active substance; min. purity: 93%).
The product is for indoor use by non-professionals and was originally intended by the applicant for targeted spot application and for application in crack & crevice, by spraying via trigger sprayer.
The targeted spot application was no longer supported for authorization at the resolution step of the formal referral, which was initiated by several cMSs after the bilateral discussion of the MRP process.
Only one use remained supported for authorization: **'Targeted spot application in crack & crevice'** on porous/non-porous surfaces at 50 mL product/m^2, by spraying via trigger sprayer with fixed capillary tube, to kill crawling insects (cockroaches, ants, silverfish, earwigs) and spiders, restricted to areas that are not wet cleaned and completely protected from water, like garages, cellars, attics, cavities, warehouses, electrical service rooms, boiler rooms.

The assessment of effects on human health was developed having as starting point the rules outlined in CLP Regulation. In particular, the article 11 of CLP Regulation states "where a mixture contains a substance classified as hazardous, whether as a component or in the form of an identified impurity or additive, this information shall be taken into account for the purposes of classification, if the concentration of that substance is equal to or greater than its cut-off value. The cut-off value referred shall be determined as set out in CLP Regulation, section 1.1.2.2 of Annex I". This approach was deemed as appropriate also in the light of the criteria outlined in article 3.1(f) of Biocidal Products Regulation to identify the substances of concern in a biocidal product.

The biocidal product Clean Kill® contains:
- several substances that are not classified (i.e. not hazardous)
- several substances that are classified for one or more endpoints, that are present in the biocidal product in concentrations below the cut-off values determined according to art. 11 of CLP Regulation.

Moreover, available toxicological information on permethrin and co-formulants are deemed sufficient to assess Clean Kill®.

For these reasons, in the sections below the human health hazard assessment shortly summarizes the information discussed in detail in the assessment report of permethrin under PT18. The use of data on active substance and model formulation is covered by the Letter of Access.

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritant.
Justification for the value/conclusion	No specific skin irritation/corrosion study is available. Conclusion are based on the available data on the active substance and other co-formulants in respect to the regulation 272/2008/EC. Classification has been estimated by calculation taking into account all the relevant components of the product. Overall, the biocidal product does not contain constituents in concentrations that exceed the cut-off values determined according to art. 11 of CLP Regulation for skin corrosion and irritation. The sum of the concentrations of components of the mixture classified as corrosive or irritant does not exceeds the concentration limit for the classification of the mixture. Finally, data reported in the CAR, state that: ▪ following various uses of products containing permethrin at different concentrations, symtoms of poisoning were not reported in any case following dermal exposure. Further to direct application to the skin, permethrin may induce some cutaneous side effects such as skin sensitisations, parasthesia and erythema. However, permethrin is not deemed to be used directly on the skin; ▪ permenthrin is not irritating to the skin. Three co-formulants are classified for skin corrosion and irritation (see separate confidential annex). They are present in a concentration below the threshold levels for the classification based on CLP regulation.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	According to the information requirement of BPR, testing on the product does not need to be conducted if there are valid data available on each of the components sufficient to allow classification of the mixture based on the rules of CLP Regulation (EC) n. 1272/2008.
Justification	Since the available data on each of the component allow to estimate the classification of the product, data waiving is acceptable.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritant.
Justification for the value/conclusion	No specific eye irritation/corrosion study is available. Conclusion are based on the available data on the active substance and other co-formulants in respect to the regulation 272/2008/EC. The "relevant ingredients" of a mixture are those which are present in concentrations of 1% (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater, unless there is a presumption (e.g. in the case of corrosive ingredients) that an ingredient present at a concentration of less than 1% is still relevant for classifying the mixture for eye irritation/serious eye damage. In general, the approach to classification of mixtures as eye irritant or seriously damaging to the eye when data are available on the components, but not on the mixture as a whole, is based on the theory of additivity, such that each corrosive or irritant component contributes to the overall irritant or corrosive properties of the mixture in proportion to its potency and concentration. A weighting factor of 10 is used for corrosive components when they are present at a concentration below the generic concentration limit for classification in Category 1, but are at a concentration that will contribute to the classification of the mixture as an irritant. The mixture is classified as seriously damaging to the eye or eye irritant when the sum of the concentrations of such components exceeds a concentration limit. Overall, the biocidal product does not contain constituents in concentrations that exceed the cut-off values determined according to art. 11 of CLP Regulation for eye irritation. The sum of the concentrations of components of the mixture classified as corrosive or irritant to eye does not exceeds the concentration limit for the classification of the mixture. Finally, data reported in the CAR, state that permenthrin is not irritating to the skin. Three co-formulants are classified for eye irritation (see separate confidential annex). They are present in a concentration below the threshold levels for the classification based on CLP regulation.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	According to the information requirement of BPR, testing on the product does not to be conducted if there are valid data available on each of the components sufficient to allow classification of the

	mixture based on the rules of CLP Regulation (EC) n. 1272/2008.
Justification	Since the available data on each of the component allow to estimate the classification of the product, data waiving is acceptable and the classification of the product can be estimated by calculation considering all the components relevant for this endpoint.

Respiratory tract irritation

No animal studies or human data are available on respiratory tract irritation.

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	There are currently no standard tests and no OECD TG available for respiratory tract irritation and there is no testing requirement for this endpoint under the BPR. All the components of the product relevant for this endpoint have to be considered for the classification made by calculation. The active substance is not skin or eye irritating. Three co-formulants are classified for skin corrosion/irritation and eye irritation/damage (see separate confidential annex). However, they do not exceed the cut-off values set according to CLP Regulation. In this case, respiratory irritation is a local effect not expected.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	There are currently no standard tests and no OECD TG available for respiratory tract irritation and there is no testing requirement for this endpoint under the BPR.
Justification	On the basis of BPR information requirements for this endpoint data waiving is acceptable.

Skin sensitization

Information on permethrin from CAR

The study submitted by applicant 1, Parcell (1991) was negative for skin sensitisation. However, two previously evaluated studies (Leah, 1989 & Thakkar, Bharat 1995) both recorded positive results for permethrin. According to applicant 2, permethrin is not a skin sensitiser and does not require classification. However, the Buehler method, which was used in Applicant 2 study, is not recommended for testing the active substance. Under Directives 67/548 and 91/414 and Regulation (EC) No. 1772/2008, permethrin is classified

as a skin sensitiser, therefore the RMS proposed to retain the classification Xn: R43; May cause sensitisation by skin contact and H317; May cause an allergic skin sensitisation.

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitizing
Justification for the value/conclusion	The mixture shall be classified as skin sensitizer when at least one ingredient has been classified as skin sensitizer and is present at or above the appropriate generic concentration limit of ≥ 1%. Some substances that are classified as sensitizers may elicit a response, when present in a mixture in quantities below the generic concentration limit, in individuals who are already sensitized to the substance or mixture. Therefore another concentration limit of ≥ 0.1% is generally used for the application of the special labelling requirements of Annex II section 2.8 of CLP Regulation to protect already sensitized individuals. The label on the packaging of mixtures containing at least one substance classified as sensitizing and present in a concentration equal to or greater than 0.1% or in a concentration equal to or greater than that specified under a specific note for the substance in part 3 of Annex VI shall bear the statement: EUH208 - 'Contains (name of sensitizing substance). May produce an allergic reaction'. Clean Kill® is not classified as a skin sensitizer since there are no ingredients classified as skin sensitizer present at or above the appropriate generic concentration limit (Table 3.4.3 of CLP Regulation); however, label on the packaging of mixtures shall bear the statement: EUH208 - 'Contains permethrin. May produce an allergic reaction', since permethrin is classified as sensitizing and is present in a concentration equal to or greater than 0.1% (i.e. 0.25% w/w). One co-formulant is classified for skin sensitisation (see separate confidential annex) present in a concentration well below the cut-off value. No other co-formulants are classified for this endpoint and synergistic effects between the components of the mixture are not expected.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Testing on the product does not to be conducted if there are valid data available on each of the components sufficient to allow

	classification of the mixture.
Justification	According to the specific adaptation rules described in Annex III of BPR, testing on the product was not conducted because there are valid data available on each of the components in the mixture sufficient to allow the classification according to the rules of CLP Regulation (EC) n. 1272/2008 and no synergistic effects between the components of the mixture are expected.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitizing
Justification for the value/conclusion	No specific respiratory sensitisation study is available, however this is an ADS. There are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. None of the component of the b.p. is classified for this endpoint. Moreover, Clean Kill® is not classified as a skin sensitizer.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	There are currently no standard tests and no OECD TG available for respiratory tract sensitisation and there is no testing requirement for this endpoint under the BPR.
Justification	Information are available on the a.s. and co-formulants.

Acute toxicity

Acute toxicity by oral route

Information on permethrin from CAR

The acute oral studies submitted had LD_{50} values ranging from 480 - 1623 mg/kg bw/day. Therefore, permethrin classifies as Xn: R22/H302; Harmful if swallowed.

Rat LD_{50} oral = 480 - 554 mg/kg bw (as reported in Assessment Report of, BAYER/SUMITOMO and TAGROS).

No other ingredients are classified for this endpoint and synergistic effects between the components of the mixture are not expected.

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not classified.
Justification for the selected value	No specific acute oral toxicity study on the product Clean Kill® is available. Data waiving has been considered acceptable. For this endpoint the classification can be estimated by Application of rules of CLP Regulation, Annex I, point 3.1.3.6. Classification of mixtures based on ingredients of the mixture (Additivity formula). Permethrin and two co-formulants are classified for acute oral toxicity (Acute Tox. 4, H302)(see separate confidential annex).
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Testing on the product does not to be conducted if there are valid data available on each of the components sufficient to allow classification of the mixture
Justification	According to the specific adaptation rules described in Annex III of BPR, testing on the product was not conducted because there are valid data available on each of the components in the mixture sufficient to allow the classification according to the rules of CLP Regulation (EC) n. 1272/2008 and no synergistic effects between the components of the mixture are expected.

Acute toxicity by inhalation

Information on permethrin from CAR

Although the inhalation studies submitted by the current applicants indicated the substance did not require classification for inhalation, permethrin is currently classified under Directive 67/548 as Xn: R20; Harmful by inhalation, and Regulation (EC) No. 1727/2008 as H332: Harmful if inhaled. This classification is based on a study (Brammer A., 1989) referenced in PPP DAR. Combining information in the PPP DAR and biocides CAR the following studies are available: one non-guideline negative study; one guideline positive study; one guideline negative study and an existing classification. The rationale of the RMS was is apply the precautionary principal and retain the classification based on the aforementioned data.

Rat LD_{50} inhalation > 4.638 (MAC) - 23.5 mg/L
Co-formulants classified for acute toxicity:

- See confidential annex (Acute Tox. 4 H332).

No other ingredients are classified for this endpoint and synergistic effects between the components of the mixture are not expected.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not classified.
Justification for the selected value	No specific study is available. Data waiving has been considered acceptable and the acute toxicity by inhalation of the product has been estimated applying the rules of CLP Regulation, Annex I, point 3.1.3.6. Classification of mixtures based on ingredients of the mixture (Additivity formula). Moreover, for Clean Kill®: - Vapour pressure of permethrin is < 1 x 10^{-2} Pa at 20 °C - size of droplets have a Dv(50)= 83.5 µm, as determined by CIPAC MT 187.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Testing on the product does not to be conducted if there are valid data available on each of the components sufficient to allow classification of the mixture
Justification	According to the specific adaptation rules described in Annex III of BPR, testing on the product was not conducted because there are valid data available on each of the components in the mixture sufficient to allow the classification according to the rules of CLP Regulation (EC) n. 1272/2008 and no synergistic effects between the components of the mixture are expected.

Acute toxicity by dermal route

Information on permethrin from CAR

Permethrin was not classified as toxic or harmful by the dermal route.

Rat LD_{50} dermal = > 2000 mg/kg bw

No other ingredients are classified for this endpoint and synergistic effects between the components of the mixture are not expected.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not classified.
Justification for the selected value	No specific acute dermal toxicity study is available. Data on all the components of Clean Kill® are available and allow classification for this endpoint. Neither the a.s. nor any other co-formulant is classified for acute dermal toxicity.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Testing on the product does not to be conducted if there are valid data available on each of the components sufficient to allow classification of the mixture
Justification	According to the specific adaptation rules described in Annex III of BPR, testing on the product was not conducted because there are valid data available on each of the components in the mixture sufficient to allow the classification according to the rules of CLP Regulation (EC) n. 1272/2008 and no synergistic effects between the components of the mixture are expected.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	permethrin
Value(s)	70%
Justification for the selected value(s)	Default value proposed by EFSA (2017) was applied for (in use) dilutions of organic solvent formulated and other types of formulations.

Data waiving	
Information requirement	According to the BPR: if no experimental data with the b.p. or studies with similar formulations are not available, the default value proposed by EFSA Guidance Document for dermal absorption (EFSA, 2017) has to be used for the Risk assessment.
Justification	No data on dermal adsorption are available for Clean Kill®. Clean Kill® is an emulsifiable concentrate formulation containing 0.25% of permethrin in the form of liquid. The extrapolation of Clean Kill® dermal absorption from data on the similar formulation assessed in the CAR (model formulation) is not possible since *pro rata* correction approach (for taking into account

	dilution rates) is not applicable due to the absence of dermal absorption data, at least, at two different concentrations of active substance. It is not reported the concentration of permethrin in the product used to determine dermal absorption of 3%; therefore, the value of dermal absorption of 3% can not be used for Clean Kill® human health risk assessment. The rate of dermal absorption is generally inversely related to the concentration of the active substance. Exceptions may include irritant and volatile compounds, and the presence of co-formulants that strongly affect absorption [EFSA Guidance Document for dermal absorption (EFSA, 2017)]. For Clean Kill® the absorption could to be greater than 3% because the concentration of the active substance could be lower. Even if it is unlikely that dermal absorption of permethrin in Clean Kill® largely exceed 3%, the default value proposed by EFSA Guidance Document for dermal absorption (EFSA, 2017) is used for the Risk Assessment. As stated by EFSA, a default dermal absorption value of 70% may be applied for (in use) dilutions of organic solvent formulated and other types of formulations.

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

None.
No substances of concern are present in the biocidal product Clean Kill®, except one: 2-ethylhexan-1-ol (CAS 104-76-7), which, however, does not require any additional risk assessment. For further details, please refer to the Annex of confidential data.

Available toxicological data relating to a mixture

None.
Mixtures containing substances of concern are not present in the biocidal product , except the one containing 2-ethylhexan-1-ol (CAS 104-76-7), which is identified as a SoC in Clean Kill®, due to a EU OEL of 5.4 mg/m^3. However, 2-ethylhexan-1-ol does not require any additional risk assessment. For further details, please refer to the Annex of confidential data.

Endocrine-distrupting properties for human health: screening for co-formulants

Screening of endocrine-distrupting properties of co-formulants has been performed using the information provided in the SDSs by the supplier of the co-formulants and consulting reliable literature sources, according to the indications provided in "CG-34-2019-02 AP 16.5 e-consultation ED potential of co-formulants_final". The information sources consulted are detailed in the tables available in the Confidential Annex, where a brief summary of the results is reported in the coloumn “Data/results”. Complete reference sources are attached to the IUCLID dossier.

Conclusion of ED assessment for co-formulants
Overall, based on available information it is concluded that the product does not contain co-formulants with endocrine distrupting properties for human health. Please, refer to the Annex of Confidential Data for further details.

2.2.6.2 Exposure assessment

General remarks

Clean Kill® is a ready-to-use EW product, containing 0.25% w/w permethrin (as pure active substance), corresponding to 0.269% w/w (as technical grade active substance; min. purity: 93%).
The product is for indoor use by non-professionals and was originally intended by the applicant for targeted spot application and for application in crack & crevice, by spraying via trigger sprayer.
The targeted spot application was no longer supported for authorization at the resolution step of the formal referral, which was initiated by several cMSs after the bilateral discussion of the MRP process. Only one use remained supported for authorization: **'Targeted spot application in crack & crevice'**, on porous/non-porous surfaces at 50 mL product/m^2 by spraying via trigger sprayer with fixed capillary tube, to kill crawling insects (cockroaches, ants, silverfish, earwigs) and spiders, restricted to areas that are not wet cleaned and completely protected from water, like garages, cellars, attics, cavities, warehouses, electrical service rooms, boiler rooms. Nevertheless, for the sake of tracebility, some considerations and exposure calculations for both uses originally intended by the Apllicant are still kept in this document.

Exposure assessment was performed on the active substance permethrin; no substances of concern were identified in Clean Kill®, except one: 2-ethylhexan-1-ol (CAS 104-76-7), which is identified as a SoC, due to an EU OEL of 5.4 mg/m^3. However, 2-ethylhexan-1-ol does not require any additional risk assessment. For further details, please refer to the Annex of confidential data.

Expected patterns of exposure

Clean Kill® is used by non-professional users. Exposure assessment has been performed according to the indications provided in Biocides Human Health Exposure Methodology (version 1, October 2015) and ECHA *Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) - Version 4.0 December 2017*.

Human exposure, both primary and secondary, arising from the use of the biocidal product by no-professional users can be summarised as follows.

The product is sold as a ready-to-use product (300 mL bottle + trigger spray with fixed capillary tube). The 500 mL re-fill bottle (originally intended by the applicant) is not covered by the product authorization. Even though mixing and loading phase is no longer relevant for this product, it has been maintained in the risk assessment.

Non professional use
- ✓ Primary exposure
  - Mixing and loading
  - Targeted spot application

- Crack and crevice application

✓ Secondary exposure (child)

- General surface post application (it is assumed that secondary exposure from general surface spraying will cover secondary exposure from both targeted spot application on surfaces and targeted spot application in crack and crevice, where the treated areas are nearly out of reach of children).

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**	**Non-professional**	**Via food**
Inhalation	n.a.	n.a.	yes	n.a.	n.a.	n.a.	n.a.
Dermal	n.a.	n.a.	yes	n.a.	n.a.	yes	n.a.
Oral	n.a.	n.a.	n.a.	n.a.	n.a.	yes	n.a.

List of scenarios

According to the above mentionated consideration, the exposure assessment included the scenarios listed in the Table below.

Summary table: scenarios		
Scenario number	**Scenario**	**Exposed group**
1.	Mixing and loading	non-professionals
2.	Targeted spot application	non-professionals
3.	Crack and crevice application	non-professionals
4	Secondary exposure	toddler

Industrial exposure

BPR is not applied to the formulation phase; therefore, risk assessment has not been performed.

Professional exposure

The product is not used by professionals.

Non-professional exposure

Primary and secondary exposure assessment (for non-professionals and children) has been performed using ConsExpo Web, version 1.0.6.

General input data for non-professional exposure estimation

General input data of ConsExpo Web for exposure estimation are reported in the table below.

XXXXXXXXXXXXXXX

Scenario 1: Mixing and loading

The 500 mL-bottle[1] was meant by the applicant as re-filling of trigger sprayers to reduce the plastic waste and the cost for consumers. As a worst-case assumption, the ConsExpo default values for 1-L re-filled bottle have been used in the exposure assessment. Mixing and loading assessment has been addressed.
For estimating potential exposure during the mixing & loading phase due to re-filling of trigger sprays, the scenario developed for "Exposure to liquid concentrate during mixing and loading" has been applied ("Pest Control Product Fact Sheet"; *RIVM report 320005002*).

According to the "General description of the scenario":
"*A private user mixes and loads liquid into a plant sprayer filled with water to produce 2 litres of ready-for-use product. The active substance evaporates from the bottle with the formulation, a one-litre bottle with a not-too-small circular opening with a 5-cm diameter, resulting in a surface area of 20 cm^2. During mixing and loading the user stays in the vicinity of the evaporating compound and it is therefore assumed that the user is present in a 'personal volume' instead of a room volume. Further, there could be dermal exposure due to spillage. To calculate the exposure of the user during mixing and loading liquid, the 'evaporation model' is used for inhalation exposure and the 'instant application' model is used for dermal exposure*".

So that, inhalation exposure can occur due to the evaporation of the product from the bottle. On the other hand, the dermal exposure is due to product spillage.

Default values for mixing and loading: dilution of a liquid.

	Default value	**References, comments**
General		
Frequency	6 year-1	The frequency of mixing and loading, related to the frequency of spraying (9 times/person/year), is calculated at 6 times

[1] Please, refer to section 2.1.7 of this document, which reflects the final conclusions and agreements during the MRP process with regard to 'size/volume of the packaging'.

		per person per year (RIVM report 320005002, p.20).
Inhalation *Evaporation from a constant surface*		
Exposure duration	1.33 min	The duration of 1.33 minutes is set as default value for both exposure duration and application duration (RIVM report 320005002, p. 29).
Product amount	500 g	This parameter is for limiting the evaporated amount of active substance from the product. It is not the used product amount but half of the bottle content. For a one-litre bottle the averaged amount liquid in the bottle is estimated at 500 g (density 1 g/cm^3), which is set as default value (RIVM report 320005002, p.29).
Room volume	1 m^3	"Room volume" is interpreted here as "personal volume": a small area of 1 m^3 around the user. A small area around the user is relevant for the inhalation exposure of the user, for the short use duration in which the treatment takes place, as it enables the evaporation of the active substance from the concentrate to be described. Since no data with regard to the personal volume were found, a quality factor Q of 1 is assigned (RIVM report 320005002, p.29).
Ventilation rate	0.6 hr^{-1}	The ventilation rate that Bremmer and Van Veen (2000) give for a non-specified room is taken as a default value; namely 0.6 hr-1. To what extent this value is applicable to the "personal volume" of 1 m^3 around the user is unknown, therefore the quality factor Q is set at 1. (RIVM report 320005002, p.30).
Inhalation rate	1.25 m^3/h	Default, as reported in Recommendation 14 "Default human factor values for use in exposure assessments of biocidal products" (p. 6).
Release area	0.002 m^2	No data was found for this parameter. It is assumed that evaporation takes place from a bottle with a not-too-small circular opening with a 5-cm diameter which gives a release area of 20 cm^2. (RIVM report 320005002, p.30).
Application duration	1.33 min	See "exposure duration".
Mass transfer rate	10 m/h	Default value
Mol. weight matrix	3000 g/mol	The parameter "molecular weight matrix" is the molecular weight of the "other"

		components in the product. In Paint Fact Sheet this parameter is extensively discussed. The "molecular weight matrix" is roughly given by Mw / fraction solvents. If the value for molecular weight matrix lacks, the molecular weight matrix is set at 3000 g/mol, which is a worst-case assumption. In this case, it is assumed that the fraction solvent is small; therefore, the partial vapour pressure will not be lowered by the solvent matrix. (worst-case value)
Dermal *Exposure, instant application*		
Product amount	0.01 g	Container of 1 L, any type of closure = 0.01 mL operation (RIVM report 320005002, p.30-31).
Contact time	1.33 min	See "exposure duration".

Calculations for Scenario 1: mixing and loading

Systemic acute and chronic exposures for mixing and loading, as calculated by ConsExpo Web, are reported in tables below.

Summary table: systemic acute exposure from Mixing & Loading				
Exposure scenario	**TIER**	**Internal inhalation dose on day of exposure**	**Internal dermal dose on day of exposure**	**Internal dose on day of exposure (total)**
Scenario 1	TIER 1	6.5×10^{-13} mg/kg bw/d	3.1×10^{-4} mg/kg bw/d	3.1×10^{-4} mg/kg bw/d

Summary table: systemic chronic exposure from Mixing & Loading				
Exposure scenario	**TIER**	**Internal inhalation average dose**	**Internal dermal average dose**	**Internal year average dose (total)**
Scenario 1	TIER 1	1.1×10^{-14} mg/kg bw/d	5.2×10^{-6} mg/kg bw/d	5.2×10^{-6} mg/kg bw/d

Scenario 2: targeted spot application (primary exposure)

Targeted spot application refers to the spraying of hiding places of crawling insects and ant tunnels. Primary exposure was assessed for Clean Kill®, the mains input used for risk assessment are reported in the table below.

Description of Scenario 2: targeted spot application			
	Parameters	Value	Comments
TIER 1	Product databse	Pest control products	-
	Product categories	Sprays	-
	Default products	Targetted spot	-
	Scenarios	Application (trigger spray)	-
	Frequency	9 1/y	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet".
	Body weight	60 kg	Default, as endorsed at TM II 2013 and reported in HEEG Opinion "Default human factor values for use in exposure assessments of biocidal products".
	Room volume	20 m^3	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (pp. 34-35).
	Ventilation rate	0.6 1/hr	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (pp. 34-35).
	Inhalatory exposure duration	240 minute	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 34).
	Spray duration	6 minute	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 34).

	Room height	2.5 meter	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 37).
	Mass generation rate *	0.4 g/s	Default, as reported in "New default values for the spray model" RIVM, March 2010.
	Airbone fraction	0.008 (fraction)	Default, as reported in "New default values for the spray model" RIVM, March 2010.
	Particle distribution median	7.7 micrometer	Default, as reported in "New default values for the spray model" RIVM, March 2010.
	Coefficient of Variation (C.V.)	1.9 (fraction)	Default, as reported in "New default values for the spray model" RIVM, March 2010.
	Dermal contact rate	46 mg/min	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 28).
	Dermal exposure duration	6 min	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet".
	Inhalation uptake fraction	100%	According to Assessment Report of permethrin.
	Inhalation rate	1.25 m^3/h	Default, as reported in Recommendation 14 "Default human factor values for use in exposure assessments of biocidal products" (p.6).
	Dermal uptake fraction	70%	No data on dermal absorption are available for Clean Kill®. Therefore, default value proposed by EFSA Guidance Document for dermal absorption (EFSA, 2017) is used for (in use) dilutions of organic solvent formulated and other types of formulations.
	Exposed group	Non-professionals	-
	Assumptions	Chronic risks were considered for non-professional users. However, as non-professional users are expected to use the biocidal product only intermittently for a few events per year, comparison of exposure to acute AEL is considered to be more reasonable.	-

* The application rate of 36 pump strokes/m^2 (equivalent to 50 mL product/m^2) has been derived from the efficacy studies, but it was not included in the HH risk assessment, since this value is not requested in the ConsExpo model.

In fact, due to the lack of information on the Clean Kill®, the HH exposure assessment has been carried out considering the default values of mass generation rate as well as spray duration.
However, considering the mass generation rate of 0.4 g b.p./s and the spray duration of 6 min (ConsExpo defaults), the released of a.s. results to be of 387 mg (*i.e.*, 0.39 g = 0.4 g b.p./sec x 360 sec x 0.269%), for which no risk has been highlighted. The value is well above amount of a.s. released under realistic conditions during each application (*i.e.*, 3 mg/pump stroke x 36 pump strokes/m^2 x 2 m^2 = 216 mg).
In conclusion, the HH risk assessment can be considered quite conservative in respect to the real exposure conditions.

Calculations for Scenario 2: targeted spot application

Systemic acute and chronic exposures for targeted spot application, as calculated by ConsExpo Web, are reported in tables below.

Summary table: systemic acute exposure from targeted spot application					
Exposure scenario	**TIER**	**Internal inhalation dose on day of exposure**	**Internal dermal dose on day of exposure**	**Oral non-respirable systemic dose on day of exposure**	**Internal dose on day of exposure (total)**
Scenario 2	TIER 1	1.4×10^{-4} mg/kg bw/d	8.7×10^{-3} mg/kg bw/d	n.a.	1.0×10^{-2} mg/kg bw/d

Summary table: systemic chronic exposure from targeted spot application					
Exposure scenario	**TIER**	**Internal inhalation average dose**	**Internal dermal average dose**	**Oral non-respirable average systemic dose**	**Internal year average dose (total)**
Scenario 2	TIER 1	3.3×10^{-5} mg/kg bw/d	2.1×10^{-4} mg/kg bw/d	n.a.	2.5×10^{-4} mg/kg bw/d

Further information and considerations on scenario 2

No further information and considerations on scenario 2.

***NOTE**: Since no safe use was demonstrated for the environment, 'Targeted spot application' was no longer supported for authorization at the resolution step of the formal referral.*

Scenario 3: crack and crevice application (primary exposure)

Crack and crevice application concerns the spraying of cracks and crevices to control silver fish, cockroaches, earwigs, ants and spiders. Primary exposure was assessed for Clean Kill®, the mains input used for risk assessment are reported in the table below.

Description of Scenario 3: crack and crevice application			
	Parameters	Value	Comments
TIER 1	Product databse	Pest control products	-
	Product categories	sprays	-
	Default products	Crack and crevice	-
	Scenarios	Application (trigger spray)	-
	Frequency	9 1/y	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet".
	Body weight	60 kg	Default, as endorsed at TM II 2013 and reported in HEEG Opinion "Default human factor values for use in exposure assessments of biocidal products".
	Room volume	20 m^3	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 39).
	Ventilation rate	0.6 1/hr	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 39).
	Inhalatory exposure duration	240 minute	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 39).
	Spray duration	4 minute	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 39).
	Room height	2.5 meter	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 42).
	Mass generation rate *	0.4 g/s	Default, as reported in "New default values for the spray model" RIVM, March 2010.
	Airbone fraction	0.008 (fraction)	Default, as reported in "New default values for the spray model" RIVM, March 2010.
	Particle distribution median	7.7 micrometer	Default, as reported in "New default values for the spray model" RIVM, March 2010.

	Coefficient of Variation (C.V.)	1.9 (fraction)	Default, as reported in "New default values for the spray model" RIVM, March 2010.
	Dermal contact rate	46 mg/min	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 28).
	Dermal exposure duration	4 min	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet".
	Inhalation uptake fraction	100%	According to Assessment Report of permethrin.
	Inhalation rate	1.25 m^3/h	Default, as reported in Recommendation 14 "Default human factor values for use in exposure assessments of biocidal products" (p. 6).
	Dermal uptake fraction	70%	No data on dermal absorption are available for Clean Kill®. Therefore, default value proposed by EFSA Guidance Document for dermal absorption (EFSA, 2017) is used for (in use) dilutions of organic solvent formulated and other types of formulations.
	Exposed group	Non- professionals	-
	Assumptions	Chronic risks were considered for non-professional users. However, as non-professional users are expected to use the biocidal product only intermittently for a few events per year, comparison of exposure to acute AEL is considered to be more reasonable.	-

* The application rate of 36 pump strokes/m^2 (equivalent to 50 mL product/m^2) has been derived from the efficacy studies, but it was not included in the HH risk assessment since this value is not requested in the ConsExpo model.
In fact, due to the lack of information on the Clean Kill®, the HH exposure assessment has been carried out considering the default values of mass generation rate as well as spray duration.
However, considering the mass generation rate of 0.4 g b.p./s and the spray duration of 6 min (ConsExpo defaults), the released of a.s. results to be of 387 mg (i.e. 0.39 g = 0.4 g b.p./sec x 360 sec x 0.269%), for which no risk has been highlighted. The value is well above amount of a.s. released under realistic conditions during each application (*i.e.*, 3 mg/pump stroke x 36 pump strokes/m^2 x 2 m^2 = 216 mg).
In conclusion, the HH risk assessment can be considered quite conservative in respect to the real exposure conditions.

Calculations for Scenario 3: crack and crevice application

Systemic acute and chronic exposures for crack and crevice application, as calculated by ConsExpo Web, are reported in tables below.

Summary table: systemic acute exposure from crack and crevice application					
Exposure scenario	**TIER**	**Internal inhalation dose on day of exposure**	**Internal dermal dose on day of exposure**	**Oral non-respirable systemic dose on day of exposure**	**Internal dose on day of exposure (total)**
Scenario 3	TIER 1	9.0×10^{-4} mg/kg bw/day	5.8×10^{-3} mg/kg bw/day	-	6.7×10^{-3} mg/kg bw/day

Summary table: systemic chronic exposure from crack and crevice application					
Exposure scenario	**TIER**	**Internal inhalation average dose**	**Internal dermal average dose**	**Oral non-respirable average systemic dose**	**Internal year average dose (total)**
Scenario 3	TIER 1	2.2×10^{-5} mg/kg bw/day	1.4×10^{-4} mg/kg bw/day	-	1.6×10^{-4} mg/kg bw/day

Further information and considerations on scenario 3

No further information and considerations on scenario 3.

Combined exposure

In the event non-professional user should apply the trigger spray by refilling the device with the biocidal product sold in 1L-bottle, potential risks should be also characterized considering contributes from both the mixing & loading phase and the application phase.

1. *Calculations for Combined Exposure of Scenario 1- Mixing and loading and Scenario 2 - Targeted spot application*

Exposure scenario	**Summary table: systemic acute exposure*** **Internal dose on day of exposure (total)**	**Summary table: systemic chronic exposure** **Internal year average dose (total)**
Scenario 1: mixing and loading	3.1×10^{-4} mg/kg bw/d	5.2×10^{-6} mg/kg bw/d
Scenario 2: targeted spot application	1.0×10^{-2} mg/kg bw/d	2.5×10^{-4} mg/kg bw/d
Combined Exposure	**1.03×10^{-2} mg/kg bw/d**	**2.55×10^{-4} mg/kg bw/d**

*To be considered in the risk assessment.

***NOTE**: Since no safe use was demonstrated for the environment, 'Targeted spot application' was no longer supported for authorization at the resolution step of the formal referral. In addition, for the crack and crevice application, it was agreed that the 300-mL RTU product is to be authorized.*

2. *Calculations for Combined Exposure of Scenario 1- Mixing and loading and Scenario 3 - Crack and crevice application*

Exposure scenario	**Summary table: systemic acute exposure*** **Internal dose on day of exposure (total)**	**Summary table: systemic chronic exposure** **Internal year average dose (total)**
Scenario 1: mixing and loading	3.1×10^{-4} mg/kg bw/d	5.2×10^{-6} mg/kg bw/d
Scenario 3: Crack and crevice application	6.7×10^{-3} mg/kg bw/day	1.6×10^{-4} mg/kg bw/day
Combined Exposure	**7.01×10^{-3} mg/kg bw/d**	**1.65×10^{-4} mg/kg bw/d**

*To be considered in the risk assessment.

***NOTE**: At the resolution step of the formal referral, for the crack and crevice application, it was agreed that the 300-mL RTU product is to be authorized. Nevertheless, the combined Exposure (including Mixing and loading phase) is maintained, for the sake of transparency.*

Scenario 4: Secondary exposure

In the CAR of permethrin it is assumed that secondary exposure from general surface spraying will cover secondary exposure from targeted spot or crack & crevice application, where the treated areas are nearly out of reach of children; therefore, the same assumption has been performed for the product.

For secondary exposure inhalation exposure is considered negligible based on the outcome of the HEEG opinion 13. HEEG 13 opinion (endorsed at TM IV 2011) on the assessment of inhalation exposure to volatilised biocides provides the following screening tool to determine whether inhalation exposure can be considered not to be a potential risk:
This is a worst-case scenario based on the saturated vapour concentration of the active substance. Where mw and vp denote the molecular weight (in g/mol) and the vapour pressure (in Pa), for a toddler (based on an inhalation rate of 8 m^3/24 hr and bw of 10 kg) and using an AEL expressed in mg a.s./kg bw/d, if

$$0.328 * (mw * vp) \div AEL \leq 1$$

the risk from inhalation exposure is considered negligible.

The assessment assumes that the individual is exposed to the saturated vapour concentration of the active substance for 24 hours a day and therefore reflects a 'worst-case' scenario. The calculation of toddler inhalation exposure represents a 'worst case' scenario as stipulated in HEEG opinion 13 and as such forms the risk envelope for the assessment of an infant, child and/or adult.

Permethrin has a molecular weight of 391 g/mol and a vapour pressure of 2.155x 10^{-6} Pa at 20 °C.

(0.328 x 391 x 0.000002155) ÷ 0.05 = 0.0055

This value is < 1 therefore risk from inhalation exposure to permethrin can be excluded.

Risk assessment has been performed for toddler to represent the most realistic case, since infants cannot walk or crawl extensively away from the place they are put to explore their environment, according to HEEG Opinion endorsed at TM 2013. Therefore, a body weight of 10 kg has been used as endorsed at TM II 2013 and reported in HEEG Opinion "Default human factor values for use in exposure assessments of biocidal products". The secondary exposure for toddler is mainly occurring *via* dermal contact. The post application exposure for toddlers was estimated using ConsExpo Web.
The model considers that exposure occurs *via* dermal contact through rubbing off and oral via hand-to-mouth exposure.

Description of Scenario 4: secondary exposure from general surface			
	Parameters	Value	Comments
TIER 1	Product database	Pest control products	-
	Product categories	Sprays	-

	Default products	General surface	In the Assessment Report of permethrin it is assumed that secondary exposure from general surface spraying will cover secondary exposure from targeted spot or crack & crevice application, where the treated areas are nearly out of reach of children.
	Scenarios	Post application (child)	-
	Frequency	126 y^{-1}	Default value as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet", p.36).
	Body weight	10 kg	Default value for toddler (irrespective of gender, based on female 1 to < 2 years old), as endorsed at TM II 2013 and reported in HEEG Opinion "Default human factor values for use in exposure assessments of biocidal products". Toddler represent most realistic case, since infants cannot walk or crawl extensively away from the place they are put to explore their environment, according to HEEG Opinion.
	Dermal data		
	Dislodgeable amount	6.5 g/m^2	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet", p. 45). By multiplying the mass generation rate (new value according to "New default values for the spray model" RIVM, March 2010) and the spray duration, the total amount of sprayed formulation can be calculated (0.8 g/sec x 600 sec = 480 g). It is assumed that this amount ends up on the floor surface of the living room, so that the amount of formulation per surface unit can be calculated (480 g on 22 m^2, or 21.8 g/m^2); 30% of this amount is dislodgeable. The Dislodgeable amount is calculated at 6.5 g/m^2.
	Rubber surface	22 m^2	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet", p. 45).
	Transfer coefficient	0.21 m^2/hr	Default value as agreed at the Human Health Working Group V on 22 November 2016 (Recommendation no. 12 of the BPC Ad hoc Working Group on Human Exposure).
	Exposure duration	60 minute	Default, as reported in ConsExpo and in the Assessment Report of permethrin.
	Oral data		
	Exposure duration	60 minute	Default, as reported in ConsExpo.

	Dermal uptake fraction	70%	No data on dermal absorption are available for Clean Kill®. Therefore, default value proposed by EFSA Guidance Document for dermal absorption (EFSA, 2017) is used for (in use) dilutions of organic solvent formulated and other types of formulations.
	Ingestion rate	2.175 mg/min	Calculated as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet", p. 28. The ingestion rate can be calculated based on the assumption that from the total dermal exposure 10% is taken in orally due to hand-mouth contact. [(0.21*6.5)/60]*1000*0.1
	Assumptions	Since the number of applications is 9 per year and the efficacy duration after treatment is 4 weeks,toddlers are expected to be exposed to the biocidal product for 9 months per year (*i.e.*, 9 applications every 4 weeks). This exposure can be regarded as a long/medium term exposure. However, since TAB –TOX v.2.0 (2018) does not recommend the averaging of exposures unless there is sufficient justification and technical agreement, a comparison of the acute exposure to $AEL_{medium\text{-}term}$ is considered to be more reasonable.	-

Calculations for Scenario 4: seconday exposure

Exposure scenario	Systemic dose (mg/kg bw/d)
Internal dose on day of exposure*	**0.28**
Internal year average dose of exposure**	**0.098**

*To be considered in the risk assessment.

**Included for information, only.

Monitoring data

Monitoring data are not available for Clean Kill®.

Dietary exposure

Since Clean Kill® should not be applied directly on or near food/feedstuff exposure is not expected. In this regards, the following RMM is proposed to be added on the label "Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks".

Information of non-biocidal use of the active substance

Permethrin

Summary table of other (non-biocidal) uses			
	Sector of use [1]	**Intended use**	**Reference value(s) [2]**
1.	Plant protection products	EU Reg. 396/2005: not approved active substance Permethrin Review Report 13 July 2000: *"Technical evidence has been provided indicating that limited further use of permethrin in forestry could be allowed whilst research is ongoing in order to find efficient alternatives providing that appropriate risk mitigation measures are taken. To minimise potential risk for aquatic organisms it was proposed by the Rapporteur Member State that a buffer zone should be applied between treated areas and surface waters.* *In view of the fact that all notifiers of the substance formally withdrew their support for permethrin within the EU Peer Review Programme and, therefore, no engagements are made to produce the necessary supplementary data, an inclusion of this active substance in Annex I of Directive 91/414 cannot be envisaged"*	Default MRL at 0.05 mg/kg or 0.1 mg/kg depending on the commodities (Reg. (EU) 2017/623)
2.	Veterinary medicinal products EU Reg. 470/2009	External application for the control of ectoparasites for cattle	MRL for bovine: Muscle, Liver, Kidney, Milk: 50 µg/kg Fat: 500 µg/kg (Reg (EU) 37/2010)

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

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

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

ARfD (acute reference dose) (AEL acute)
The 90-day inhalation rat study submitted by Applicant 2 (Kumar, 2006) was deemed the most appropriate sub-chronic study to provide an NOAEL value that can be used to establish systemic AEL ACUTE-TERM or ARfD reference values. An NOAEL of 0.2201 mg/L was established in the study. This was based on findings of toxicity signs such as nasal irritation and mild tremor at the high dose group (0.4363 mg/L). The overall NOAEL for this study is 0.2201 mg/L, which corresponds to 59.46 mg/kg bw/day.
Dividing the NOAEL value 59.43-mg/kg bw/day by an overall assessment factor of 100 derives a reference value of 0.59-mg/kg bw/day. However, this AELacute from an inhalation study requires estimate of received dose with all the attendant uncertainties. The oral Ishmael and Litchfield gives a very similar AEL of 0.5 mg/kg bw/day.

Therefore, ARfD or AEL_{ACUTE} reference value is set at of 0.5 mg/kg bw/day.

AEL_{ACUTE} reference value of 0.5 mg/kg bw/day

Acceptable operator exposure level (AOEL) AELmedium
The 90-day oral rat study submitted by Applicant 2 (Ramesh, 2002) appeared to be the most appropriate study for AEL MEDIUM-TERM. However, the NOAEL of 7.9, 9.3, and 8.6 mg/kg bw day for males, females and combined sex respectively was established based on liver hypertrophy with no clinical chemistry or hispathological signs and liver weight increases of less than 10%. The effects noted by author my constitute a NOEL but in the opinion of the RMS do not constitute a NOAEL. On this basis the RMS has re-set the NOAEL of this study to the top dose of 172 mg/kg bw/day.
Consequently, AEL must be derived from the dog 12 month study submitted by applicant 1 Bayer Sumatomo.

$AEL_{MEDIUM\text{-}TERM}$ reference value of 0.05 mg/kg bw/day.

AELchronic
The lowest NOAEL in key long-term carcinogenicity study was 50 mg/kg bw/day in the rat (McSheehy & Finn 1980). However, in the 12-month dog study (Kalinowski et al, 1982 (key)) a more conservative value was derived. In addition, the effects seen in the dog are those normally associated with pyrethroid toxicity. On this basis the AELLONG-TERM has been set to 0.05 mg/kg bw/day.

$AEL_{LONG\text{-}TERM}$ is 0.05 mg/kg bw/day.

Acceptable daily intake (ADI)
In data, unavailable for review, a chronic rat study exists which has a NOAEL of 5 mg/kg bw/day, and this study has been used by the WHO/FAO JMPR to calculate an ADI for technical-grade permethrin with cis:trans ratios of 25:75 to 40:60) on the same basis as outlined above, resulting in an ADI of 0.05 mg/kg bw.

Risk for industrial users

BPR is not applied to the formulation phase; therefore, risk assessment has not been performed.

Risk for professional users

The product is not used by professionals.

Risk for non-professional users

Summary of risk assessment for primary exposure

Scenario	**Systemic NOAEL mg/kg bw/d**	**Internal dose on day of exposure (total)** **(Acute exposure)**	**Internal year average dose (total)** **(Chronic exposure)**	**Total acute dose * / AEL (%) (short term)** **AEL = 0.5 mg/kg bw/d**	**Total chronic dose / AEL (%) (long term)** **AEL = 0.05 mg/kg bw/d**	**Acceptable (yes/no)**
Scenario 1 - Mixing and loading	5	3.1×10^{-4} mg/kg bw/d	5.2×10^{-6} mg/kg bw/d	0.062	0.010	yes
Scenario 2 - targeted spot application	5	1.0×10^{-2} mg/kg bw/d	2.5×10^{-4} mg/kg bw/d	2	2.404	yes
Scenario 3 - crack and crevice application	5	6.7×10^{-3} mg/kg bw/day	1.6×10^{-4} mg/kg bw/day	1.34	0.007	yes
Combined scenario 1 + 2 (worst-case)	5	1.03×10^{-2} mg/kg bw/d	2.55×10^{-4} mg/kg bw/d	2.06	3.831	yes

Combined scenario 1 + 3 (worst-case)	5	7.01×10^{-3} mg/kg bw/d	1.65×10^{-4} mg/kg bw/d	1.402	0.004	yes

*To be considered in the risk assessment.

***NOTE 1**: Since no safe use was demonstrated for the environment, 'Targeted spot application' was no longer supported for authorization at the resolution step of the formal referral.*

***NOTE 2**: At the resolution step of the formal referral, for the use covered by the authorization (crack and crevice application), it was agreed that the 300-mL RTU product is to be authorized. Nevertheless, combined Exposure (including Mixing and loading phase) is maintained, for the sake of transparency.*

Summary of risk assessment for secondary exposure

For secondary exposure, risk assessment should be performed by using the values of acute systemic exposure in combination with the $AEL_{medium\text{-}term}$ (0.05 mg/kg bw/d).

Scenario	**Systemic dose (mg/kg bw/d)**	**%AEL long-term (0.05 mg/kg bw/d)**	**MoE long-term (5 mg/kg bw d)**
Internal dose on day of exposure (Acute exposure)	0.28	568	17.6

Combined scenarios

Primary exposures arising from mixing and loading (Scenario 1) and targeted spot application (Scenario 2) have been assessed as worst-case combined scenario. However, since no safe use was demonstrated for the environment, 'Targeted spot application' was no longer supported for authorization at the resolution step of the formal referral.

On the other hand, for sake of completeness the combined scenario - considering exposure from mixing and loading (Scenario 1) and crack and crevice application (Scenario 3) - has been also added.
At the resolution step of the formal referral, for the use covered by the authorization (crack and crevice application), it was agreed that the 300-mL RTU product is to be authorized. Nevertheless, combined Exposure (including Mixing and loading phase) is maintained, for the sake of transparency.

Local effects

There is no need to consider local effects separately, since the product Clean Kill® is not classified due to its local effects.

Conclusion

As a result of the human health risk assessment, no risks have been identified for primary and secondary exposure as regards the only envisaged use: **'Targeted spot application in crack & crevice'** (at 50 mL product/m^2, porous/non-porous surfaces, application by spraying via trigger sprayer with fixed capillary tube).

In addition:
- RMM "Avoid contact with treated surfaces" is also proposed, justified by the fact that for the application phase no risk assessment has been performed for non-professionals touching treated surface;
- RMM "Keep children away during treatment" is proposed, since during the application phase no risk assessment has been performed for children directly exposed to the product;
- RMM "Application of the biocidal product only in areas inaccessible to children" is also adopted due to a potential risk for children indirectly exposed, although it seems to be over-conservative (ConsExpo model - exposure scenario after application of general surface spray - should be regarded as a very worst-case scenario which does not

properly address the real use of the BP, which is only applied where exposure to children is not expected)

Risk for consumers via residues in food

Risk for consumers via residues in food was not assessed since the proposal is for non-crop use.

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

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product is not necessary since the only active substance in Clean Kill® is permethrin and no substances of concern are present, except one which does not require any additional risk assessment.

2.2.7 Risk assessment for animal health

Risk assessment for animal health is not necessary, since exposure of animals is not expected (i.e. Clean Kill® is not intended to be applied to animals). The product is not used on animals. Direct exposure is not foreseen as the following RMM is proposed: "Keep pets away during treatment."
In addition, for pets, where normal behaviour can imply crawling and jumping on inaccessible areas, RMM "Application of the biocidal product only in areas inaccessible to pets" is also included.

Indirect exposure to the product may occur for pets and animals particularly in private area. However, due to the lack of appropriate guidance, exposure is assumed to be similar to these of toddlers and children and no specific measure is needed (except for cats due to the presence of permethrin into the biocidal product).

Cats are known to be more sensible to pyrethroids than others animals due to a slower metabolisation of these substances. Intoxication is very common and may be lethal. In order to protect cats, the following RMM must be added on the label:
"Do not apply in presence of cats and keep cats away from treated surfaces due to high sensitivity to permethrin toxicity".

2.2.8 Risk assessment for the environment

General consideration

The assessment of effects on environment was developed having as starting point the rules outlined in CLP Regulation. In particular, the article 11 of CLP Regulation states "where a mixture contains a substance classified as hazardous, whether as a component or in the form of an identified impurity or additive, this information shall be taken into account for the purposes of classification, if the concentration of that substance is equal to or greater than its cut-off value. The cut-off value referred shall be determined as set out in CLP Regulation, section 1.1.2.2 of Annex I". This approach was deemed as appropriate also in the light of the criteria outlined in article 3.1(f) of Biocidal Products Regulation to identify the substances of concern in a biocidal product.

The biocidal product Clean Kill® contains:
- several substances that are not classified (i.e. not hazardous)
- several substances that are classified for one or more endpoint(s), that are present in the biocidal product in concentration(s) below the cut-off values determined according to art. 11 of CLP Regulation.

Therefore, these substances can be realistically regarded as not relevant for the risk assessment of the biocidal product and they will not be further taken into account in the following evaluation.

The only relevant substance (since its concentration is above the cut-off values determined according to art. 11 of CLP Regulation) is permethrin. Moreover, permethrin is the active substance of the biocidal product Clean Kill®.

For these reasons, in the sections below the environmental hazard assessment shortly summarizes the information discussed in detail in the CAR of permethrin. The use of data on active substance and model formulation is covered by the Letter of Access.

2.2.8.1 Effects assessment on the environment

The following information is related to ecotoxicity of permethrin, as reported in the Assessment Report of permethrin.

Effects on aquatic organisms

Permethrin is highly toxic to aquatic organisms, especially invertebrates. The highest risk for environmental toxicity is in the water column immediately after the release incident, because permethrin will bind rapidly to sediment and become less bioavailable to organisms. While permethrin does have a tendency to bioconcentrate based upon its lipophilicity, terrestrial and aquatic organisms have demonstrated the ability to depurate permethrin through excretion.
In general, the results of toxicity studies were similar/comparable between Bayer/Sumitomo and Tagros. Both sets of data indicated clearly that acute exposure to permethrin is highly toxic to fish (0.0051 mg a.s./L (Bayer/Sumitomo)) and to aquatic invertebrates, with *Daphnia* 0.00127 mg a.s/L (Bayer/Sumitomo), being the most sensitive of the aquatic organisms tested. A definitive EC_{50} could not be derived from either of the algal studies due to the limited range of concentrations tested (due to solubility issues). Although the EC_{50} values are quite low (> 1.13 mg a.s./L (Bayer/Sumitomo)), they are in excess of the limit of water solubility.

Chronic exposure to permethrin was also highly toxic to the three groups of aquatic organisms, affecting reproduction and survival in fish and *Daphnia* (again, *Daphnia* was the most sensitive species; NOEC 0.0047 µg/L). Permethrin does not appear to have an endocrine affect in fish.
There was a substantial difference (> 2000 fold) in the concentration of test substance used in the Bayer/Sumitomo and Tagros microbial inhibition studies but both studies indicated that permethrin is of low toxicity to these microorganisms and will not inhibit microbial respiration in activated sludge in the field. For substances with a low water solubility and if no effect is seen on the micro-organisms at the highest level, then the NOEC is set at the water solubility concentration (0.00495 mg/L).
For sediment-dwelling organisms, the LC_{50} and NOEC were determined to be 2.110 mg/kg and 0.1 mg/kg, respectively (based upon midge survival and emergence), expressed as concentrations arising in spiked sediment, and were determined to be >0.01 mg/L and 0.001 mg/L, respectively (based upon midge survival and emergence), expressed as concentrations arising in water.

Effects on terrestrial organisms

Permethrin was found to be toxic to bees (acute contact toxicity; LD_{50}: 0.0235 µg/ bee; acute oral toxicity LD50: 0.163 µg/ bee (Bayer/Sumitomo)). Permethrin may be hazardous to small mammals following acute exposure (rat oral LD_{50}: 480 mg as/kg bw (Bayer/Sumitomo)).
Permethrin is of low toxicity to terrestrial soil-dwelling organisms, including earthworms (EC_{50} = 371 mg a.s./kg), micro-organisms (no observed effect on carbon (40 days) or nitrogen (18 days) metabolism to >31.7 mg/kg dwt) and plants (effects on biomass for all species was < 20% at dose of 6875 g/ha).
Permethrin was found to have low acute avian toxicity LD_{50}: >4640 mg/kg bw (Bayer/Sumitomo) and the long-term dietary study on bobwhite quail showed no effect on reproduction at 500 ppm. A known issue, from veterinary monitoring, indicates that permethrin toxicity to cats can result from the exposure to concentrated permethrin containing products.
Results of the seedling emergence study indicated that permethrin technical may affect the emergence of *Helianthus annuus* (sunflower) above nominal concentrations of 0.0128 mg/kg dry soil, though the effects did not follow a continuous dose-response pattern and emergence was not affected in any of the other 5 plant species tested at permethrin concentrations as high as 696 mg/kg dry soil (actual measured value). The study did however show that biomass reduction can occur for non-target plants like *Avena sativa* above 8 mg/kg dry soil. However, both of these endpoints are based on nominal concentrations – the actual concentrations were likely to have been much lower than these values (but could not be determined from the data provided). As such, the results of this test were considered rather tentative (especially the results of the emergence test) and the study was given a reliability score of 2-3.
No phytotoxic effects were observed in any plant species in a 21-day vegetative vigour test (limit test, test concentration 6875 g/ha (9.17 mg/kg)). Significant effects on the inhibition of biomass were observed for *Avena sativa* and *Allium cepa* (most sensitive species) at 6875 g/ha. However, these effects were <20%, suggesting permethrin poses a low risk to terrestrial plants. This is further supported by the justification provided by Bayer/Sumitomo for non-submission of plant toxicity tests. According to Bayer/Sumitomo, "Permethrin has been used in the crop protection field since 1977.
During that time it has been cleared for use on several monocotyledonous and dicotyledonous crops, including cotton plants, corn, soybean, coffee, tobacco, oilseed rape, wheat, barley, alfalfa, vegetables, and fruits.

Metabolites in aquatic compartment

Aquatic metabolites including 3-(2,2-dichlorovinyl)-2,2-dimethyl-(1-cyclopropane) carboxylate (DCVA) and 3-phenoxybenzoic acid (PBA) are far less toxic to aquatic organisms than the parent active ingredient and are not considered to be ecotoxicologically relevant. The metabolites L(E)C_{50}s for fish and aquatic invertebrates are more than three orders of magnitude higher than that observed in tests with permethrin. DCVA *Daphnia magna* 48 hr LC_{50} is ≥ 25 mg a.s./L.

Metabolites in terrestrial compartment

DCVA and FPB-acid (4-fluoro-3-phenoxybenzoic acid) displayed low toxicity to soil-dwelling arthropods (both substances were less toxic to soil macro-organisms than permethrin) and thus are not considered to be ecotoxicologically relevant. The study on FPB-acid was considered relevant to estimate the toxicity of metabolite PBA on soil macro-organisms. In fact, the approach can be regarded as conservative because a QSAR estimation (with the program ECOSAR, vs. 0.99h) gave a 1-day LC_{50} of 3400 mg/kg dry wt soil for 3-phenoxybenzoic acid in earthworms, further supporting the indication that PBA is not toxic to soil organisms.

New data reported in CAR Addendum for permethrin, March 2017

Toxicity to terrestrial organisms, chronic tests.

Summary table – long term terrestrial toxicity							
Method, Guideline, GLP status, Reliability	**Species**	**End point/ Type of test**	**Exposure**		**Results**	**Remarks**	**Reference**
			Design	**Duration**	**LOEC/NOEC/EC_{10}**		
Earthworm/soil-dwelling non-target invertebrates reproduction							
Permethrin a.s.: Effects on the reproduction of the collembolan *Folsomia candida* OECD guideline 232 2009, GLP The study was considered acceptable with a Reliability score of 1	*Folsomia candida*	Reproduction	0, 18, 32, 56, 100, 178, 316, 562, 1000 mg a.s./kg soil dry weight nominal concentration	28 days	NOEC (Reproduction) 562 mg/kg soil d.w. LOEC (Reproduction) 1000 mg/kg soil d.w. EC_{10}: (Reproduction) 579 mg/kg soil d.w. (Probit analysis)	None	Section A7.5.6-01 (CAR Addendum for permethrin, March 2017)

Value used in Risk Assessment	
Value/conclusion (from CAR addendum March 2017)	NOEC = 562*(0.034/0.050) = 382.16 mg/kg soil, dwt LOEC = 1000*(0.034/0.050) = 680 mg/kg soil, dwt. Values have been amended in accordance with the Guidance for BPR, vol. IV, part B, p. 132

Derivation of PNECsoil:

Compartment	PNEC	Remarks/Justification
Soil	0.198 mg/kg dry weight (0.175 mg/kg wwt)	Organism: Soil micro-organism Endpoint: EC_{50} > 9.9 mg/kg dry weight (8.76 mg/kg wwt) Assessment factor: 50 Extrapolation method: Assessment factor Justification: As there are results from two long-term studies for two species of two trophic levels are available, an assessment factor of 50 is applied.

Applicant's proposal to modify the $PNEC_{surface\ water}$

The Schäfers (2006) report is the study of Tagros resulting in the $PNEC_{surfacewater}$ of 0.47 ng/L and is invalidated.
The reported NOEC by Schäfers (2006) cannot be considered reliable due to the large variation in permethrin exposure concentrations within a specific treatment. This variation makes it actually impossible to establish a robust relationship between effect and a specific exposure concentration.
The NOEC of 4.8 ng/L that was determined by Schäfers (2006) is therefore considered unreliable, and should not be used for setting a PNEC for permethrin in the aquatic environment.
The 21d-EC10 of 141 ng/L – as derived with the data that were reported by Kent et al. (1995) – should be used instead as relevant reference value for *Daphnia magna*.
Based on the data in the dossier and literature data, an SSD (Species Sensitivity Distribution) has been applied. Using a refined dataset on chronic toxicity data for permethrin in the aquatic environment (seven reliable NOEC values for seven relevant taxonomic groups including insects and crustaceans) an HC5,50% of 12.1 ng/L was calculated (SSD method). By applying an assessment factor of 3 to this HC5,50%, a $PNEC_{freshwater}$ of 4.0 ng/L was determined for permethrin.

CA-IT conclusions: The applicant provided a PNEC proposal based on a SSD. In fact, this proposal was derived from a Canadian study report incorporating an overview of studies. This SSD proposal was discussed at BPC ENV-WG level upon the CA-NL's request.
As in the final WGVII2018 meeting minutes (WGVII2018_ENV_6-6_PNECwater_STP_biodeg_Permethrin_minutes_FINAL.docx), the BPC ENV-WG agreed not to change the reliability indicator from the study by Schäfers (2006) at this point in time.

It was suggested by some Member States that the endpoint and the $PNEC_{surface\ water}$ derivation should be revised at the active substance renewal stage.

As a result, since the original *Daphnia*-endpoint from Schäfers (2006) was considered by the BPC ENV-WG still as valid, applying a factor of 10 to the lowest chronic NOEC of 0.0047 µg/L derived from the most sensitive organism (*Daphnia magna)*, the resulting PNEC water is confirmed to be the one as in the AR drafted by eCA-IE under PT18 in April 2014:

PNECwater = 0.00047 µg a.i./L (0.47 ng a.i./L)

PNECs values

PNECs values used for the risk assessment are detailed in the table below.

Permethrin	
Surface water	4.7×10^{-7} mg/L a.s./L
Freshwater sediment	0.001 mg/kg dwt (2.17×10^{-4} wwt)
Microorganisms in STP	4.95×10^{-3} mg a.s./L
Soil	0.198 mg/kg dry/weight (0.175 mg/kg wwt)
Oral bird	≥ 16.7 mg a.s/kg food
Oral small mammal	120 mg a.s/kg food

DCVA	
Surface water	0.015 mg/L
Soil (wet weight)	4.6 mg/kg wwt
Sediment	0.055 mg/kg dwt (0.012 mg/kg wwt)

PBA	
Surface water	> 0.010 mg/L
Soil (wet weight)	1.44 mg/kg wwt
Sediment	0.042 mg/kg dwt (0.009 mg/kg wwt)

Fate and distribution in the environment

The technical material supported by the applicants (in the Assessment Report of permethrin) relates to permethrin as a reaction mass of four stereoisomers (1Rcis, 1Scis, 1Rtrans, and 1Strans), with two pairs of diastereoisomers in an isomeric ratio of 25:75 (cis:trans). Studies were conducted with permethrin 25:75 or with a mixture of isomers where the permethrin samples contain 50-78% of the trans-isomer.

Aquatic compartment including STP and sediment

Permethrin was observed to be hydrolytically stable between pH 3.0/4.0 to 7.6/7 at 25/50°C respectively. Only at pH 9.0/9.6 was permethrin observed to hydrolyse, with DT_{50} values for cis- and trans-permethrin estimated at 35 days and 42 days, respectively (at pH 9.6 and 25°C).

Permethrin is not readily biodegradable according to OECD 301B (CO_2 evolution method)/US EPA OPPTS 835.3110 and OECD 301 F (oxygen consumption). Permethrin (25:75 cis:trans) exhibited inherent primary biodegradability, since its biodegradation was found to be above 20% in a validly conducted test (OECD302 C, BOD test). The results

cannot be regarded as evidence of inherent ultimate biodegradability, since biodegradation was not above 70%. An effects study on microorganisms in sewage sludge was provided as a STP simulation test of permethrin degradation (40:60 cis:trans). From the data no clear evidence for degradation is observed. Whilst permethrin as a percentage of radioactivity was observed to decline it is likely that permethrin adsorbed to the sewage sludge (~80%AR) due to the strong adsorption characteristics of the parent compound. The remainder of the parent compound was observed in the supernatant. Permethrin is strongly adsorbed to soil (Mean Kf oc 73,442 L/kg (n= 10)). The two metabolites are more mobile. DCVA exhibited Kfocs ranging from 13.95 L/kg to 356.15 L/kg. Corresponding values for PBA ranged from 70.5 L/kg to 157.3 L/kg.
Permethrin (46:54 and 53:47 cis:trans) was observed to degrade in aerobic water/sediments systems, with whole-system DT_{50} values of cis- and trans-permethrin calculated at 63.7 days and 27.3 days, respectively at 25°C (equivalent to corresponding values at 12 °C of 180.2 days and 77.2 days). Whole-system first order degradation DT50 values for permethrin (25:75 cis:trans) incubated aerobically in water-sediment systems derived from a creek and a pond, in the dark for 120 days at 20 ± 2 °C were much faster and ranged from 14.3 days to 24.6 days (equivalent to a corresponding range at 12 °C of 27.1 days to 46.7 days). The reason for this difference is not clear.
The degradation scheme proposed for the behaviour of permethrin in aerobic water-sediment systems involves as a first step transformation along parallel pathways to 3-phenoxybenzyl alcohol (PB alcohol) and 3-(2,2-dichlorovinyl)-2,2-dimethyl-(1-cyclopropane)carboxylate (DCVA), followed by transformation of 3-phenoxybenzyl alcohol to 3-phenoxybenzoic acid (PBA), with carbon dioxide and bound residues as terminal products.
Maximum observed levels of DCVA, PBA and PB alcohol in the water compartment were 62.6%AR, 28.8%AR and 38.2%AR respectively. DCVA and PBA were also major metabolites in the sediment compartment (21.7% and 16.4% respectively). The whole-system first order degradation DT_{50} values for PB alcohol was measured at 2.7 days for the pond system (5.1 days at 12°C). No reliable DT_{50} value could be determined for the creek system. Whole-system first order degradation DT_{50} values for PBA were measured at 31.8 days for the creek system (60.3 days at 12°C) and 33.4 days for the pond system (63.3 days at 12°C). A reliable DT_{50} value could not be evaluated for DCVA in either aquatic system since the maximum observed levels occurred towards the end of the study incubations and only showed small declines thereafter. Whilst no reliable DT_{50} value could be obtained for DCVA in the water/sediment system, the metabolite is common to other pyrethroid chemistry (e.g. cypermethrin) and reliable DT_{50} values have been reported that provide indicative DT_{50} values in water/sediment (whole system) from 80-145 days for trans-DCVA and 62 to 188 days for cis-DCVA. Further confirmatory data on the degradation of DCVA in water/sediment systems will need to be supplied by the applicants.
Permethrin was observed to degrade more slowly under anaerobic conditions, with whole-system DT_{50} values of cis- and trans-permethrin calculated at 179.4 days and 114.5 days, respectively (equivalent to corresponding values at 12 °C of 507.6 days and 323.9 days).
A field aquatic dissipation study on a formulated product containing 10.1% w/w permethrin (cis:trans ratio not specified) indicated rapid dissipation from the water phase to sediment for both cis- and trans-permethrin, with DT_{50} values for the water phase calculated in the range 1.3 days to 3.1 days. Cis- and trans-permethrin appeared to be rather immobile in the sediment, remaining in the upper portion (0-5 cm). DT_{50} values determined for the cis- and trans-permethrin isomers in the sediment phase ranged from 118 to 256 days and 18 to 62 days, respectively. Metabolites were only detected in the water compartment and had disappeared by 90 days after the last application in the North Carolina test site and 120 days after the last application in the California test site. Based on the above results, biodegradation of permethrin in freshwater occurred under both aerobic and anaerobic conditions.

Direct photolysis of permethrin (49:51 cis:trans) indicated slow degradation of the test material resulting in a DT_{50} value of 118 days with 12 hr sunlight per day under outdoor conditions at latitude of 50°N and the fall season. Control experiments revealed that permethrin was stable in water for a period of 32 days under exclusion of light. Slow degradation of permethrin under aqueous photolysis was also confirmed using the ABIWAS computer program. Overall, it is concluded that significant photolysis of permethrin will not occur under environmentally relevant pH and temperature conditions (12°C).

Atmosphere

Volatilization of permethrin is considered to be negligible based on the vapour pressure (2.155×10^{-6} Pa at 20°C, 25:75 cis:trans) and Henry constant (4.6×10^{-3} - > 4.5×10^{-2} Pa m^3 mol^{-1}). Permethrin volatilisation loss from a soil surface over 24 hours to the atmosphere was calculated to be 0.73% assuming a temperature of 25°C. This calculation was performed by the CA using the Dow method (as detailed under Doc III, A7.3.1); the associated volatilisation constant for permethrin was estimated at 7.31×10^{-3} day^{-1}. The software AOPWIN v1.91, which utilises QSAR methods, was used to calculate an atmospheric half-life value of 0.701 d for the gas phase reaction of permethrin with photo-chemically produced hydroxyl radicals (24-hour day and a hydroxyl radical concentration of 5 x 105 radicals/cm^3) and 49.27 d for the gas phase reaction of permethrin with ozone (assuming a 24-hour day and an ozone concentration of 7×10^{11} molecules/cm^3). The calculations show that reaction with hydroxyl radicals would be expected to be the major contribution to atmospheric degradation of permethrin via gas phase reaction with photo-chemically generated species. Based on the short half-life for this transformation pathway, it is concluded that permethrin is rapidly degraded and would not be transported over large distances in the atmosphere in gaseous phase.

Terrestrial compartment

Degradation of permethrin was investigated under aerobic conditions in several soils. The range of reliable SFO DT_{50}s ranged from 77 d to ~141 d at 12°C. The corresponding geomean DT_{50} was 106 d. The cis isomer degraded more slowly than the trans isomer based on the cis:trans ratio at the time of application changing from 40:60 to 50:50 by day 30 and 78:22 by day 365. The geomean DT_{50} is derived from permethrin samples containing 50-78% of the trans- isomer. It can be expected that a DT_{50} value of 106 days is conservative enough to represent the degradation in soil at 12°C of permethrin samples containing a cis:trans ratio of 25:75.
Results from another submitted set of studies (giving DT_{50} values at 12°C ranging from 11.0 - 21.2 days) are not considered representative of the behaviour of permethrin in soil since the route of degradation was not identified in these latter studies but was shown not to proceed via formation of DCVA and PBA.
The route of degradation of permethrin in soil appears to be dominated by a two-step process. Permethrin breaks down to form DCVA (max 11.3%AR, SFO DT_{50} 12°C 33.1-~175 d) and PBA (max 15.0%AR, 1.7-2.5 d at 12°C), and ultimately converts to CO_2. Laboratory test data indicated that NER amounts do not exceed 70% AR after 100 days nor do mineralisation rates fall below 5%AR after 100 days for permethrin.
Permethrin was observed to be relatively stable when exposed to photoylsing conditions in soil. A DT_{50} of 200 d (Florida autumn sunlight) was estimated. However, confidence in the accuracy of this value was low since it was beyond the duration of the test (33 d & 3 hr of Florida autumn sunlight). No transformation product greater than 10%AR was observed.
Permethrin is strongly adsorbed to soil (Mean Kfoc 73,441 L/kg, Koc 26,930 n = 9). Therefore, leaching is not expected to occur. The two major soil metabolites (DCVA & PBA) are expected to be more mobile. The mean Kfoc for DCVA was 93.2 L/kg (n = 5). For PBA the Kfoc was 141.2 L/kg.

New data reported in CAR Addendum for permethrin, March 2017

Confirmatory water/sediment degradation study for the permethrin metabolite DCVA.

Summary table – fresh water/sediment degradation							
Method, Guideline, GLP status, Reliability	**Test type**	**Test system**		**Test substance concentration**	**Incubation period**	**Degradation (DT_{50})**	**Reference**
		Water	Sediment				
Aerobic and Anaerobic Transformation in Aquatic Sediment Systems, OECD guideline 308, GLP. The study was considered acceptable with a Reliability score of 1	Biodegradation of DCVA (metabolite of AS permethrin) in fresh-water	*Leverkusen, North Rhine Westphalia, Germany*		50 µg/mL (trans/cis ratio = 3/1)	98 days	26 days @ T = 20°C = 49.3 days @ T = 12°C	Hellpointner, E., Kasel, D., 2015, Permethrin DCVA: Aerobic Aquatic Metabolism, Bayer CropScience AG, BCS-D-EnSa-Testing, 40789 Monheim, Germany, laboratory report number M1512320-4, (final unpublished)
		Nespen, Reichshof, North Rhine Westphalia, Germany		50 µg/mL (trans/cis ratio = 3/1)	113 days	49.8 days @ T = 20°C = 94.4 days @ T = 12°C	

The route and rate of degradation of [cyclopropane-1-14C]DCVA (permethrin-DCVA, a mixture with a trans/cis ratio of 3/1 (w/w), as it is to be expected from degradation of the parent compound permethrin) were studied in two water/sediment systems under aerobic laboratory conditions in the dark at 20 ± 2 °C for 113 days at maximum. A study application rate of 20 µg permethrin-DCVA/test system (corresponding to 38 µg permethrin-DCVA/L) was applied, based on a maximum predicted environmental concentration of DCVA in surface waters (PECSW) and considering an over-dose factor of 3.8 due to technical needs.

- Mean **material balances** were 98.1% AR for system Anglersee (range from 92.7 to 101.5% AR) and 99.6% AR for system Wiehltalsperre (range from 97.5 to 101.1% AR).

- The maximum amount of **carbon dioxide** was 54.2 and 28.6% AR at study end (DAT-98 and DAT-113) in system Anglersee and Wiehltalsperre, respectively. Formation of volatile organic compounds (VOC) was insignificant as demonstrated by values of ≤ 0.1% AR at all sampling intervals for both water/sediment systems. Residues in water decreased from 91.2% AR at DAT-0 to 9.0% AR at DAT-98 in system Anglersee and from 86.0% AR at DAT-0 to 3.6% AR at DAT-113 in system Wiehltalsperre.

- **Extractable residues** in sediment of system Anglersee increased from 8.3 AR at DAT-0 to 13.4% AR at DAT-4 and then decreased to 2.3% AR at DAT-98. In system Wiehltalsperre extractable residues in sediment increased from 11.4% AR at DAT-0 to 23.4% AR at DAT-98 and then decreased to 13.2% AR at DAT-113. Extractable residues in the total system (water and sediment extracts) decreased from 99.5% AR at DAT-0 to 11.3% AR at DAT-98 in system Anglersee and from 97.5% AR at DAT-0 to 16.8% AR at DAT-113 in system Wiehltalsperre. **Non-extractable residues (NER)** in system Anglersee increased from 0.9% AR at DAT-0 to 29.6% AR at DAT-70 and then slightly decreased to 28.7% AR at DAT-98. In system Wiehltalsperre NER increased from 3.2% AR at DAT-0 to 52.1% AR at DAT-113.

- Permethrin-DCVA dissipated from the **water** due to degradation and translocation into the sediment. In system Anglersee the amount of permethrin-DCVA (sum of trans-DCVA and cis-DCVA) in the water decreased from 90.7% AR at DAT-0 to 2.0% AR at DAT-98. The amounts of trans-DCVA and cis-DCVA decreased from DAT-0 to DAT-98 from 67.5 to 2.0% AR and from 23.1% AR to non-detectable amounts, respectively. In system Wiehltalsperre the amount of permethrin-DCVA (sum of trans-DCVA and cis-DCVA) in the water decreased from 86.0% AR at DAT-0 to 1.0% AR at DAT-113. The amounts of trans-DCVA and cis-DCVA decreased from DAT-0 to DAT-113 from 65.8 to 1.0% AR and from 20.3% AR to non-detectable amounts, respectively.

- In system Anglersee the amount of permethrin-DCVA (sum of trans-DCVA and cis-DCVA) in **sediment** extracts increased from 8.3% AR at DAT0 to 13.4% AR at DAT-4 and then decreased to 1.2% AR at DAT-98. The amount of trans-DCVA in sediment extracts of system Anglersee increased from 6.4% AR at DAT-0 to 10.0% AR at DAT-4 and then decreased to 1.2% AR at DAT-98. The amount of cis-DCVA in sediment extracts of system Anglersee increased from 1.9% AR at DAT-0 to 3.4% AR at DAT-4 and then decreased to non-detectable amounts at DAT-98.
  In system Wiehltalsperre the amount of permethrin-DCVA (sum of trans-DCVA and cis-DCVA) in sediment extracts increased from 11.4% AR at DAT-0 to 22.0% AR at DAT-98 and then decreased to 6.7% AR at DAT-113. The amount of trans-DCVA in sediment extracts of system Wiehltalsperre increased from 8.5% AR at DAT-0 to 17.2% AR at DAT-98 and then decreased to 5.3% AR at DAT-113. The amount of cis-DCVA in sediment extracts of system Wiehltalsperre increased from 2.9% AR at DAT-0 to 5.9% AR at DAT-35 and then decreased to 1.3% AR at DAT113.

- DCVA) in the **total system** decreased from 99.0% AR at DAT-0 to 3.2% AR at DAT-98. The amounts of trans-DCVA and cis-DCVA decreased from DAT-0 to DAT-98 from 73.9 to 3.2% AR and from 25.1% AR to non-detectable amounts, respectively. In system Wiehltalsperre the amount of permethrin-DCVA (sum of trans-DCVA and cis-DCVA) in the total system decreased from 97.5% AR at DAT-0 to 7.7% AR at DAT-113. The amounts of trans-DCVA and cis-DCVA decreased from DAT-0 to DAT-113 from 74.3 to 6.3% AR and from 23.2% AR to 1.3% AR, respectively.

- Besides carbon dioxide, no **degradation products** of permethrin-DCVA > 5% AR in each compartment or > 10% AR in the total system were found. The total unidentified residues in the total system amounted to a maximum of 7.9% AR and no single component exceeded 6.4% AR at any sampling interval in both water/sediment systems.

Kinetic analysis: The experimental data could be best described by the single first order (SFO) kinetic model. The DT50 values for the dissipation of permethrin-DCVA from the water were 22.6 and 29.8 days (sum of DCVA isomers), 24.7 and 32.1 days (trans-DCVA) as well as 16.8 and 22.4 days (cisDCVA in the water of the tested water/sediment systems under aerobic conditions in system Anglersee and Wiehltalsperre, respectively). Dissipation of sum of isomers and of both individual isomers from water was faster in Anglersee as in Wiehltalsperre system. Further it is indicated that cis-DCVA is dissipating faster from water than trans-DCVA.

The DT_{50} values for the degradation of permethrin-DCVA in the total water/sediment system were 26.0 and 49.8 days (sum of DCVA isomers), 28.4 and 52.5 days (trans-DCVA) and 19.8 and 42.0 days (cis-DCVA). Degradation of sum of isomers and of both individual isomers in total test system was faster in Anglersee than in Wiehltalsperre system. Further it is indicated that cis-DCVA is degrading faster in both total systems than trans-DCVA.

These kinetic parameters are summarised in the table below along with the equivalent values back-calculated to 12 °C calculated according to Guidance on the Biocidal Products Regulation, Volume IV: Environment, Part A: Information Requirements, IV Testing Strategies, Section 4.2.3: $DT_{50}(12\ °C) = DT_{50}(20\ °C) \bullet e(0.08\ (20 - 12))$. Overall DCVA will be well degraded in water/sediment systems under aerobic conditions. Formation of significant amounts of non-extractable residues and carbon dioxide indicates a participation in the natural carbon cycle and the potential for a complete mineralization of DCVA.

Anglersee

			20°C		**12°C**	
		Kinetic Model	**DT_{50}**	**DT_{90}**	**DT_{50}**	**DT_{90}**
Sum of trans- and cis- DCVA	Water	SFO	22.6	75.1	42.9	142.4
	Total system	SFO	26.0	86.5	49.3	164.0
trans-DCVA	Water	SFO	24.7	82.0	46.8	155.5
	Total system	SFO	28.4	94.2	53.9	178.6
cis-DCVA	Water	SFO	16.8	56.0	31.9	106.2
	Total system	SFO	19.8	65.9	37.6	125.0

Wiehltalsperre

			20°C		**12°C**	
		Kinetic Model	**DT_{50}**	**DT_{90}**	**DT_{50}**	**DT_{90}**
Sum of trans- and cis- DCVA	Water	SFO	29.8	98.9	56.5	187.6
	Total system	SFO	49.8	165	94.4	312.9
trans-DCVA	Water	SFO	32.1	107	60.9	202.9
	Total system	SFO	52.5	174	99.6	330.0
cis-DCVA	Water	SFO	22.4	74.3	42.5	140.9
	Total system	SFO	42.0	139	79.7	263.6

PBT Assessment (following Annex XIII to Regulation (EC) No 1907/2006)

Assessment of persistence
Based on the comments received from the PBT Expert group, the balance of opinion suggests there is sufficient evidence to conclude that the cis-isomer of permethrin is persistent in at least one environmental compartment (sediment). The WG agreed to take into account the worst-case water/sed DT_{50} lab value of 180.2 d at 12 °C to derive the vP criterion. According to the conclusion of the WG-ENV III-2019, permethrin is considered to be very persistent.

Assessment of bioaccumulation
Members of the PBT expert group have noted that the BCF study with bluegills for permethrin has been performed with a mixture of the cis and trans isomers. The BCF has been determined for the sum of the two. However, it is possible that one of the two isomers has a significantly higher BCF than the other one. A recent monitoring study found the cis-isomer is found in much higher concentrations in fish than the trans-isomer (Corcellas *et al.* 2015, Environment International 75: 110–116). Some members of the group felt that the "conclusion not B is therefore far too premature and an isomer specific reassessment of the BCF study should be performed before the conclusion not B can be drawn." One member of the PBT group also expressed concern about potential bioaccumulation in terrestrial organisms as the EPISuite KOAWIN (1.10) model predicts a log Koa values of 10.61. According to the ECHA guidance R11, "an efficiently absorbed, non-biotransformed neutral organic substance with a log Koa ≥ 5 in combination with a log Kow ≥ 2 has the potential to biomagnify in terrestrial food chains and air-breathing marine wildlife as well as in humans." Hence, based on the log Koa and log Kow values the substance meets the screening criteria for bioaccumulation in terrestrial organisms.

Assessment of toxicity
The most critical long-term aquatic endpoint was the reproductive NOEC of 0.0000047 mg a.s./L on *Daphnia magna*, which is less than the 0.01 mg/L trigger.
Permethrin (25:75) is considered to fulfil the T criteria.

Further Ecotoxicological studies

Further Ecotoxicological studies are not available.

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

Effects on terrestrial organisms

Permethrin was found to be toxic to bees (acute contact toxicity; LD_{50}: 0.0235 µg/bee; acute oral toxicity LD_{50}: 0.163 µg/bee). Permethrin may be hazardous to small mammals following acute exposure (rat oral LD_{50}: 480 mg as/kg bw).
Permethrin is of low toxicity to terrestrial soil-dwelling organisms, including earthworms (EC_{50} = 371 mg a.s./kg), micro-organisms (no observed effect on carbon (40 days) or nitrogen (18 days) metabolism to >31.7 mg/kg dwt) and plants (effects on biomass for all species was < 20% at dose of 6875 g/ha.

Permethrin was found to have low acute avian toxicity LD_{50}: >4640 mg/kg bw and the long-term dietary study on bobwhite quail showed no effect on reproduction at 500 ppm. A known issue, from veterinary monitoring, indicates that permethrin toxicity to cats can result from the exposure to concentrated permethrin containing products.
Results of the seedling emergence study indicated that permethrin technical may affect the emergence of Helianthus annuus (sunflower) above nominal concentrations of 0.0128 mg/kg dry soil, though the effects did not follow a continuous dose-response pattern and emergence was not affected in any of the other 5 plant species tested at permethrin concentrations as high as 696 mg/kg dry soil (actual measured value). The study did however show that biomass reduction can occur for non-target plants like Avena sativa above 8 mg/kg dry soil. However, both of these endpoints are based on nominal concentrations – the actual concentrations were likely to have been much lower than these values (but could not be determined from the data provided). As such, the results of this test were considered rather tentative (especially the results of the emergence test) and the study was given a reliability score of 2-3.
No phytotoxic effects were observed in any plant species in a 21-day vegetative vigour test (limit test, test concentration 6875 g/ha (9.17 mg/kg)). Significant effects on the inhibition of biomass were observed for *Avena sativa* and *Allium cepa* (most sensitive species) at 6875 g/ha. However, these effects were <20%, suggesting permethrin poses a low risk to terrestrial plants. This is further supported by the justification provided by Bayer/Sumitomo for non-submission of plant toxicity tests. According to Bayer/Sumitomo, "Permethrin has been used in the crop protection field since 1977. During that time it has been cleared for use on several monocotyledonous and dicotyledonous crops, including cotton plants, corn, soybean, coffee, tobacco, oilseed rape, wheat, barley, alfalfa, vegetables, and fruits.

Data waiving	
Information requirement	Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)
Justification	Data submitted by the applicants for the approvation of permethrin as active substance are deemed sufficient for the assessment of Clean Kill®.

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

No data available. Clean Kill® is not in the form of bait or granules.

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

No data available. Clean Kill® is not in the form of bait or granules.

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

Information of secondary ecological effect is not available.

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

The main emission route of the product is via wastewater from sewage treatment plants after cleaning of treated surfaces and/or applicators clothing. There are no direct emissions to surface water or sediment. Consequently, aquatic or sediment organisms are not directly exposed to the active substance. Direct exposure of the air compartment is considered negligible. The half-life of permethrin in the trophosphere was calculated to be 0.701 d assuming a hydroxyl radical concentrations of 5 x 10^5 radicals/cm^3 (24 hr day). Therefore, permethrin is rapidly degraded by photochemical processes. Soil and groundwater maybe indirectly contaminated via the land application of sewage sludge. The concentration in porewater of agricultural soil has been calculated to provide an indication for potential groundwater contamination risk.

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

Summary and conclusions of the OECD 314B degradation in STP (as proposed by the Applicant)

The route and rate of degradation of [phenyl-U-^{14}C]permethrin were studied in an activated sludge system under aerobic and dark laboratory conditions at room temperature (mean 22.5 °C) for a maximum duration of 7.25 days.

The study followed the OECD Guideline for the Testing of Chemicals No. 314 B and was conducted in compliance with the OECD Principles of Good Laboratory Practice and the Principles of Good Laboratory Practice – German Chemical Law (ChemG), Annex 1.
A study application rate of 150 µg permethrin/L sludge was applied. The test was performed in test systems consisting of Erlenmeyer flasks with baffles. Each flasks contained 200 mL sludge and was equipped with traps (permeable for oxygen) for the collection of carbon dioxide and volatile organic compounds. During incubation, the sludge was in smooth motion.
Duplicate samples were processed and analyzed 0, 0.21, 1, 2, 3, 6 and 7.25 days after treatment (DAT). At each sampling interval, the sludge was extracted five times at ambient temperature using a high speed disperser. The first extraction solvent was acetonitrile followed by two extractions using acetonitrile/water 4/1 (v/v). Afterwards, the sludge was extracted once with acetonitrile and finally with methanol. The amounts of test item and degradation products in sludge extracts were determined by liquid scintillation counting (LSC) and by HPLC/radio-detection analysis. The amounts of volatiles and non-extractable residues were determined by LSC and combustion/LSC, respectively. Identity

of degradation products and test item was identified by HPLC-MS(/MS) including accurate mass determination and GC-MS, respectively.
Mean material balance was 97.4% AR (range from 95.1 to 99.1% AR).
The maximum amount of carbon dioxide was 46.3% AR at study end (DAT 7.25). Formation of volatile organic compounds (VOC) was insignificant as demonstrated by values of < 0.1% AR at all sampling intervals.
Extractable residues decreased from DAT 0 to DAT 7.25 from 97.2 to 15.5% AR.
Non-extractable residues (NER) increased from DAT 0 to DAT 6 from 0.5 to 38.6% AR and decreased then slightly to 36.9% AR at DAT 7.25.
The amount of permethrin (sum of trans-permethrin and cis-permethrin) in the sludge extracts decreased from DAT 0 to DAT 7.25 from 95.0 to 7.4% AR. The amounts of trans-permethrin and cispermethrin decreased from DAT 0 to DAT 7.25 from 66.3 to 4.1% AR and from 28.7 to 3.3% AR, respectively.
Besides the formation of carbon dioxide, two degradation products were identified with the following maximum occurrence: trans-permethrin-OH with 8.6% AR at DAT 0.21 and cis-permethrin-OH with 11.3% AR at DAT 2. Both metabolites declined to the end of study, thus it is indicated that they are fast degradable in the activated sludge as well. From similarities to the very well-known metabolic pattern of deltamethrin the most reasonable position of hydroxyl group is the 4-hydroxy position.
The total unidentified residues amounted to a maximum of 10.3% AR, however, no single component exceeded 2.8% AR at any sampling interval.
The degradation of permethrin (sum of trans- and cis-permethrin) followed double first order in parallel (DFOP) kinetics based on lowest chi2 error values and visual assessments of fits. Individual analysis of normalized values for both isomers were best described using first order multi compartment (FOMC) kinetics for trans-permethrin and single first order (SFO) kinetics for cispermethrin. The DT_{50} values of permethrin in sludge BS under aerobic conditions at 22.5 °C were 0.46 days (for the sum of trans- and cis-permethrin), 0.29 days (for trans-permethrin) and 2.24 days (for cis-permethrin).
In addition, so-called distribution samples were prepared to investigate what portion of radioactivity and compounds might be present in the supernatant water that could be released into a water body after a distinct residence time in the biological cleaning step of a wastewater plant. Therefore, duplicate samples were processed and analyzed 2, 3 and 7.25 days after treatment (DAT). Water and sludge were separated by centrifugation and decantation, only. The amounts of test item and degradation products in the supernatant water were determined by liquid scintillation counting (LSC) and by HPLC/radio-detection analysis. Results showed that radioactivity in the supernatant water was rather low, i.e. ≤ 3.7% AR after 2 days of incubation, and it remained almost constant until end of the test after 7.25 days. The amount of permethrin (sum of trans-permethrin and cispermethrin) in the supernatant water was ≤ 0.5% AR after two days of incubation. The two permethrin-OH metabolites could not be found above the LOQ therein. The total unidentified residues amounted to a maximum of 3.5% AR and no single component exceeded 2.3% AR at any of the three selected wastewater cleaning cycles. In consequence, the release of permethrin or its residues with the wastewater effluent to the environment (e.g. to surface waters) is regarded very low.
In conclusion permethrin will be rapidly degraded in activated sludge under aerobic conditions. Formation of significant amounts of non-extractable residues and carbon dioxide indicates a participation in the natural carbon cycle and the potential for a complete mineralization of permethrin.
A strong reduction of permethrin content in normal biological cleaning cycles of a wastewater treatment plant was shown. This strong reduction was not only caused by adsorption of test item to solids, it was as well a result of significant degradation and entire mineralization of the test item by the activated sludge. Thus, a release of permethrin or its degradation products with the wastewater effluent to the environment (e.g. to surface water) is negligible.

CA-IT conclusions: OECD 314B Degradation in STP was discussed at ENV-WGVII2018 and during a subsequent *Ad hoc* follow up. It was concluded to be valid, but for the time being (June 2020) the final conclusions have not been agreed by the ENV-WG nor formalized at BPC level, yet. As a result, following to the comments received by some cMSs in the bilateral discussion of the MRP process, the study was not considered in the exposure assessment.

Leaching behaviour (ADS)

Not relevant under PT18.

Testing for distribution and dissipation in soil (ADS)

No other information is available respect to that is reported in section "2.2.8.1 Effects assessment on the environment".

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

No other information is available respect to that is reported in section "2.2.8.1 Effects assessment on the environment".

Testing for distribution and dissipation in air (ADS)

No other information is available respect to that is reported in section "2.2.8.1 Effects assessment on the environment".

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)

The biocidal product Clean Kill® is not sprayed near to surface waters.

Acute aquatic toxicity

Conclusion used in Risk Assessment – Acute aquatic toxicity	
Value/conclusion	Aquatic Acute 1 H400: Very toxic to aquatic life.
Justification for the value/conclusion	The classification system for mixtures covers all classification categories which are used for substances, i.e. categories Acute 1 and Chronic 1 to 4. In order to make use of all available data for purposes of classifying the aquatic environmental hazards of the mixture, the following is applied where appropriate: The 'relevant components' of a mixture are those which are classified 'Acute 1'or 'Chronic 1' and present in a concentration of 0.1 % (w/w) or greater, and those which are classified 'Chronic 2', 'Chronic 3' or 'Chronic 4' and present in a concentration of 1 % (w/w) or greater,

	unless there is a presumption (such as in the case of highly toxic components (see section 4.1.3.5.5.5 of CLP Regulation)) that a component present in a lower concentration can still be relevant for classifying the mixture for aquatic environmental hazards. Generally, for substances classified as 'Acute 1' or 'Chronic 1' the concentration to be taken into account is (0.1/M) %. The approach for classification of aquatic environmental hazards is tiered, and is dependent upon the type of information available for the mixture itself and for its components. Elements of the tiered approach include: - classification based on tested mixtures, - classification based on bridging principles, - the use of 'summation of classified components' and/or an 'additivity formula'. The classification of Clean Kill® was obtained as reported in section "4.1.3.5. Classification of mixtures when toxicity data are available for some or all components of the mixture", Annex I of CLP Regulation. Relevant toxicity data used are related to permethrin that is 0.25% in Clean Kill®. Toxicity data indicated clearly that acute exposure to permethrin is highly toxic to fish (0.0051 mg a.s./L (Bayer/Sumitomo)) and to aquatic invertebrates, with *Daphnia* 0.00127 mg a.s/L (Bayer/Sumitomo), being the most sensitive of the aquatic organisms tested. A definitive EC_{50} could not be derived from either of the algal studies due to the limited range of concentrations tested (due to solubility issues). Although the EC_{50} values are quite low (> 1.13 mg a.s./L (Bayer/Sumitomo)), they are in excess of the limit of water solubility.

Data waiving	
Information requirement	Acute aquatic toxicity
Justification	According to the specific adaptation rules described in Annex III of BPR, testing on the product was not conducted because there were valid data available on each of the components in the mixture sufficient to allow the classification according to the rules of CLP Regulation (EC) n. 1272/2008 and no synergistic effects between the components of the mixture were expected.

Chronic aquatic toxicity

Conclusion used in Risk Assessment- Chronic Aquatic toxicity	
Value/conclusion	Aquatic Chronic 1 H410: Very toxic to aquatic life with long lasting effects.
Justification for the value/conclusion	The classification system for mixtures covers all classification categories which are used for substances, i.e. categories Acute 1 and Chronic 1 to 4. In order to make use of all available data for purposes of classifying the aquatic environmental hazards of the mixture, the following is applied where appropriate: The 'relevant components' of a mixture are those which are classified 'Acute 1'or 'Chronic 1' and present in a concentration of 0.1 % (w/w) or greater, and those which are classified 'Chronic 2', 'Chronic 3' or 'Chronic 4' and present in a concentration of 1 % (w/w) or greater, unless there is a presumption (such as in the case of highly toxic components (see section 4.1.3.5.5.5 of CLP Regulation)) that a component present in a lower concentration can still be relevant for classifying the mixture for aquatic environmental hazards. Generally, for substances classified as 'Acute 1' or 'Chronic 1' the concentration to be taken into account is (0.1/M) %. (For explanation M-factor see section 4.1.3.5.5.5.) The approach for classification of aquatic environmental hazards is tiered, and is dependent upon the type of information available for the mixture itself and for its components. Elements of the tiered approach include: - classification based on tested mixtures, - classification based on bridging principles, - the use of 'summation of classified components' and/or an 'additivity formula'. The classification of Clean Kill® was obtained as reported in section "4.1.3.5. Classification of mixtures when toxicity data are available for some or all components of the mixture", Annex I of CLP Regulation. Relevant toxicity data used are related to permethrin that is 0.25% in Clean Kill®. Chronic exposure to permethrin was also highly toxic to the three groups of aquatic organisms, affecting reproduction and survival in fish and *Daphnia* (again, *Daphnia* was the most sensitive species; NOEC 0.0047 µg/L). Permethrin does not appear to have an endocrine affect in fish.

Data waiving	
Information requirement	Chronic aquatic toxicity
Justification	According to the specific adaptation rules described in Annex III of BPR, testing on the product was not conducted because there were valid data available on each of the components in the mixture sufficient to allow the classification according to the rules of CLP Regulation (EC) n. 1272/2008 and no synergistic effects between the components of the mixture were expected.

Aquatic bioconcentration

Conclusion used in Risk Assessment – Aquatic bioconcentration	
Value/conclusion	Permethrin does not meet the B or vB screening criteria.
Justification for the value/conclusion	Information on aquatic bioconcentration reported in the Assessment Report of permethrin has been used. In principle, the assessment of the (potential for) bioaccumulation in the context of the PBT assessment makes use of measured bioconcentration factors in marine or freshwater organisms. Where these are not available BCF values may be estimated from the octanol/water partition coefficient (Kow) using QSAR models. In addition, Kow values, either experimentally determined or estimated can be used directly to assess the potential for bioaccumulation. Bioaccumulation data from other species may also be used, based on evidence from specific laboratory tests or from field studies. A substance is considered to fulfil the B (bioaccumulative) criterion when the bioconcentration factor (BCF) exceeds a value of 2000 and the vB (very bioaccumulative) criterion when the BCF exceeds a value of 5000. The Log Kow and some of the estimated BCF values would indicate permethrin has a strong potential to bioconcentrate following uptake via water/porewater (e.g. in fish/worms) and subsequently bioaccumulate through the food chain, resulting in toxic concentrations in predatory birds or mammals ingesting biota containing the chemical. A study Spehar R.L., 1983, was carried out to assess the toxicity of the synthetic pyrethroid, permethrin, in early life-stages of fathead minnows and snails. This information is presented as a scientific peer-reviewed paper in Aquatic Toxicology Volume 3, Issue 2, February 1983, Pages 171–182. The BCF values reported were 2800 L/Kg for fathead minnows and 800 L/Kg for snails. Data is not lipid normalised and non- GLP. The specification isomeric ratio of permethrin was not given. This study triggered the applicant to include a more recent study, Burgess et. al. 1989. This 28-day bioconcentration study in fish, performed by BAYER/SUMITOMO,

	measured the BCF at only 570. Both this study and the Chironomid study showed that while permethrin does appear to accumulate rapidly in the tissues of these aquatic organisms, depuration following exposure cessation was also rapid in both cases. Therefore, *in vivo*, any bioaccumulated permethrin residues will most likely be readily eliminated from organisms. However, it should be noted that in the Bayer/Sumitomo 28-day flow through test, the lipid content was not normalised in Blugill sunfish. This could have the effect of underestimating the BCF value if the fish had a low lipid content. Likewise the two log Kow values submitted for permethrin, 4.6 Tagros and 6.1 Bayer Sumitomo, gave different BCF values when calculated using the log kow (equation 74 and 75 TGD). These two uncertainties should be recognized when reporting the BCF value of 570 L/kg. These findings and conclusions are supported by information gleaned from the literature, by Tagros, who stated that BCFfish values ranging from 290 – 620 have been reported in sheepshead minnows by WHO Permethrin EHC 94, (1990) and Hansen et al, (1983). Based on measured BCFfish and BCFchironomid values < 2000 it is concluded that permethrin does not meet the B or vB screening criteria.

Data waiving	
Information requirement	Aquatic bioconcentration
Justification	No data on Clean Kill®. Data suggest that permethrin does not meet the B or vB screening criteria.

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)

Not relevant for Clean Kill®, since only indoor use is intended.

Endocrine-distrupting properties for environment: screening for co-formulants

Conclusion of ED assessment for co-formulants

Screening of endocrine-distrupting properties of co-formulants has been performed using the information provided in the SDSs by the supplier of the substance and consulting reliable literature sources, according to the indications provided in "CG-34-2019-02 AP 16.5 e-consultation ED potential of co-formulants_final". The information sources consulted are detailed in the tables available in the Confidential Annex, where a brief

summary of the results is reported in the coloumn "Data/results". Complete reference sources are attached in the IUCLID dossier. Overall, based on available information it is concluded that the product does not contain co-formulants with endocrine distrupting properties for environment.

2.2.8.2 Exposure assessment

General information

The environmental exposure assessment has been performed in accordance with the emission scenario document for insecticides, acaricides and products to control arthropods (PT 18) for household and professional use (OECD, 2008) and was based on information relating to the use patterns of Clean Kill®.

Clean Kill® is a ready-to-use EW product, containing 0.25% w/w permethrin (as pure active substance), corresponding to 0.269% w/w (as technical grade active substance; min. purity: 93%). The product is for indoor use by non-professionals and was originally intended by the applicant for targeted spot application and for application in crack & crevice, by spraying via trigger sprayer.
The targeted spot application was no longer supported for authorization at the resolution step of the formal referral, which was initiated by several cMSs after the bilateral discussion during the MRP process. Only one use remained supported for authorization: **'Targeted spot application in crack & crevice'** on porous/non-porous surfaces at 50 mL product/m^2 by spraying via trigger sprayer with fixed capillary tube, to kill crawling insects (cockroaches, ants, silverfish, earwigs) and spiders, restricted to areas that are not wet cleaned and completely protected from water, like garages, cellars, attics, cavities, warehouses, electrical service rooms, boiler rooms.

Exposure assessment was performed on active substance permethrin; no substances of concern for the environment were identified in Clean Kill® (please, also refer to the separate confidential annex).

The main emission route of the product is via wastewater from sewage treatment plants after the cleaning of treated surfaces and/or applicators clothing. There are no direct emissions to surface water or sediment. Consequently, aquatic or sediment organisms are not directly exposed to the active substance.

Direct exposure of the air compartment is considered negligible. The half-life of permethrin in the trophosphere was calculated to be 0.701 d assuming a hydroxyl radical concentrations of 5 x 10^5 radicals/cm^3 (24 hr day). Therefore, permethrin is rapidly degraded by photochemical processes.

Soil and groundwater may be indirectly contaminated via the land application of sewage sludge. The concentration in porewater of agricultural soil has been calculated to provide an indication for potential groundwater contamination risk. All groundwater concentrations must be lower than the EU trigger value of 0.1 µg/L.

Three major metabolites (>10% AR) were observed in water-sediments systems:
2,-dimethyl-3-(2,2-dichorovinyl)-2,2-dimethylcyclopropane carboxylic acid (DCVA), 3-phenoxybenzoic acid (PBA) and PB alcohol.

In order to estimate potential environmental exposure to the major metabolites associated with losses to the wastewater compartment during the service life of Clean Kill®, it has been assumed that metabolites are formed at the point of emission (from $Clocal_{eff}$ and diluted by the default factor of 10) at a quantity equivalent to 100% of the parent adjusted to take into account differences in the molar masses of the compounds. These PECs represents an extreme worst-case estimate of surface water exposure as experimental data have shown that the metabolites are formed at only a fraction of the quantity of parent under a range of environmental conditions. PECs for the major sediment metabolites (> 10% AR) have been calculated from the surface water PECs using the equilibrium partitioning method.

DCVA and PB acid were observed at 11.3% AR and 15.0% AR in soil. It is difficult to predict the actual quantity of metabolites present in soil after sludge application, since the parent will potentially have been subject to transformation either in soil or in the sludge itself under very different environmental conditions. Initial concentrations of the metabolites in soil following application of sewage sludge to land were estimated on the worst-case assumption that the metabolite is formed in the sludge at a quantity equivalent to 100% of the parent (adjusted to take into account differences in the molar masses of the compounds). The concentrations arising in soil after 10 successive yearly applications of sludge was then calculated. Finally, the time weighted average concentration arising in soil was calculated in accordance with the Guidance on the Biocidal Products Regulation Volume IV Environment - Assessment and Evaluation (Parts B + C) Version 2.0 October 2017. The concentration in porewater of agricultural soil was calculated to provide an indication of potential groundwater contamination.

The emission estimation was calculated by means the European Union System for the Evaluation of Substances (EUSES 2.1.2). Full EUSES Reports are provided in annex.

Assessed PT	PT 18
Assessed scenario	Targeted spot application in crack and crevice
ESD(s) used	The environmental exposure assessment has been performed in accordance with the emission scenario document for insecticides, acaricides and products to control arthropods (PT 18) for household and professional use (OECD, 2008) and was based on information relating to the use patterns of Clean Kill®.
Distribution in the environment	Calculated based on Guidance on the Biocidal Products Regulation Volume IV Environment - Assessment and Evaluation (Parts B + C) Version 2.0 October 2017.
Groundwater simulation	The concentration in porewater of agricultural soil has been calculated to provide an indication for potential groundwater contamination risk.

Emission estimation

Formulation of Clean Kill®

Production of Clean Kill® is an industrial formulation process. Exposure estimation for the formulation of Clean Kill® was not performed since:

- releases into the environment can not take place from formulation process since in the formulation plants typically automated equipment is used to add the formulation ingredients and to fill the formulated product into the respective vessels (closed

systems). Since a close system is used no emission is expected; in any case eventual (i.e. accidental or due to manteinance) relases of the product are collected and managed as waste emissions from product formulation are considered less relevant (since potentially covered by other legislations) compared to emissions from the application - and in service phase of the product, as reported in "Guidance on the Biocidal Products Regulation, Volume IV Environment - Part B Risk Assessment, Version 1.0".

Fate and distribution in exposed environmental compartments

The main emission route of the product is via wastewater from sewage treatment plants after the cleaning of treated area and/or the applicators clothing. There are no direct emissions to surface water or sediment. Consequently, aquatic or sediment organisms are not directly exposed to the active substance. Direct exposure of the air compartment is considered negligible. The half-life of permethrin in the trophosphere was calculated to be 0.701 d assuming a hydroxyl radical concentrations of 5 x 10^5 radicals/cm^3 (24 hr day). Therefore, permethrin is rapidly degraded by photochemical processes. Soil and groundwater maybe indirectly contaminated via the land application of sewage sludge.

Calculated fate and distribution in the STP Simple Treat 4.0		
Compartment	Percentage [%] Scenario Targeted spot application in crack and crevice	Remarks
Air	0.0023	
Water	26.19	
Sludge	73.81	
Degraded in STP	0	

Proposals from the Applicant in the bilateral discussion phase

During the commenting phase of the MRP process, comments were received from some cMSs questioning the approach adopted for the ERA for the two uses originally intended by the Applicant (please, refer to the first draft PAR_Jan 2020 version).

In the subsequent bilateral discussion phase, the Applicant proposed to set the Fraction emitted to the applicator during application to 0.006 instead of 0.02 and the Fraction emitted to the floor during application to 0.124 instead of 0.11, according to ESD for PT18, p. 53, Table 3.3-3 "Emission factors to floor for the treatment of surfaces depending on the device used". Values used corresponds to the type of sprayer for surface treatment with a trigger spray. According to ESD (p. 54), in the case where the insecticide product is dedicated to a unique mode of application, the specific emission factors in Table 3.3-1, Table 3.3-2, and Table 3.3-3, related to this mode of application, can be used. In addition, the Applicant proposed to restrict the application of the product in areas where wet cleaning is not carried out and set the cleaning efficiency FCE to 0. However, the proposed refinement was not accepted by some cMSs.
Since the risk assessment showed an unacceptable risk for surface water and sediment, in agreement with the applicant, to contain the environmental exposure the following restriction of use was proposed by the refMS-IT: 'Apply the product only in areas that are not wet cleaned and completely protected from water, like garages, cellars, attics, cavities, warehouses, electrical service rooms, boiler rooms.' The RMM 'Do not wet clean the

treated surfaces or surrounding areas' was also proposed (please, refer to the April 2020 version of the draft PAR).
The above combination 'restriction of use/RMM' was deemed still insufficient to mitigate the risk to the aquatic compartment and a formal referral was initiated by some cMSs.

Revised exposure assessment as agreed at the resolution step of the formal referral

The use as targeted spot application, though originally intended by the applicant, was no longer supported at the resolution step of the formal referral.

The Applicant eventually supported for authorization the '**Targeted spot application in crack & crevice'** on porous/non-porous surfaces at 50 mL product/m^2 by spraying via trigger sprayer with fixed capillary tube, to kill crawling insects (cockroaches, ants, silverfish, earwigs) and spiders, restricted to areas that are not wet cleaned and completely protected from water, like garages, cellars, attics, cavities, warehouses, electrical service rooms, boiler rooms.
The following RMMs were agreed: '**Do not apply to areas susceptible to wet cleaning**' and '**Do not use in kitchens or bathrooms**'.
Based on these RMMs and considering that the application by trigger sprayer with capillary tube allows the correct application of the product into the crack/crevice, in the exposure evaluation the fraction to treated surfaces and to floor have been set to zero and only emissions to the applicator clothing have been considered.
The following input parameters were considered: FCE was set to 0.25 (for crack & crevice application), both the fraction emitted to floor and to treated surface were set to 0 considering the RMMs and the application with fixed capillary tube, whereas the fraction emitted to the applicator was set to 0.006, as provided for in cases where the insecticide product is dedicated to a unique mode of application [specific emission factors related to this mode of application can be used according to ESD PT18, p. 50 "Hand-held trigger spray (surface treatment)].

The proposal was accepted at the resolution step of the formal referral specifically for Clean Kill®. Revised calculations are presented as follows.

Scenario 'Targeted spot application in crack & crevice' by spraying via trigger sprayer with fixed capillary tube (50 mL product/m^2, porous/non-porous surfaces)

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
General			
Fraction of active ingredient	0.002688	-	technical grade of a.s.
Surface or air space treatment	Surface treatment (area)	-	
Application scope	Targeted spot application		
Treatment rate, amount of product per area	0.1354752	g/m^2	As g of active substance per area (50.4* g/m^2 x 0.2688/100)
Area of treated surface, house	2	m^2	Default value for spot or crack and crevice treatment for domestic house in 2 m^2 as stated in the ESD. The default value for barrier treatment for a domestic house is 20 m^2. Agreed in MOTA v.6.
Preparation (mixing and loading)			
Number of preparation per day, house	1	-	-
Applied dose	50 50.4	ml/m^2 g/m^2	50 mL product/m^2 = 50.4 g product/m^2 (product density: 1.0083 g/mL).
Quantity of product used per preparation, house	100.8	g	Calculated as: 0.1354752 g/m^2 × 2 m^2 = 0.2709504 g/m^2 100 × 0.2709504/ 0.2688 = 100.8 g
Type of formulation	Liquid	-	-
Type of container	1 Liter		
Fraction emitted to air during mixing and loading	0	-	Default value.
Fraction emitted to the applicator during mixing and loading	0.0012	-	Default value.
Fraction emitted to the floorcator during mixing and loading	0.001	-	Default value.
Application			
Number of applications per day, house	1	-	As reported in ESD.

Number of applications per year	1-2	Appl/year	SPC
Quantity of product used per application, house	100.8	-	Calculated: 50.4 g/m^2 x 2 m^2
Fraction emitted to air during application	0.02	-	*In the case where the insecticide product is dedicated to a unique mode of application, specific emission factors related to this mode of application should be used. According to ESD for PT18 table 3.3.1 pg 50. ** Do not apply to areas susceptible to wet cleaning
Fraction emitted to the applicator during application	0.006*	-	
Fraction emitted to the floor during application	0**	-	
Fraction emitted to treated surfaces during application	0	-	
Cleaning			
Washable or disposable applicators	washable	1	Fraction emitted to solid waste from applicator = 0 Fraction emitted to wastewater from applicator = 1
Cleaning method for treated surfaces	Other methods	-	Fraction emitted to solid waste from cleaning treated surfaces = 0 Fraction emitted to wastewater from cleaning treated surfaces = 1
Cleaning efficiency	25	%	According to Table 3.3-8 and TAB-entries ENV 144 and 149 of the TAB (Vers. 2.1 (2019))
Number of houses per STP	4000	-	For indoor use a number of 4000 households will be used as default. Agreed in MOTA v.6.
Simultaneity factor	0.2042	%	Calculated from Table on page 39 of ESD PT18. Frequency of use is 1-2 time per year.

Calculations

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission (Elocal$_{compartment}$) [kg/d]**	**Remarks**
Wastewater	1.65 x 10^{-5}	50 mL/m^2

Main input parameters according to the Guidance on the Biocidal Products Regulation Volume IV Environment - Assessment and Evaluation (Parts B + C) Version 2.0 October

2017 used for calculating the fate and distribution in the environment are reported in the table below.

Input parameters for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	391.29	g/mol	-
Melting point	35	°C	-
Boiling point	305	°C	-
Vapour pressure (at 20°C)	$2.155 \cdot 10^{-6}$	Pa	-
Water solubility (at 20°C)	0.18	mg/L	
Log Octanol/water partition coefficient	4.67	Log 10	at 25°C
Organic carbon/water partition coefficient (Koc)	26930	L/kg	arithmetic mean, n=10
Henry's Law Constant (at 25 °C)	$4.5 \cdot 10^{-2}$	$Pa/m^3/mol$	-
Biodegradability	Not readily biodegradable	-	
Rate constant for biodegradation STP	0	(h^{-1})	
DT_{50} for biodegradation in surface water	4.4	d (at 12ºC)	Tagros dataset, worst case.
DT_{50} for hydrolysis in surface water	365	d (at 12ºC)	Tagros dataset. pH from 3.0/4.0 to 7.6/7.
DT_{50} for photolysis in surface water	$6.42 \cdot 10^{5}$	d	Experimental rate constant for photolysis in surface water is not available in Tagros dataset. Tagros reported a calculation with ABIWAS programme, assuming quantum yield equals one, and using molar absorption coefficients obtained from UV/Vis study on 25/75 cis/trans permethrin. Estimated theoretical half-lives (for latitude 55°N) range from $6.42 \cdot 10^{5}$ days (July) to $3.35 \cdot 10^{14}$ days (December).
DT_{50} for biodegradation in aerated sediment	46.7	d (at 12ºC)	According to assessment report of active substance in absence of specific DT_{50} for sediment it is considered that comparison of whole-

			system degradation values with the trigger value for sediment is appropriate in this case, since adsorption data indicate that permethrin partitions very strongly to sediment.
Total rate constant for degradation in bulk sediment	467	d (at 12ºC)	Value for 25:75 cis:trans ratio of permethrin not available. Value calculated by EUSES has been used.
DT_{50} for biodegradation in soil	106	d (at 12ºC)	geometric mean, n=5 at 12 °C
DT_{50} for degradation in air	0.701	d	-

Calculated PEC values

PEC values for permethrin for 'Targeted spot application in crack & crevice' on porous/non-porous surfaces at 50 mL product/m^2 by spraying via trigger sprayer with fixed capillary tube, as calculated using EUSES 2.1.2 (see paragraph 3.2 Output tables from exposure assessment tools – Environment), are showed in the table below.

PEC	**Unit**	**Scenario 'Targeted spot application in crack & crevice' (porous/non-porous surfaces, 50 mL product/m^2, trigger sprayer with fixed capillary tube)**
PEC_{STP}	mg/L	2.28×10^{-6}
PEC_{water}	mg/L	2.19×10^{-7}
PEC_{sed}	mg/kgwwt	2.28×10^{-4}
$PEC_{agric.\ soil}$ (averaged over 30 days)	mg/kgwwt	2.22×10^{-5}
$PEC_{agric.\ soil}$ (averaged over 180 days)	mg/kgwwt	1.44×10^{-5}
$PEC_{grassland}$ (averaged over 180 days)	mg/kgwwt	5.74×10^{-6}
$PEC_{groundwater}$	mg/L	3.02×10^{-8}
PEC_{air}	mg/m^3	1.15×10^{-15}

PEC values for the metabolites DCVA and PBA are detailed in section 2.2.8.3 Risk characterisation.

Primary and secondary poisoning

Primary poisoning

According to OECD Emission Scenario Document for PT18 primary poisoning for birds or mammals, i.e. the direct consumption of insecticide by birds or mammals may mainly occur in the following cases:
- insecticides are applied together with food attractant, or
- insecticides are applied as granular formulation.
Therefore, for Clean Kill® primary poisoning assessment for birds or mammals is not relevant.

Secondary poisoning

The log Kow of permethrin was calculated as 4.67: 99% technical a.s. 25:75 indicating it is a fat-soluble molecule with a potential to bioconcentrate following uptake via water/porewater (e.g. in fish/worms) leading to secondary poisoning. The bioconcentration factors recorded in a 28 day bioconcentration study with permethrin in Bluegill sunfish measured 500-570 L/kg. Data obtained during the subsequent depuration phase indicate removal of residues from whole fish, with time to 50% depuration of 4.7 days.

PEC oral,predator/PNEC oral ratios (for permethrin and relevant metabolites) were then determined, according to the Guidance for BPR: Vol. IV Part B+C (2017), for fish-eating mammals and birds and for earthworm eating mammals and birds to demonstrate that there is no unacceptable risk of secondary poisoning following the appropriate use of permethrin.

2.2.8.3 Risk characterisation

Revised risk characterization following the revised exposure assessment as agreed at the resolution step of the formal referral

The risk characterization ratios for the two scenarios as originally intended by the applicant proved to be higher than 1 for surface water and sediment, indicating an unacceptable risk for the aquatic compartment (please, refer to the April 2020 version of the draft PAR). The exposure refinements proposed by the applicant in the discussion phase of the MRP process were not accepted by some cMSs and a formal referral was initiated.
The use as targeted spot application was no longer supported at the resolution step of the formal referral.
The Applicant eventually supported for authorization the '**Targeted spot application in crack & crevice'** on porous/non-porous surfaces at 50 mL/m^2 by spraying via trigger sprayer with fixed capillary tube, to kill crawling insects (cockroaches, ants, silverfish, earwigs) and spiders, restricted to areas that are not wet cleaned and completely protected from water, like garages, cellars, attics, cavities, warehouses, electrical service rooms, boiler rooms. The following RMMs were proposed: '**Do not apply to areas susceptible to wet cleaning**' and '**Do not use in kitchens or bathrooms**'.

The risk assessment for the private use of Clean Kill® as 'Targeted spot application in crack & crevice' by spraying via trigger sprayer with fixed capillary tube (porous/non-porous surfaces, 50 mL product/m^2) is reported as follows.

Atmosphere

The low vapour pressure and Henry's Law constant of the active substance permethrin ($K > 4.5 \times 10^{-2}$ Pa · m^3 · mol^{-1}) indicate that loss of permethrin in the atmosphere will be negligible.

Sewage treatment plant (STP)

PEC / PNEC ratios are reported in Table below.

Use	PEC (mg/L)	PNEC (mg/L)	PEC / PNEC
50 mL/m^2	2.28×10^{-6}	0.00495	0.0004

Conclusion

PECs for STP were not calculated for DCVA, PBA or PB alcohol. The applicant for the active substance did not consider metabolites in the exposure assessment submitted to the eCA. No data are available concerning the formation of these metabolites from residual deposits of permethrin in areas treated with Clean Kill®. No data is available to reliably estimate the potential formation of the metabolites in STPs.

It is also difficult to predict the actual quantity of metabolites present in wastewater after cleaning of treated area, since the parent will potentially have been subject to transformation either *in situ* or in the STP itself under very different environmental conditions.

In order to estimate potential environmental exposure to the major metabolites associated with losses to the wastewater compartment during the service life of Clean Kill®, it has been assumed that metabolites are formed at the point of emission i.e. surface water (from $C_{localeff}$ and diluted by the default factor of 10) at a quantity equivalent to 100% of the parent adjusted to take into account differences in the molar masses of the compounds.

Risk characterisation ratios for STP calculated for permethrin is below 1, indicating no unacceptable risk for microorganisms of the sewage treatment plant.

Aquatic compartment

Surface water

Due to the intended indoor use, there are no direct emissions of permethrin to surface water. The exposure of surface water is indirect via STP effluents.

Permethrin

Use	PEC (mg/L)	PNEC (mg/L)	PEC / PNEC
50 mL product/m^2	2.19×10^{-7}	4.7×10^{-7}	0.47

Risk characterisation ratio for surface water calculated for permethrin is lower than 1, indicating no unacceptable risk to the aquatic organisms during the use of the product.

DCVA

In order to estimate potential environmental exposure to the metabolite DCVA it has been assumed that DCVA is formed at the point of emission (from $C_{localeff}$ and diluted by the default factor of 10) at a quantity equivalent to 100% of the parent adjusted to take into account differences in the molar mass of the compound.
This PEC represents an extreme worst-case estimate of surface water exposure as experimental data have shown that the metabolites (i.e. DCVA and PBA) are formed at only a fraction of the quantity of parent under a range of environmental conditions.

Calculations:

PEC surface water permethrin = 2.19 x 10^{-7} mg a.s./L (50 mL product/m^2)

PEC surface water DCVA = (PEC surface water permethrin x molecolar weight DCVA)/ molecolar weight permethrin

MW DCVA = 209.1 g/mol
MW permethrin = 391.29 g/mol

Use	**PEC**	**PNEC**	**PEC / PNEC**
50 mL product /m^2	1.17 x 10^{-7} mg/L	0.015 mg/L	<< 0.001

Risk characterisation ratio for surface water calculated for DCVA is below 1, indicating no unacceptable risk to aquatic organisms for the environmental emission scenario.

PBA

In order to estimate potential environmental exposure to metabolite PBA, it has been assumed that PBA is formed at the point of emission (from $C_{localeff}$ and diluted by the default factor of 10) at a quantity equivalent to 100% of the parent adjusted to take into account differences in the molar mass of the compound.
This PEC represents an extreme worst-case estimate of surface water exposure as experimental data have shown that the metabolites (i.e. DCVA and PBA) are formed at only a fraction of the quantity of parent under a range of environmental conditions.

Calculations:
PEC surface water permethrin = 2.19 x 10^{-7} mg a.s./L (50 mL product/m^2)

PEC surface water PBA = (PEC surface water permethrin x molecular weight PBA)/ molecular weight permethrin

MW PBA = 214.22 g/mol
MW permethrin = 391.29 g/mol

Use	**PEC**	**PNEC**	**PEC / PNEC**
50 mL product /m^2	1.20 x 10^{-7} mg/L	> 0.010 mg/L	<< 0.001

Risk characterisation ratio for surface water calculated for PBA is below 1, indicating no unacceptable risk to aquatic organisms for the environmental emission scenario.

Sediment

Due to the intended use, there are no direct emissions of permethrin to sediments. The exposure to sediment is indirect via STP effluents.

Permethrin

Use	PEC (mg/kg wwt)	PNEC (mg/kg wwt)	PEC / PNEC
50 mL product /m^2	1.28 x 10^{-4}	2.17 x 10^{-4}	0.59

Risk characterisation ratio for sediment calculated for permethrin is lower than 1, indicating no unacceptable risk to the sediment organisms during the use of the product.

DCVA

PEC for the metabolite DCVA has been calculated from the surface water PEC using the equilibrium partitioning method.

Calculation was performed by means EUSES 2.1.2 using as input PEC surface water of DCVA (1.17 x 10^{-7} mg/L) and Kfoc for DCVA of 93.2 L/kg.

Use	PEC	PNEC	PEC / PNEC
50 mL product /m^2	3.29 x 10^{-7} mg/kg wwt	0.012 mg/kg wwt	<< 0.001

Risk characterisation ratio for sediment calculated for DCVA is below 1, indicating no unacceptable risk to sediment for the environmental emission scenario.

PBA

PECs for the metabolite PBA have been calculated from the surface water PECs using the equilibrium partitioning method.

Calculation was performed by means EUSES 2.1.2 using as input PEC surface water of PBA (1.20 x 10^{-7} mg/L) and Kfoc for PBA of 141.2 L/kg.

Use	PEC	PNEC	PEC / PNEC
50 mL product /m^2	4.50 x 10^{-7} mg/kg wwt	0.009 mg/kg wwt	<< 0.001

Risk characterisation ratio for sediment calculated for PBA is below 1, indicating no unacceptable risk to sediment for the environmental emission scenario.

Overall conclusion for the aquatic compartment

Risk characterisation ratios for surface water and sediment calculated for permethrin and its metabolites for 'Targeted spot application in crack & crevice' by spraying via trigger sprayer with fixed capillary tube (porous/non-porous surfaces, 50 mL product/m^2) are lower than 1, indicating no unacceptable risk to the aquatic compartment when the RMMs & IFU proposed are considered, as agreed specifically for Clean Kill® at the resolution step of the formal referral.

Terrestrial compartment

Soil

Indirect exposure to the soil compartment can occur through application of sewage sludge from a sewage treatment plant. Exposure estimation has been performed using EUSES.
Three different PECs soil were generated:

- PEC in local soil for comparison against terrestrial ecosystem endpoints (for the terrestrial ecosystem the concentration is averaged over 30 days),
- PEC in agricultural soil for comparison against crop endpoints for human consumption (for human indirect exposure a period of 180 days is used)
- PEC in grassland soil for comparison against endpoints in grass for cattle.

Permethrin

Use	PEC (mg/kg wwt)	PNEC (mg/kg wwt)	PEC / PNEC
50 mL product/m^2	PEC in local soil 2.22×10^{-5}	0.175	<< 0.001
	PEC in agricultural soil 1.44×10^{-5}		<< 0.001
	PEC in grassland soil 5.74×10^{-6}		<< 0.001

Conclusion

Risk characterisation ratios calculated for permethrin for all types of soils are below 1, indicating no unacceptable risk to terrestrial organisms during the use of the product.

DCVA

In order to estimate potential environmental exposure to the metabolite DCVA it has been assumed that DCVA is formed at the point of emission (from $C_{localeff}$ and diluted by the default factor of 10) at a quantity equivalent to 100% of the parent adjusted to take into account differences in the molar mass of the compound.
This PEC represents an extreme worst-case estimate of soil exposure as experimental data have shown that the metabolites (i.e. DCVA and PBA) are formed at only a fraction of the quantity of parent under a range of environmental conditions.

Calculations:
PECsoil permethrin = 1.44×10^{-5} mg a.s./kg (50 mL product/m^2)

PEC surface water DCVA = (PEC surface water permethrin x molecular weight DCVA)/ molecular weight permethrin

MW DCVA = 209.1 g/mol
MW permethrin = 391.29 g/mol

Use	PEC	PNEC	PEC / PNEC
50 mL product /m^2	7.70 x 10^{-6} mg/kg wwt	4.6 mg/kg wwt	<< 0.001

Conclusion

Risk characterisation ratio for soil calculated for DCVA is below 1, indicating no unacceptable risk to soil organisms for the environmental emission scenario.

PBA

In order to estimate potential environmental exposure to metabolite PBA it has been assumed that PBA is formed at the point of emission (from $C_{localeff}$ and diluted by the default factor of 10) at a quantity equivalent to 100% of the parent adjusted to take into account differences in the molar mass of the compound.
This PEC represents an extreme worst-case estimate of soil exposure as experimental data have shown that the metabolites (i.e. DCVA and PBA) are formed at only a fraction of the quantity of parent under a range of environmental conditions.

Calculations:
PECsoil permethrin = 1.44 x 10^{-5} mg a.s./kg (50 mL product /m^2)

PECsoil PBA = (PECsoil permethrin x molecolar weight PBA)/ molecolar weight permethrin

MW PBA = 214.22 g/mol
MW permethrin = 391.29 g/mol

Use	PEC	PNEC	PEC / PNEC
50 mL product /m^2	7.88 x 10^{-6} mg/kg wwt	1.44 mg/kg wwt	<< 0.001

Conclusion

Risk characterisation ratio for soil calculated for PBA is below 1, indicating no unacceptable risk to soil organisms for the environmental emission scenario.

Overall soil conclusion

The risk ratios for soil organisms were calculated using the most conservative PEC and PNEC values.
No unacceptable risks to soil from permethrin and its metabolites were identified.

Groundwater

The concentration of permethrin in porewater of agricultural soil has been calculated to provide an indication for potential groundwater contamination risk.

PEC	Unit	Scenario
$PEC_{groundwater}$ 50 mL product/m^2	µg/L	3.02 x 10^{-5}

The groundwater concentration of permethrin is below the EU trigger value of 0.1 µg/L.

Primary and secondary poisoning

Primary poisoning

According to OECD Emission Scenario Document for PT18 primary poisoning for birds or mammals, i.e. the direct consumption of insecticide by birds or mammals may mainly occur in the following cases:
- insecticides are applied together with food attractant, or
- insecticides are applied as granular formulation.

Therefore, for Clean Kill® primary poisoning assessment for birds or mammals is not relevant.

Secondary poisoning

To assess the secondary poisoning the *Guidance on the Biocidal Products Regulation Volume IV Environment - Assessment and Evaluation (Parts B + C) Version 2.0 October 2017* was followed, which has adapted the Technical Guidance Document on Risk Assessment Part II (EU-TG, 2003) to references and contents of the BPR.
The general approach is based on a comparison of the (predicted) concentration in the food of the top predators and the (predicted) no-effect concentration of these predators which is based on studies with laboratory animals.

Non-compartment specific effects relevant to the food chain

A predicted no effect oral concentration (PNECoral) can be calculated based on the results of the mammalian and avian repeat dose toxicity tests. The result of this calculation gives a predicted no-effect concentration in food that should be protective to other mammalian and avian species.
According to the to the criteria given in *Guidance on BPR Vol IV*, secondary poisoning effects on bird populations rarely become manifested in short-term studies. Therefore, results from long-term studies are strongly preferred, such as NOECs for mortality, reproduction or growth. Considering a one-generation study with the Northern Bobwhite (Colinus virginianus) (Beavers, J.; 1992) performed to GLP standards according to FIFRA guideline 71-4, the lowest NOEC exceeds 500 ppm. Taking into account a safety factor of 30 (as indicated in Table 25 of the *Guidance on BPR Vol IV*, page 161), a PNECbird of 16.7 mg/kg food is obtained.

According to the criteria given in *Guidance on BPR Vol IV*, secondary poisoning effects on mammal populations rarely become manifested in short-term studies. Therefore, results from long-term studies are strongly preferred, such as NOECs for mortality, reproduction or growth. Considering the reproduction study conducted in rats with permethrin (3 generation study), the NOAEL was set at 180 mg/kg bw/d. For the assessment of secondary poisoning, the results always have to be expressed as the concentration in food. Where toxicity data are presented only as NOAELs, these NOAELs can be converted to NOECs with the following two formulae:

$$NOEC_{mammal,food\_chr} = NOAEL_{mammal,oral\_chr} \cdot CONV_{mammal}$$

A conversion factor ($CONV_{mammal}$) of 20 is selected from Table 24 page 160 as the 3 generation study was conducted with rats aged 6 weeks at the initiation of the study. The $NOEC_{mammal.food\_chr}$ is hence calculated to be 3600 ppm.

Taking into account a safety factor of 30 (as indicated in Table 25), a PNECsmall mammal of 120 mg/kg food is obtained.

PNECoral bird ≥16.7 mg a.s./kg food
PNECoral small mammal = 120 mg a.s./kg food

According to the *Guidance on BPR Vol IV,* a calculation for PECoralpredator should be conducted if the a.s. shows a potential for bioaccumulation, indicated by a log Kow value >3. Since permethrin has a slight potential for bioaccumulation (log Kow of 4.5) the calculation of a possible risk to man via the food chain was conducted in compliance with the aforementioned guidance.
The concentration of a contaminant in food (fish) of fish-eating predators (PECoralpredator) is derived from the PEC for surface water, the measured BCF for fish (see Document II-A, section 4.1.3 for details) and the biomagnification factor (BMF). Since the log Kow of permethrin is 4.5 and a measured BCF for permethrin in Bluegill sunfish was reported at 500-570 L/kg the default BMF of 1 is used in the calculation (Table 23). The calculation of PECoralpredator is presented below.

Aquatic Compartment (including Risk characterisation for fish eating organisms)

Calculating Risk to Fish Eating Predator – Permethrin - Targeted spot application in crack & crevice (50 mL product/m^2)

Calculation of the predicted environmental concentration of permethrin in food (cf. Equation 95).

Parameter	Definition	Value
Local concentration of permethrin in surface water [mg/L]	Clocal water	2.19×10^{-7}
Bioconcentration factor in fish	BCF	500-570 L/kg
Biomagnification factor	BMF	1
Predicted concentration of permethrin in food of the predator [mg/kg]	$PEC_{oral,\ predator} = PEC_{water} \times BCF_{fish} \times BMF$	1.25×10^{-4}

The calculation for $PEC_{oral,\ predator}$ as an indicator for possible secondary poisoning, resulted in a PEC value of 0.12 µg/kg.

PEC/PNEC ratio for fish eating birds:

Compartment	$PEC_{oral\ predator}$ (µg/kg)	$PNEC_{oral}$ (µg/kg)	PEC/PNEC
Biota	5.93	16700	7.47×10^{-7}

PEC/PNEC ratio for fish eating mammals:

Compartment	$PEC_{oral\ predator}$ (µg/kg)	$PNEC_{oral}$ (µg/kg)	PEC/PNEC
Biota	5.93	120000	1.04×10^{-6}

Calculating Risk to Fish Eating Predator – DCVA - Targeted spot application in crack & crevice (50 mL product/m²)

Calculation of the predicted environmental concentration of DCVA in food (cf. Equation 95).

Parameter	Definition	Value
Local concentration of DCVA in surface water [mg/L]	Clocal water	1.17×10^{-7}
Bioconcentration factor in fish	BCF	500-570 L/kg
Biomagnification factor	BMF	1
Predicted concentration of DCVA in food of the predator [mg/kg]	$PEC_{oral,\ predator} = PEC_{water} \times BCF_{fish} \times BMF$	6.67×10^{-5}

The calculation for $PEC_{oral,\ predator}$ as an indicator for possible secondary poisoning, resulted in a PEC value of 0.067 µg/kg for DCVA.

PEC/PNEC ratio for fish eating birds:

Compartment	$PEC_{oral\ predator}$ (µg/kg)	$PNEC_{oral}$ (µg/kg)	PEC/PNEC
Biota	0.067	16700	3.99×10^{-6}

PEC/PNEC ratio for fish eating mammals:

Compartment	$PEC_{oral\ predator}$ (µg/kg)	$PNEC_{oral}$ (µg/kg)	PEC/PNEC
Biota	0.067	120000	5.56×10^{-7}

Calculating Risk to Fish Eating Predator – PBA - Targeted spot application in crack & crevice (50 mL/m²)

Calculation of the predicted environmental concentration of PBA in food (cf. Equation 95).

Parameter	Definition	Value
Local concentration of PBA in surface water [mg/L]	Clocal water	1.20×10^{-7}
Bioconcentration factor in fish	BCF	500-570 L/kg
Biomagnification factor	BMF	1
Predicted concentration of PBA in food of the predator [mg/kg]	$PEC_{oral,\ predator} = PEC_{water} \times BCF_{fish} \times BMF$	6.84×10^{-5}

The calculation for $PEC_{oral,predator}$ as an indicator for possible secondary poisoning, resulted in a PEC value of 0.068 µg/kg for PBA.

PEC/PNEC ratio for fish eating birds:

Compartment	$PEC_{oral\ predator}$ (µg/kg)	$PNEC_{oral}$ (µg/kg)	PEC/PNEC
Biota	0.068	16700	4.01×10^{-6}

PEC/PNEC ratio for fish eating mammals:

Compartment	$PEC_{oral\ predator}$ (µg/kg)	$PNEC_{oral}$ (µg/kg)	PEC/PNEC
Biota	0.068	120000	5.70×10^{-7}

Permethrin
Comparing these values to the calculated PEC oral, predator 0.12 µg/kg wet fish it can be determined that there is no unacceptable risk for fish-eating birds and mammals. By comparing the PECoral predator with the respective PNECs, PEC/PNEC ratios are below one for birds and mammals, indicating no unacceptable risk for fish-eating birds and mammals.

DCVA
Comparing these values to the calculated PEC oral, predator 0.067 µg/kg for wet fish it can be determined that there is no unacceptable risk for fish-eating birds and mammals. By comparing the PECoral predator with the respective PNECs, PEC/PNEC ratios are below one for birds and mammals, indicating no unacceptable risk for fish-eating birds and mammals.

PBA
Comparing these values to the calculated PEC oral, predator 0.068 µg/kg wet fish it can be determined that there is no unacceptable risk for fish-eating birds and mammals. By comparing the PECoral predator with the respective PNECs, PEC/PNEC ratios are below one for birds and mammals respectively, indicating no unacceptable risk for fish-eating birds and mammals.

Terrestrial Compartment (including risk characterisation for earthworm eating organisms)

Calculated Risk to Worm Eating Predators

It is accepted that substances adsorbed to soil particles can be ingested and may bioaccumulate in worms. Since birds and mammals consume worms and the gut of earthworms can contain substantial amounts of soil, the exposure of the predators may be affected by the quantity of active substance that is present in this soil.

The total concentration in an entire worm can be calculated as the weighted average of the worm's tissues (through BCF and pore water) and guts contents (through soil concentration). A quantitative risk characterisation for secondary poisoning in the terrestrial compartment (for the food chain soil → earthworm → worm-eating birds or mammals) has been performed below for completeness sake.

$PNEC_{oral}$ derivation:
$PNEC_{oral}$ bird ≥16.7 mg a.s./kg food
$PNEC_{oral}$ small mammal = 120 mg a.s./kg food

Permethrin

$PEC_{oral,\ predator}$ derivation:
The calculation method described in the *Guidance on BPR Vol IV* was used to determine the $PEC_{oral,\ predator}$ for earthworm eating predators as:

Based on Equation 10, the concentration of permethrin in an entire worm is:

$$C_{earthworm} = [(BCF_{earthworm} \times C_{porewater}) + (C_{soil} \times F_{gut} \times CONV_{soil})] / [1 + (F_{gut} \times CONV_{soil})]$$

$BCF_{earthworm}$ = 15108 L/kg

$C_{porewater}$ = 3.02 x 10^{-8} mg/L (EUSES 2.1.2)
C_{soil} = 1.44 x 10^{-5} mg/kg wwt soil corresponding to local PEC in agricultural soil.
F_{gut} = 0.1 (*Guidance on BPR Vol IV*, page 163)

$CONV_{soil}$ = RHOsoil / (Fsolid x RHOsolid) = 1700 / (0.6 x 2500) = 1.13.

Permethrin $PEC_{oral,\ predator}$ = 4.11 x 10^{-4} mg/kg wet earthworm ($C_{earthworm}$)

Risk characterisation for earthworm-eating birds:
The risk to the earthworm-eating birds is calculated as the ratio between the concentration in their food ($PEC_{oral,\ predator}$) and the no-effect-concentration for oral intake ($PNEC_{oral}$) as follows:
$PEC_{oral,\ predator}$/ $PNEC_{oral}$ = 4.11 x 10^{-4}/16.7 = 2.46 x 10^{-5}

Risk characterisation for earthworm-eating mammals:
The risk to the earthworm-eating mammals is calculated as the ratio between the concentration in their food (PECoral, predator) and the no-effect-concentration for oral intake (PNECoral) as follows:
$PEC_{oral,\ predator}$/ $PNEC_{oral}$ = 4.11 x 10^{-4}/120 = 3.43 x 10^{-6}

DCVA

Based on the following equation, the concentration of DCVA in an entire worm is:

$C_{earthworm} = [(BCF_{earthworm} \times C_{porewater}) + (C_{soil} \times F_{gut} \times CONV_{soil})] / [1 + (F_{gut} \times CONV_{soil})]$

BCF $_{earthworm}$ = 15108 L/kg
$C_{porewater}$ = 1.61 x 10^{-8} mg/L
C_{soil} = 7.70 x 10^{-6} mg/kg wwt soil corresponding to local PEC in agricultural soil.
F_{gut} = 0.1 (*Guidance on BPR Vol IV,* page 163)
$CONV_{soil}$ = RHOsoil / (Fsolid x RHOsolid) = 1700 / (0.6 x2500) = 1.13.

DCVA $PEC_{oral,\ predator}$ = 2.19 x 10^{-4} mg/kg wet earthworm ($C_{earthworm}$)

Risk characterisation for earthworm-eating birds:
The risk to the earthworm-eating birds is calculated as the ratio between the concentration in their food ($PEC_{oral,\ predator}$) and the no-effect-concentration for oral intake ($PNEC_{oral}$) as follows:
$PEC_{oral,\ predator}$/ $PNEC_{oral}$ = 2.19 x 10^{-4}/16.7 = 1.31 x 10^{-4}

Risk characterisation for earthworm-eating mammals:
The risk to the earthworm-eating birds is calculated as the ratio between the concentration in their food ($PEC_{oral,\ predator}$) and the no-effect-concentration for oral intake ($PNEC_{oral}$) as follows:
$PEC_{oral,\ predator}$/ $PNEC_{oral}$ = 2.19 x 10^{-4}/120 = 1.83 x 10^{-6}

PBA

Based on the following equation, the concentration of PBA in an entire worm is:

$C_{earthworm} = [(BCF_{earthworm} \times C_{porewater}) + (C_{soil} \times F_{gut} \times CONV_{soil})] / [1 + (F_{gut} \times CONV_{soil})]$

BCF $_{earthworm}$ = 15108 L/kg
$C_{porewater}$ = 1.65 x 10^{-8} mg/L
C_{soil} = 7.88 x 10^{-6} mg/kg wwt soil corresponding to local PEC in agricultural soil.
F_{gut} = 0.1 (*Guidance on BPR Vol IV*, page 163)
$CONV_{soil}$ = RHOsoil / (Fsolid x RHOsolid) = 1700 / (0.6 x 2500) = 1.13.

PBA $PEC_{oral,\ predator}$ = 2.25 x 10^{-4} mg/kg wet earthworm ($C_{earthworm}$)

Risk characterisation for earthworm-eating birds:
The risk to the earthworm-eating birds is calculated as the ratio between the concentration in their food ($PEC_{oral,\ predator}$) and the no-effect-concentration for oral intake ($PNEC_{oral}$) as follows:
$PEC_{oral,\ predator}$/ $PNEC_{oral}$ = 2.25 x 10^{-4} /16.7 = 6.58 x 10^{-6}

Risk characterisation for earthworm-eating mammals:
The risk to the earthworm-eating birds is calculated as the ratio between the concentration in their food ($PEC_{oral,\ predator}$) and the no-effect-concentration for oral intake ($PNEC_{oral}$) as follows:
$PEC_{oral,\ predator}$/ $PNEC_{oral}$ = 2.25 x 10^{-4}/120 = 9.17 x 10^{-7}

Scenario	**Concentration**	**$PEC_{oral\ predator}$**	**PEC/PNEC birds**	**PEC/PNEC mammals**
Scenario: Application, Aquatic compartment	**PECsurface water (mg/L)**	**(mg/kg wet fish)**		
Permethrin	2.19 x 10^{-7}	1.25 x 10^{-4}	7.47 x 10^{-6}	1.04 x 10^{-6}
DCVA	1.17 x 10^{-7}	6.67 x 10^{-5}	3.99 x 10^{-6}	5.56 x 10^{-7}
PBA	1.20 x 10^{-7}	6.84 x 10^{-5}	4.10 x 10^{-6}	5.70 x 10^{-7}
Scenario: Application, Terrestrial compartment	**$PEC_{porewater}$ (mg/L)**	**(mg/kg wet earthworm)**		
Permethrin	3.02 x 10^{-8}	4.11 x 10^{-4}	2.46 x 10^{-5}	3.43 x 10^{-6}
DCVA	1.61 x 10^{-8}	2.19 x 10^{-4}	1.31 x 10^{-5}	1.83 x 10^{-6}
PBA	1.65 x 10^{-8}	2.25 x 10^{-4}	1.35 x 10^{-5}	1.87 x 10^{-6}

The predicted concentrations of Clean Kill® in the environment from use in PT18 suggests no unacceptable risk of toxicity to birds and mammals from permethrin or its metabolites DCVA and PBA from secondary poisoning via the food chain.
The log Kow of permethrin was calculated as 4.67: 99% technical a.s. 25:75 indicating it is a fat-soluble molecule with a potential to bioconcentrate following uptake via water/porewater (e.g. in fish/worms) leading to secondary poisoning. The Bioconcentration factors recorded in a 28 day bioconcentration study with permethrin in Bluegill sunfish measured 500-570 L/kg. Data obtained during the subsequent depuration phase indicate removal of residues from whole fish, with time to 50% depuration of 4.7 days.

All PECoral,predator/PNECoral ratios determined indicate that there is no unacceptable risk of secondary poisoning following the appropriate use of Clean Kill®. The calculated $PEC_{oral,predator}/PNEC_{oral}$ ratios showed no unacceptable risk of metabolite poisoning for aquatic or terrestrial organisms.

The rapid rate of depuration demonstrates that, in practice, any permethrin taken up by aquatic or terrestrial organism will be rapidly eliminated once exposure ceases, thereby mitigating any perceived potential for biomagnification through the food chain that may otherwise lead to secondary poisoning.

Mixture toxicity

Mixture toxicity is not relevant for Clean Kill®.

Aggregated exposure (combined for relevant emmission sources)

Aggregated exposure is not relevant, based on the decision scheme developed by UBA for the following reasons.

1. In EU permethrin is used only as a biocide.
2. Permethrin is approved in EU as a biocide in 2 PTs: (i) PT 8 and (ii) PT18; however, as a result of the uses of these products, there is no overlap in time and space in Europe, since in PT 8 permethrin is used in industrial preventive wood preservation applied in automated spraying, vacum pressure, double vacum pressure, flow coating or dipping treatment plants.
3. The main constituent of a.s. is not part of other a.s., and a.s. is not a relevant metabolite of other a.s. (and *vice versa*), and there are no other active substances that form the same relevant metabolites.

Therefore, according the decision scheme developed by UBA, no aggregated exposure estimation is required.

Overall conclusion on the risk assessment for the environment of the product
As regards to the environment, the risk assessment was performed considering permethrin and its metabolites DCVA and PBA; no substances of concern for the environment were identified in Clean Kill®. During the bilateral discussion of the MRP process, several cMSs did not accept the Applicant's proposals to refine the exposure assessment setting the Fce equal to 0%. The additional exposure refinements proposed by the applicant were not accepted, either, and a formal referral was initiated by some cMSs. During the dispute resolution step, the use as targeted spot application, though originally intended by the applicant, was no longer supported. The Applicant eventually supported for authorization the sole '**Targeted spot application in crack & crevice'** on porous/non-porous surfaces at 50 mL product/m^2, by spraying via trigger sprayer with fixed capillary tube, to kill crawling insects (cockroaches, ants, silverfish, earwigs) and spiders, restricted to areas that are not wet cleaned and completely protected from water, like garages, cellars, attics, cavities, warehouses, electrical service rooms, boiler rooms. The following RMMs were also agreed: '**Do not apply to areas susceptible to wet cleaning**' and '**Do not use in kitchens or bathrooms**'. Based on these RMMs and considering that the trigger sprayer with fixed capillary tube allows the correct application of the product into the crack/crevice, in the exposure evaluation the fraction to treated surfaces and to floor have been set to zero and only emissions to the applicator clothing have been considered. This approach was accepted

specifically for Clean Kill®. RCR values below 1 for surface water and sediment indicate the risk is controlled also for the aquatic compartment.

The above considered, as far as permethrin and its metabolites DCVA and PBA are concerned, no unacceptable risks were identified for microorganisms of STP, surface water & sediment, and soil. Permethrin concentration in groundwater proved to be lower than the trigger value set by DWD. No unacceptable risks of secondary poisoning via the food chain were identified, for permethrin and its metabolites, either.

2.2.9 Measures to protect man, animals and the environment

Recommended methods as precautions concerning handling, use, storage, transport or fire

Open and handle containers with care, avoid contact with skin and eyes. Ensure the work area is well ventilated. Do not eat, drink or smoke or apply cosmetics in work area. Always wash after handling product.
Avoid contamination of drains or bodies of water.
Store upright in the original tightly closed container. Store in a cool, well ventilated, bunded area, away from heat and ignition sources such as smoking and open flames. Keep away from direct sunlight and protect against frost. Store away from strong oxidizing agents.
Store away from food and animal feed.

Transport ADR/RID/ADN

Class	9
Classification code	M6
Packing group	III
Hazard identification no.	90
UN number	UN3082
Technical name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
Danger releasing substance	permethrin
Tunnel restriction code	E
Label	9
Environmentally hazardous substance mark	Symbol "fish and tree"

Transport IMDG

Class	9
Packing group	III
UN number	UN3082
Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
Danger releasing substance	permethrin
EmS	F-A+S-F
Label	9
Marine pollutant mark	Symbol "fish and tree"

Transport ICAO-TI / IATA

Class	9
Packing group	III
UN number	UN3082
Proper shipping name	Environmentally hazardous substance, liquid, n.o.s.
Danger releasing substance	permethrin
Label	9
Environmentally hazardous substance mark	Symbol "fish and tree"

Suitable Extinguishing Media
DO NOT use water stream. : Use class B extinguishing devices: CO2, foam, chemical powder, sand, earth, nebulized water

In case of fire, nature of reaction products, combustion gases, etc.

Specific Hazards
Carbon monoxide might be formed in fire

Fire fighting advice
Individual protection devices equipped with oxygen respirator. Use water stream only to cool surfaces of containers exposed to fire.

Use water spray or fog, dry chemical carbon dioxide.
Do not use water jets.
Use appropriate containment equipment to avoid environmental contaminations especially watercourses and drainage systems.
Smoke from fires is toxic, take precautions to protect personnel from exposure. Wear positive breathing apparatus.

Emergency measures in case of an accident

Direct or indirect effects: Pyrethroids, like permethrin, may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

First aid instructions are detailed below.

If inhaled:
Remove affected person to fresh air and apply artificial respiration if required. Seek medical advice is specific symptomatic reactions are observed.

If swallowed:
Immediately call a poison control centre or doctor for treatment advice. Do not give any liquid to the person. Do not induce vomiting. If vomiting occurs spontaneously, keep head below hips to prevent aspiration. Do not give anything by mouth to an unconscious person.

If on skin or hair:
Remove contaminated clothing and wash with soap and running water. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control centre or doctor for treatment advice if irritation persists.

If in eyes:
Remove contact lenses, if present. Hold eyelids apart and flush eye continuously with running water for 15 – 20 minutes. Call a poison control centre or doctor for treatment advice or if irritation persists.

In the event of a leak or spillage:
- Shut off the source of the leak if it is safe to do so

Immediate actions:
- Contain the product to avoid environmental contamination.
- Recover product where possible.

Clean up-actions:
- Absorb spillage in earth, sand or sawdust or other inert material.
- Place in appropriate metal or plastic containers.
- Seal the containers and label them.
- Remove the contaminated material to a safe location for subsequent disposal.

If contamination of drainage systems or watercourses is unavoidable, immediately inform the appropriate authorities.

Possibility of destruction or decontamination following release in or on the following: air, water, including drinking water and soil

Contamination of water may occur in the case of leakage at the manufacturing plant.
Should any contamination of water occur outside the plant, the contaminated water should be collected or contained with clean-up via suction and filtering.
If surface waters are contaminated, Permethrin will be durably bound to the sediment where it is susceptible to biotic and abiotic degradation. The buffer capacity of sediment can be enhanced by addition of organic matter. Sediments can also be dredged and removed to an approved dumping site.
If the product is spilled in soil, permethrin will be durably bound to the soil where it is susceptible to biotic and abiotic degradation. Soil could also be collected and removed to an incineration plant or approved landfill site.
Prevent the product from flowing into sewers or contaminating surface waterways. Soak up spills with inert absorbent material. Contaminated waters should be isolated where possible to limit the extent of contamination. Expert advice should be sought to establish the degree of contamination and the feasibility of available treatment techniques such as flocculation, carbon adsorption, etc. Where relevant the appropriate authorities should be notified. Wear appropriate personal protective equipment during any cleanup operations.

Procedures for waste management of the active substance for industry or professional users

For industrial users waste and contaminated materials are hazardous waste and can be disposed of by incineration.
The product is supplied to professional and non-professional users in a range of packaging sizes. Empty containers must not be used for any other purpose. They should be punctured and disposed of according to national waste disposal requirements.
Ventilate area. Collect leaking and spilled liquid in sealable containers (heavy duty plastic drums). Absorb remaining liquid in sand or inert absorbent and transfer to sealable containers for disposal. Wash area thoroughly with water and detergent, preventing runoff from entering drains. Wear chemical resistant goggles, gloves and boots, light protective clothing and self-contained breathing apparatus if contaminated area is not well ventilated. If material enters drains advise emergency services.
Solid absorbent material collected from spillage incidents should be disposed of at approved landfill sites. Triple- (or preferably) pressure-rinse containers before disposal. Do not dispose of undiluted chemicals on-site. Do not wash product or spillages into waterways, drains or sewers.

Possibility of re-use or recycling

None.

Conditions for controlled discharge including leachate qualities on disposal

Under Hazardous Waste Directive (91/689/EEC) surplus permethrin and contaminated materials (including sawdust) must be classified a "Special Waste".
Disposal must be in accordance with these regulations and requirements set out in the Integrated Pollution Prevention and Control Directive.
The active substance can be disposed to an approved landfill site as specified by the local or county authorities. Due to the high binding capacity of Permethrin to soil any release from an approved landfill site would not leach significantly into surrounding soil.

Observations on undesirable or unintended side-effects e.g. on beneficial and other non-target organisms

The products containing permethrin are likely to be extremely dangerous to fish and other aquatic life.

Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances

Permethrin falls within the scope of List I of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substance.

2.2.10 Assessment of a combination of biocidal products

Clean Kill® is not intended to be authorised for the use with other biocidal products.

2.2.11 Comparative assessment

Please refer to section 2.1.2.2. of this document.

3 ANNEXES

3.1 List of studies for the biocidal product

In relation to the product application, the following data on product are submitted:
- Physical state, color and odor
- pH value
- Density
- Storage stability test and reactivity towards container material
- Storage stability test – long term storage at ambient temperature
- Emulsifiability, re-emulsifiability and emulsion stability
- Particle size
- Pourability / rinseability
- Surface tension
- Viscosity
- Flammable liquids
- Corrosive to metals
- Auto-ignition temperatures of products (liquids and gases)
- Methods for detection and identification
- Efficacy against target organisms.

In relation to the product application, no new data on the active substance and other substances contained in the product are submitted.
It shall be noted that the tested batches and the study reports of Clean Kill® refer to the trade name as originally proposed by the applicant (i.e. Bio Kill®).

Reference List – Biocidal Product BIO KILL®

Section No	Author	Year	Title	Data protection claimed (Y/N)	Owner of data
Section 3, Physical and Chemical Properties	Gimeno, B.	2016	Accelerated storage stability of Bio Kill. July 2016. Report No. GAT-22-07.16. GLP/GEP: no Published: no	Y	Jesmond Holding AG
Section 3, Physical and Chemical Properties	Belussi, C.	2019	SHELF-LIFE STABILITY STUDY AT 25°C/60%RH FOR 24 MONTHS ON THE TEST ITEM "BIO KILL 0.25% PERMETHRIN EW". Eurofins Biolab S.r.l. 2016/271AM. 2019 GLP: yes Published: no	Y	Jesmond Holding AG
Section 3, Physical and Chemical Properties - Surface	Campbell, N.	2015	'BIO KILL Classic' - Determination of specified physical properties. Oxford Analytical Ltd. Study Number: OA02627	Y	Jesmond Holding AG

tension			GLP: yes Published: no		
Section 3, Physical and Chemical Properties - Physical state, color and odor	Gimeno, B.	2016	Accelerated storage stability of Bio Kill. July 2016. Report No. GAT-22-07.16. GLP/GEP: no Published: no	Y	Jesmond Holding AG
Section 3, Physical and Chemical Properties - pH	Gimeno, B.	2016	Accelerated storage stability of Bio Kill. July 2016. Report No. GAT-22-07.16. GLP/GEP: no Published: no	Y	Jesmond Holding AG
Section 3, Physical and Chemical Properties - Density	Gimeno, B.	2016	Accelerated storage stability of Bio Kill. July 2016. Report No. GAT-22-07.16. GLP/GEP: no Published: no	Y	Jesmond Holding AG
Section 3, Physical and Chemical Properties - Emulsifiability, re-emulsifiability and emulsion stability	Gimeno, B.	2016	Accelerated storage stability of Bio Kill. July 2016. Report No. GAT-22-07.16. GLP/GEP: no Published: no	Y	Jesmond Holding AG
Section 3, Physical and Chemical Properties - Particle size	Gimeno, B.	2016	Accelerated storage stability of Bio Kill. July 2016. Report No. GAT-22-07.16. GLP/GEP: no Published: no	Y	Jesmond Holding AG
Section 3, Physical and Chemical Properties - Pourability	Gimeno, B.	2016	Accelerated storage stability of Bio Kill. July 2016. Report No. GAT-22-07.16. GLP/GEP: no Published: no	Y	Jesmond Holding AG
Section 3, Physical and Chemical Properties - Viscosity	Gimeno, B.	2016	Accelerated storage stability of Bio Kill. July 2016. Report No. GAT-22-07.16. GLP/GEP: no Published: no	Y	Jesmond Holding AG
Section 4, Flammable liquids - Flash point	Sheraz, H.	2019	Determination of specified physico-chemical properties. Report No. OA03301. GLP/GEP: yes Published: no	Y	Jesmond Holding AG
Section 4, Corrosive to metals	Cheng, K.	2019	'Bio Kill - (Permethrin 0.25% EW)' - Determination of specified physico-chemical properties	Y	Jesmond Holding AG

			Report No. OA03313. GLP/GEP: yes Published: no		
Section 4, Auto-ignition temperature	Sheraz, H.	2019	Determination of specified physico-chemical properties. Report No. OA03301. GLP/GEP: yes Published: no	Y	Jesmond Holding AG
Section 5, Methods of detection and identification - HPLC Analysis	Sowa, R.	2016	Determination of Permethrin in Bio Kill by High Performance Liquid Chromatography (HPLC) Report No. GAT-15-05.16. GLP/GEP: yes Published: no	Y	Jesmond Holding AG
Section 6.7, Efficacy data - Efficacy data - dose range intended to control various pests	Serrano, B.	2016	LABORATORY TESTING OF A DOSE RANGE OF AN INSECTICIDAL SPECIALITY INTENDED TO CONTROL VARIOUS PESTS Report No. 1998a2-BKC/0915R GLP/GEP: yes Published: no	Y	Jesmond Holding AG
Section 6.7, Efficacy data - Efficacy data - crawling, flying insects and spiders	Serrano, B.	2015	LABORATORY MEASUREMENT OF THE EFFECTIVENESS OF AN INSECTICIDE SPECIALITY INTENDED FOR THE DESTRUCTION OF CRAWLING AND FLYING INSECTS AND SPIDERS IN HOUSEHOLD ENVIRONMENT Report No. 1909a-BKC/0315R GLP/GEP: no Published: no	Y	Jesmond Holding AG
Section 6.7, Efficacy data - Efficacy data - simulated use trial of a residual insecticide against various pests	Serrano, B.	2015	SIMULATED USE TRIAL ON THE EFFICACY OF A RESIDUAL INSECTICIDE AGAINST VARIOUS PESTS Report No. 1909-b3/0315R GLP/GEP: yes Published: no	Y	Jesmond Holding AG
Section 6.7, Efficacy data - Efficacy data - simulated use trial of a residual insecticide against various pests	Serrano, B.	2019	SIMULATED USE TRIAL ON THE EFFICACY OF A RESIDUAL INSECTICIDE AGAINST VARIOUS PESTS Report No. 2519/1119R GLP/GEP: yes Published: no	Y	Jesmond Holding AG

3.2 Output tables from exposure assessment tools

Human health

Primary exposure - ConsExpo Web

General information

Substance		
Name	Permethrin	
CASNumber	52645-53-1	
Molecular weight	391	g/mol
KOW	4.67	10Log
Product		
Name	Clean Kill®	
Weight fraction substance	0.269 (technical percentage)	%
Population		
Name	Adult	
Body weight	60	kg

Scenario 1: Mixing and loading

Frequency	6	per year
Description		
Inhalation		
Exposure model	Exposure to vapour - Evaporation	
Exposure duration	1.33	minute
Product in pure form	No	
Molecular weight matrix	3.00E+03	g/mol
The product is used in dilution	No	
Product amount	500	g
Weight fraction substance	0.269	%
Room volume	1	m^3
Ventilation rate	0.6	per hour
Inhalation rate	1.25	m^3/h
Application temperature	25	°C
Vapour pressure	2.00E-06	Pa
Molecular weight	391	g/mol
Mass transfer coefficient	10	m/hr
Release area mode	Constant	
Release area	0.002	m^2
Emission duration	1.33	minute
Absorption model	Fixed fraction	
Absorption fraction	100	%
Oral		
Exposure model	n.a.	
Absorption model	n.a.	
Dermal		
Exposure model	**Direct contact - Instant application**	
Exposed area	820	cm^2
Weight fraction substance	0.269	%
Product amount	0.01	g
Absorption model	Fixed fraction	
Absorption fraction	70	%
Oral		
Exposure model	n.a.	
Absorption model	n.a.	
Results for scenario Mixing and loading		
Inhalation		
Mean event concentration	1.4E-09	mg/m^3
Peak concentration (TWA 15 min)	1.4E-09	mg/m^3

Mean concentration on day of exposure	1.3E-12	mg/m³
Year average concentration	2.1E-14	mg/m³
External event dose	6.5E-13	mg/kg bw
External dose on day of exposure	6.5E-13	mg/kg bw
Internal event dose	6.5E-13	mg/kg bw
Internal dose on day of exposure	**6.5E-13**	**mg/kg bw/day**
Internal year average dose	**1.1E-14**	**mg/kg bw/day**
Dermal		
Dermal load	3.3E-05	mg/cm²
External event dose	4.5E-04	mg/kg bw
External dose on day of exposure	4.5E-04	mg/kg bw
Internal event dose	3.1E-04	mg/kg bw
Internal dose on day of exposure	**3.1E-04**	**mg/kg bw/day**
Internal year average dose	**5.2E-06**	**mg/kg bw/day**
Integrated		
Internal event dose	3.1E-04	mg/kg bw
Internal dose on day of exposure	**3.1E-04**	**mg/kg bw/day**
Internal year average dose	**5.2E-06**	**mg/kg bw/day**

Scenario 2: Targeted spot application

Frequency	9	per year
Description		
Inhalation		
Exposure model	**Exposure to spray - Spraying**	
Spray duration	6	minute
Exposure duration	240	minute
Product in pure form	No	
Molecular weight matrix		
The product is used in dilution	No	
Weight fraction substance	0.269	%
Room volume	20	m^3
Room height	2.5	m
Ventilation rate	0.6	per hour
Inhalation rate	1.25	m^3/h
Spraying towards person	No	
Mass generation rate	0.4	g/s
Airborne fraction	0.008	
Density non volatile	1.8	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	LogNormal	
Median diameter	7.7	µm
Arithmic coefficient of variation	1.9	
Maximum diameter	50	µm
Include oral non-respirable material exposure	No	
Absorption model	Fixed fraction	
Absorption fraction	100	%
Dermal		
Exposure model	**Direct contact - Constant rate**	
Exposed area	820	cm^2
Weight fraction substance	0.269	%
Contact rate	46	mg/min
Release duration	6	minute
Absorption model	Fixed fraction	
Absorption fraction	70	%
Oral		
Exposure model	n.a.	
Absorption model	n.a.	
Results for scenario Targeted spot application		
Inhalation		

Mean event concentration	0.016	mg/m³
Peak concentration (TWA 15 min)	0.072	mg/m³
Mean concentration on day of exposure	0.0027	mg/m³
Year average concentration	6.7E-05	mg/m³
External event dose	1.4E-03	mg/kg bw
External dose on day of exposure	1.4E-03	mg/kg bw
Internal event dose	1.4E-03	mg/kg bw
Internal dose on day of exposure	**1.4E-03**	**mg/kg bw/day**
Internal year average dose	**3.3E-05**	**mg/kg bw/day**
Dermal		
Dermal load	0.00091	mg/cm²
External event dose	0.012	mg/kg bw
External dose on day of exposure	0.012	mg/kg bw
Internal event dose	8.7E-03	mg/kg bw
Internal dose on day of exposure	**8.7E-03**	**mg/kg bw/day**
Internal year average dose	**0.00021**	**mg/kg bw/day**
Integrated		
Internal event dose	0.01	mg/kg bw
Internal dose on day of exposure	**0.01**	**mg/kg bw/day**
Internal year average dose	**0.00025**	**mg/kg bw/day**

Scenario 3: Crack and crevice

Frequency	9	per year
Description		
Inhalation		
Exposure model	**Exposure to spray - Spraying**	
Spray duration	4	minute
Exposure duration	240	minute
Product in pure form	No	
Molecular weight matrix		
The product is used in dilution	No	
Weight fraction substance	0.269	%
Room volume	20	m^3
Room height	2.5	m
Ventilation rate	0.6	per hour
Inhalation rate	1.25	m^3/h
Spraying towards person	No	
Mass generation rate	0.4	g/s
Airborne fraction	0.008	
Density non volatile	1.8	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	LogNormal	
Median diameter	7.7	µm
Arithmic coefficient of variation	1.9	
Maximum diameter	50	µm
Include oral non-respirable material exposure	No	
Absorption model	Fixed fraction	
Absorption fraction	100	%
Dermal		
Exposure model	**Direct contact - Constant rate**	
Exposed area	820	cm^2
Weight fraction substance	0.269	%
Contact rate	46	mg/min
Release duration	4	minute
Absorption model	Fixed fraction	
Absorption fraction	70	%
Oral		
Exposure model	n.a.	
Absorption model	n.a.	
Results for scenario Crack and crevice		
Inhalation		

Mean event concentration	0.011	mg/m³
Peak concentration (TWA 15 min)	0.049	mg/m³
Mean concentration on day of exposure	0.0018	mg/m³
Year average concentration	4.5E-05	mg/m³
External event dose	0.0009	mg/kg bw
External dose on day of exposure	0.0009	mg/kg bw
Internal event dose	0.0009	mg/kg bw
Internal dose on day of exposure	**0.0009**	**mg/kg bw/day**
Internal year average dose	**2.2E-05**	**mg/kg bw/day**
Dermal		
Dermal load	0.0006	mg/cm²
External event dose	0.0082	mg/kg bw
External dose on day of exposure	0.0082	mg/kg bw
Internal event dose	0.0058	mg/kg bw
Internal dose on day of exposure	**0.0058**	**mg/kg bw/day**
Internal year average dose	**0.00014**	**mg/kg bw/day**
Integrated		
Internal event dose	0.0067	mg/kg bw
Internal dose on day of exposure	**0.0067**	**mg/kg bw/day**
Internal year average dose	**0.00016**	**mg/kg bw/day**

Secondary exposure - ConsExpo Web

Scenario 4: Secondary exposure from general surface

Substance		
Name	Permethrin	
CASNumber	52645-53-1	
Molecular weight	391	g/mol
KOW	4.67	10Log
Product		
Name	Clean Kill	
Weight fraction substance	0.269	%
Population		
Name	Toddler	
Body weight	10	kg
Scenario post application (child)		
Frequency	126	per year
Description		
Inhalation		
Exposure model	n.a.	
Absorption model	n.a.	
Dermal		
Exposure model	**Direct contact - Rubbing off**	
Exposed area	230	cm^2
Weight fraction substance	0.269	%
Transfer coefficient	0.21	m^2/hr
Dislodgeable amount	6.5	g/m^2
Contact time	60	minute
Contacted surface	22	m^2
Release duration	22	m^2
Absorption model	Fixed fraction	
Absorption fraction	70	%
Oral		
Exposure model	**Direct product contact - Constant rate**	
Weight fraction substance	0.269	%
Ingestion rat	2.75	mg/min
Exposure duration	60	minute
Absorption model	Fixed fraction	
Absorption fraction	100	%
Results for scenario post application (child)		

Dermal		
Dermal load	0.016	mg/cm²
External event dose	0.37	mg/kg bw
External dose on day of exposure	0.34	mg/kg bw
Internal event dose	0.24	mg/kg bw
Internal dose on day of exposure	**0.24**	**mg/kg bw/day**
Internal year average dose	**0.083**	**mg/kg bw/day**
Oral		
External event dose	0.044	mg/kg bw
External dose on day of exposure	0.044	mg/kg bw
Internal event dose	0.044	mg/kg bw
Internal dose on day of exposure	**0.044**	**mg/kg bw/day**
Internal year average dose	**0.015**	**mg/kg bw/day**
Integrated		
Internal event dose	0.28	mg/kg bw
Internal dose on day of exposure	**0.28**	**mg/kg bw/day**
Internal year average dose	**0.098**	**mg/kg bw/day**

Environment

EUSES report for targeted spotted application in crack & crevice on porous/non-porous surfaces by trigger sprayer with fixed capillary tube

Permethrin – Clean Kill – 50 mL product/m²

Section/parameter	Actual value	Unit	Stat
STUDY			
STUDY IDENTIFICATION			
Study name	Clean Kill		S
Study description	Clean Kill 50 mL/m²		S
DEFAULTS			
CHARACTERISTICS OF COMPARTMENTS			
GENERAL			
Temperature correction method	Temperature correction for local distribution		S
SUBSTANCE			
SUBSTANCE IDENTIFICATION			
General name	Permethrin		S
Description			S
CAS-No	52645-53-1		S
EC-notification no.			S
EINECS no.	258-067-9		S
PHYSICO-CHEMICAL PROPERTIES			
Molecular weight	391,29	[g.mol-1]	S
Melting point	35	[oC]	S
Boiling point	305	[oC]	S
Vapour pressure at test temperature	2,155E-06	[Pa]	S
Temperature at which vapour pressure was measured	20	[oC]	S
Vapour pressure at 25 [oC]	2,82E-06	[Pa]	O
Octanol-water partition coefficient	4,67	[log10]	S
Water solubility at test temperature	0,18	[mg.l-1]	S
Temperature at which solubility was measured	20	[oC]	S
Water solubility at 25 [oC]	0,1	[mg.l-1]	O
PARTITION COEFFICIENTS AND BIOCONCENTRATION FACTORS			

SOLIDS-WATER			
Chemical class for Koc-QSAR	Non-hydrophobics (default QSAR)		S
Organic carbon-water partition coefficient	26930	[l.kg-1]	S
AIR-WATER			
Henry's law constant at test temparature	0,045	[Pa.m3.mol-1]	S
BIOCONCENTRATION FACTORS			
PREDATOR EXPOSURE			
Bioconcentration factor for earthworms	570	[l.kgwwt-1]	S
DEGRADATION AND TRANSFORMATION RATES			
CHARACTARIZATION			
Characterization of biodegradability	Not ready biodegradable		S
STP			
Rate constant for biodegradation in STP	0	[d] (DT50)	S
WATER/SEDIMENT			
WATER			
Rate constant for hydrolysis in surface water	365	[d] (DT50,20[oC])	S
Rate constant for photolysis in surface water	6,42E+05	[d] (DT50)	S
Rate constant for biodegradation in surface water	4,4	[d] (DT50,12[oC])	S
SEDIMENT			
Rate constant for biodegradation in aerated sediment	46,7	[d] (DT50,12[oC])	S
AIR			
Rate constant for degradation in air	0,701	[d] (DT50)	S
SOIL			
Rate constant for biodegradation in bulk soil	106	[d] (DT50,12[oC])	S
RELEASE ESTIMATION			
BIOCIDE SCENARIO INPUT DATA			

Usage/production title	Spot treatment product		S
Scenario choice for biocides	(18) Insecticides		S
Additional scenario information	(18.2.1) Indoor, spray application		S
PRIVATE USE			
Emission scenario	Local emissions (STP)		S
INTERMEDIATE RESULTS			
RELEASE FRACTIONS AND EMISSION DAYS			
PRIVATE USE			
GENERAL			
Fraction of active ingredient	0,2688	[%]	S
Surface or air space treatment	Surface treatment (area)		S
Application scope	Targeted spot application		S
Treatment rate, amount of product per area	0,1354752	[g.m-2]	S
Area of treated surface, house	2	[m2]	S
PREPARATION 1/2			
Quantity of product used per preparation, house	100.8	[g]	S
Type of formulation	Liquid		S
Type of container	1 liter		S
APPLICATION 1/2			
Number of applications per day, house	1	[-]	S
Fraction emitted to air during application	0,02	[-]	S
Fraction emitted to the applicator during application	6,00E-03	[-]	S
Fraction emitted to the floor during application	0	[-]	S
Fraction emitted to treated surfaces during application	0	[-]	S
CLEANING 1/2			
Washable or disposable applicators	Washable		S
Cleaning method for treated surfaces	Other methods		S
Fraction emitted to solid waste from cleaning treated surfaces	0,1	[-]	S
Cleaning efficiency	25	[%]	S
TOTAL			
Number of houses per STP	4,00E+03	[-]	S
Simultaneity factor	0,2042	[%]	S
Number of emission days per year	1	[-]	S

DISTRIBUTION			
SEWAGE TREATMENT			
[PRIVATE USE]			
INPUT AND CONFIGURATION [PRIVATE USE]			
INPUT			
Use or bypass STP (local freshwater assessment)	Use STP		S
Use or bypass STP (local marine assessment)	Bypass STP		S
CONFIGURATION			
Calculate dilution from river flow rate	No		S
LOCAL PECS [PRIVATE USE]			
AIR			
Annual average local PEC in air (total)	1,15E-15	[mg.m-3]	O
WATER, SEDIMENT			
Local PEC in surface water during emission episode (dissolved)	2,19E-07	[mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)	No		O
Annual average local PEC in surface water (dissolved)	5,99E-10	[mg.l-1]	O
Local PEC in fresh-water sediment during emission episode	1,28E-04	[mg.kgwwt-1]	O
Local PEC in seawater during emission episode (dissolved)	7,92E-08	[mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)	No		O
Annual average local PEC in seawater (dissolved)	2,17E-10	[mg.l-1]	O
Local PEC in marine sediment during emission episode	4,65E-05	[mg.kgwwt-1]	O
SOIL, GROUNDWATER			
Local PEC in agric. soil (total) averaged over 30 days	2,22E-05	[mg.kgwwt-1]	O
Local PEC in agric. soil (total) averaged over 180 days	1,44E-05	[mg.kgwwt-1]	O
Local PEC in grassland (total) averaged over 180 days	5,74E-06	[mg.kgwwt-1]	O
Local PEC in pore water of agricultural soil	3,02E-08	[mg.l-1]	O
Local PEC in pore water of grassland	1,21E-08	[mg.l-1]	O
Local PEC in groundwater under agricultural soil	3,02E-08	[mg.l-1]	O

3.3 New information on the active substance

New information on the active substance is not available.

3.4 Residue behaviour

No residues of Clean Kill® in food or feed occur.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)

Permethrin is a contact insecticide. i.e. 0.269% w/w technical material, to be applied indoor by non-professional users. Bio Kill® is applied by spraying via trigger sprayer with fixed capillary tube and is used under PT18 for targeted spot application in crack & crevice to kill crawling insects (cockroaches, ants, silverfish, earwigs) and spiders.

Test organisms in efficacy studies are detailed below.

FLYING INSECTS:
Musca domestica (common house fly)
Aedes aegypti (mosquito)
Culex pipiens (mosquito)
Anopheles gambiae (tropical mosquito)

CRAWLING INSECTS/MITES:
Blattella germanica (German cockroach)
Periplaneta americana (American cockroach)
Lasius niger (common black ant)
Lepisma saccharina (silverfish)
Cimex lectularius (bed bug)
Forficula auricularia (earwig)
Tineola bisselliella (clothe moth)
Dermatophagoides pteronyssinus (house dust mite)

SPIDERS:
Tegenaria domestica (barn funnel weaver - house spider)

3.6 Confidential annex

Please, see separate confidential annex.