



## HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

### 1 TOELATING

Gelet op de aanvraag d.d. 27 augustus 2013 (20131193 TNBWE) van

Sumitomo Chemical (UK) Plc.  
77 -85 Fulham Palace Road  
LONDON W6 8JA  
GROOT-BRITTANNIË

tot verkrijging van een toelating als bedoeld in artikel 19 van de Verordening (EU) 528/2012, op basis van de werkzame stof metofluthrin,

#### **SumiOne Liquid Vaporiser**

Mede gelet op artikel 89 lid 2 juncto artikel 91 van de Verordening (EU) 528/2012, juncto artikel 44, eerste lid, Wet gewasbeschermingsmiddelen en biociden zoals deze luidde voor de inwerkingtreding van Verordening (EU) 528/2012

**BESLUIT HET COLLEGE** als volgt:

#### **1.1 Toelating**

1. Het middel SumiOne Liquid Vaporiser is toegelaten voor de in bijlage I genoemde toepassingen onder nummer 14308 N met ingang van datum dezes. Voor de gronden van dit besluit wordt verwezen naar bijlage II bij dit besluit.
2. De toelating geldt tot 30 april 2021.

## 1.2 Samenstelling, vorm en verpakking

De toelating geldt uitsluitend voor het middel in de samenstelling, vorm en de verpakking als waarvoor de toelating is verleend.

## 1.3 Gebruik

Het middel mag slechts worden gebruikt met inachtneming van hetgeen in bijlage I onder A bij dit besluit is voorgeschreven.

## 1.4 Classificatie en etikettering

Mede gelet op artikel 50 Wet gewasbeschermingsmiddelen en biociden worden voorschriften gegeven.

Dit leidt tot de volgende voorschriften:

De aanduidingen, welke moeten worden vermeld, worden hierbij vastgesteld als volgt:

*aard van het preparaat:* Andere vloeistoffen voor directe toepassing

<i>werkzame stof:</i>	<i>gehalte:</i>
Metofluthrin	0,69 %

*de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel:*

-

## PICTOGRAM(MEN)

*pictogram:*  
GHS08-gezondheidsrisico's  
GHS09-milieu

## SIGNAALWOORD

Gevaar

## Gevarenaanduidingen

- H304 Kan dodelijk zijn als de stof bij inslikken in de luchtwegen terechtkomt.  
H400 Zeer giftig voor in het water levende organismen.

## Voorzorgsmaatregelen

- P101 Bij het inwinnen van medisch advies, de verpakking of het etiket ter beschikking houden.  
P102 Buiten het bereik van kinderen houden.  
P273 Voorkom lozing in het milieu.  
P301 + P330 + P331 + P310 NA INSLIKKEN: de mond spoelen – GEEN braken opwekken.  
Onmiddellijk een ANTIGIFCENTRUM of een arts raadplegen.  
P501 Inhoud/verpakking afvoeren naar inzamelpunt voor gevaarlijk of bijzonder afval.

Overeenkomstig de Warenwet en artikel 1, 3 en 4 van het Warenwetbesluit veilige verpakking huishoudchemicaliën dienen uitsluitend die verpakkingen van bestrijdingsmiddelen die (mede) voor niet-professioneel gebruik zijn bestemd te worden voorzien van:

- kindveilige sluiting
- tastbare gevaarsaanduiding.

Behalve de voorgeschreven aanduidingen en vermeldingen moeten op de verpakking voorkomen:

- a. letterlijk en zonder enige aanvulling:  
**het wettelijk gebruiksvoorschrift**  
De tekst van het wettelijk gebruiksvoorschrift is opgenomen in Bijlage I, onder A.
- b. hetzij letterlijk, hetzij naar zakelijke inhoud:  
**de gebruiksaanwijzing**  
De tekst van de gebruiksaanwijzing is opgenomen in Bijlage I, onder B.  
De tekst mag worden aangevuld met technische aanwijzingen voor een goede bestrijding mits deze niet met die tekst in strijd zijn.

## 2 DETAILS VAN DE AANVRAAG

### 2.1 Aanvraag

Het betreft een aanvraag tot verkrijging van een toelating van het middel SumiOne Liquid Vaporiser (14308 N), een middel op basis van de werkzame stof metofluthrin. Het middel wordt aangevraagd als middel ter bestrijding van muggen binnenshuis.

### 2.2 Informatie met betrekking tot de stof

De werkzame stof metofluthrin betreft een nieuwe stof. Er zijn in Nederland nog geen andere middelen op basis van deze werkzame stof toegelaten.

De werkzame stof metofluthrin is bij Richtlijn 2010/71/EG, dd 4 november 2010 van de Europese Commissie van de Europese Gemeenschappen opgenomen in Bijlage I van Richtlijn 98/8/EG.

### 2.3 Karakterisering van het middel

SumiOne Liquid Vaporiser is an electrically-powered heated vaporiser containing 0.69 % w/w metofluthrin as the active substance. Metofluthrin is a synthetic pyrethroid. Pyrethroids are contact insecticides which can cause knockdown of flying insects within a few seconds of application. Their primary mode of action is a prolongation of the opening of voltage-gated sodium channels in nerve cell membranes. This causes hyperexcitation of the insect nervous system which is manifested by convulsions, knockdown and ultimately death.

### 2.4 Voorgeschiedenis

De aanvraag is op 30 augustus 2013 ontvangen; op 30 september 2013 zijn de verschuldigde aanvraagkosten ontvangen.

## **2.5 Eindconclusie**

Bij gebruik volgens het Wettelijk Gebruiksvoorschrift/Gebruiksaanwijzing is het middel SumiOne Liquid Vaporiser op basis van de werkzame stof metofluthrin voldoende werkzaam en heeft het geen schadelijke uitwerking op de gezondheid van de mens en het milieu.

*Degene wiens belang rechtstreeks bij dit besluit is betrokken kan gelet op artikel 119, eerste lid, Wet gewasbeschermingsmiddelen en biociden en artikel 7:1, eerste lid, van de Algemene wet bestuursrecht, binnen zes weken na de dag waarop dit besluit bekend is gemaakt een bezwaarschrift indienen bij: het College voor de toelating van gewasbeschermingsmiddelen en biociden (Ctgb), Postbus 217, 6700 AE WAGENINGEN. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.*

Wageningen, 7 februari 2014

HET COLLEGE VOOR DE TOELATING VAN  
GEWASBESCHERMINGSMIDDELEN EN  
BIOCIDEN,

ir. J.F. de Leeuw  
voorzitter

Dit middel is uitsluitend bestemd voor niet-professioneel gebruik

## **HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN**

**BIJLAGE I** bij het besluit d.d. 7 februari 2014 tot toelating van het middel SumiOne Liquid Vaporiser, toelatingnummer 14308 N

### **A.** WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als middel ter bestrijding van muggen binnenshuis.

De gebruiksinstructies zoals aangegeven in de gebruiksaanwijzing moeten worden aangehouden.

Om in het water levende organismen te beschermen dient voorkomen te worden dat middelresten op het riool of direct op oppervlaktewater worden geloosd.

Het middel is uitsluitend bestemd voor niet-professioneel gebruik.

### **B.** GEBRUIKSAANWIJZING

SumiOne Liquid Vaporiser is een vloeistofverdamer die op het stopcontact wordt aangesloten tegen muggen binnenshuis.

#### **Gebruiksaanwijzing**

Steek de container SumiOne@LV in de verdamer en sluit deze aan op een stopcontact (220V).

Schakel de verdamer aan. Het duurt 2 uur voordat het middel afdoende werkt. Houd de verdamer ingeschakeld voor een periode van maximaal 12 uur. Wanneer het gebruik niet langer is vereist, schakel de verdamer dan uit, zonder de eenheid te verwijderen; de verdamer is vervolgens klaar voor het volgende gebruik.

Het middel is niet geschikt voor ruimtes met airconditioning of veel beluchting.

Wanneer het toestel gedurende 12u per dag wordt gebruikt, kan de vulling gedurende ongeveer 60 dagen (40 dagen als er een 30 ml flesje wordt gebruikt) worden gebruikt. Een eenheid SumiOne@LV is geschikt voor een ruimte van ongeveer 30 m<sup>3</sup>.

#### **Voorzorgmaatregelen**

Niet gebruiken in kleine ruimten.

Niet gebruiken in keukens of in ruimten waar voedsel wordt bereid en andere opslagruimten, om besmetting van voeding te voorkomen.

Buiten het bereik van kinderen houden.

Verwijder terrariums, aquariums en dierenkooien of dek ze af.

Schakel het luchtfilter van het aquarium uit.

#### **Tijdens gebruik**

Raak de eenheid niet aan tijdens gebruik.

Raak ook de lont niet aan.

Dek de eenheid niet af.

Was de handen na het hanteren van het product.

Breng de verdamper niet in contact met stoffen, papier of brandbare materialen.

**Afval**

Middelresten niet op het riool of oppervlaktewater lozen.

Houder niet opnieuw vullen of hergebruiken, lege houders veilig verwijderen als chemisch afval.

**HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN**

**BIJLAGE II** bij het besluit d.d. 7 februari 2014 tot toelating van het middel SumiOne Liquid Vaporiser, toelatingnummer 14308 N

# **Product Assessment Report Mutual Recognition**

## **SumiOne Liquid Vaporiser**

03-01-2014

Internal registration/file no:	20131193
Authorisation/Registration no:	14308N
Granting date/entry into force of authorisation/ registration:	07-02-2014
Expiry date of authorisation/ registration:	30-04-2021
Active ingredient:	Metofluthrin
Product type:	18

---

Biocidal product assessment report related to product authorisation under EU regulation 528/2012/EC

# Contents

<b>1</b>	<b>General information about the product application .....</b>	<b>1</b>
1.1	Applicant.....	1
1.2	Current authorisation holder .....	1
1.3	Proposed authorisation holder.....	1
1.4	Information about the product application .....	1
1.5	Information about the biocidal product.....	1
<b>2</b>	<b>Summary of the product assessment.....</b>	<b>2</b>
2.1	Identity related issues.....	2
2.2	Classification, labelling and packaging .....	2
2.2.1	Proposal for the classification and labelling of the formulation concerning physical chemical properties.....	2
2.2.2	Proposal for the classification and labelling of the formulation concerning health	2
2.2.3	Proposal for the classification and labelling of the formulation concerning the environment.....	3
2.3	Physico/chemical properties and analytical methods .....	3
2.4	Risk assessment for Physico-chemical properties .....	4
2.5	Effectiveness against target organisms .....	4
2.6	Exposure assessment .....	4
2.6.1	Description of the intended use(s).....	4
2.6.2	Assessment of exposure to humans and the environment.....	4
2.7	Risk assessment for human health.....	6
2.8	Risk assessment for the environment.....	6
2.9	Measures to protect man, animals and the environment.....	10
<b>3</b>	<b>Proposal for decision .....</b>	<b>11</b>



# **1 General information about the product application**

## **1.1 Applicant**

Sumitomo Chemical (UK) PLC  
Horatio House, 77-85 Fulham Palace Road  
W6 8JA  
London

## **1.2 Current authorisation holder**

Not applicable.

## **1.3 Proposed authorisation holder**

Sumitomo Chemical (UK) PLC

## **1.4 Information about the product application**

Application for authorisation based on mutual recognition. The primary assessment has been carried out by reference member state UK.

## **1.5 Information about the biocidal product**

Product name: SumiOne Liquid Vaporiser  
Product name in RMS: SumiOne Liquid Vaporiser  
PT: 18  
Active substance: Metofluthrin

## 2 Summary of the product assessment

### 2.1 Identity related issues

For the assessment of the identity related issues we refer to Product Assessment Report of the original authorisation.

### 2.2 Classification, labelling and packaging

#### 2.2.1 Proposal for the classification and labelling of the formulation concerning physical chemical properties

The identity of all substances in the mixture that contribute to the classification of the mixture *:			
Paraffins (petroleum), normal C5-20			
Pictogram:	GHS08	Signal word:	Danger
H-statements:	H304	May be fatal if swallowed and enters airways.	
P-statements:	P102	Keep out of reach of children.	
	P301 + P310	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.	
	P331	Do NOT induce vomiting.	
Supplemental Hazard information:	-		
Child-resistant fastening obligatory?			yes
Tactile warning of danger obligatory?			yes

The proposed classification and labelling of the preparation for phys-chem is identical to that proposed in the Product Assessment Report by the competent authority UK.

#### Packaging

	Packaging authorised by RMS	Packaging applied for in NL	Packaging authorised in NL
Packaging size and type	HDPE or PET screw-topped refill bottles (supplied with or without electrically-heated vaporiser unit) up to 45 ml.	HDPE or PET screw-topped refill bottles (supplied with or without electrically-heated vaporiser unit) up to 45 ml.	HDPE or PET screw-topped refill bottles (supplied with or without electrically-heated vaporiser unit) up to 45 ml.

#### 2.2.2 Proposal for the classification and labelling of the formulation concerning health

---

The identity of all substances in the mixture that contribute to the classification of the mixture \*:

---

Pictogram:	-	Signal word:	-
H-statements:	-		-
P-statements:	P101		If medical advice is needed, have product container or label at hand.

---

	P102 P301+P330+P331+P310	Keep out of reach of children IF SWALLOWED: rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician.
Supplemental Hazard information:	-	-
Child-resistant fastening obligatory?		No
Tactile warning of danger obligatory?		No

Explanation:	
Pictogram:	-
H-statements:	-
P-statements:	The proposal of the applicant is accepted.
Other:	-

\* according to Reg. (EC) 1272/2008, Title III, article 18, 3 (b)

### 2.2.3 Proposal for the classification and labelling of the formulation concerning the environment

Pictogram:	GHS09	Signal word:	Warning
H-statement:	H400	Very toxic to aquatic life	
P-statements:	P501	Dispose of contents/container to hazardous or special waste collection point	
	P273	Avoid release to the environment.	
	P391	Collect spillage	
SP 1-statement: (gewas)	-	-	
<b>Explanation</b>			
Pictogram:	Classification based on toxicity of the active substance and the triggers laid down in Regulation (EC) 1272/2008		
H-statement:	Classification based on toxicity of the active substance and the triggers laid down in Regulation (EC) 1272/2008		
P-statements:	P501 is highly recommended for products classified for environmental hazards that apply to non-professional use. P273 is recommended and proposed by the applicant, and the proposal of the applicant has been accepted. Additionally P391 is recommended and can be added to the label in case this would not lead to more than 6 P-statements.		
Other:	...		

\* according to Reg. (EC) 1272/2008, Title III, article 18, 3 (b)

The proposed classification and labelling of the preparation differs from that proposed in the Product Assessment Report by the competent authority UK (N, R50/53 according to directive 67/548/EC which is roughly translated into H400, H410 according to EC Regulation 1272/2008).

## 2.3 Physico/chemical properties and analytical methods

For the assessment of the physical and chemical properties we refer to Product Assessment Report of the original authorisation.

## **2.4 Risk assessment for Physico-chemical properties**

For the risk assessment for physico-chemical properties we refer to Product Assessment Report of the original authorisation.

## **2.5 Effectiveness against target organisms**

For the assessment of the effectiveness against target organisms we refer to Product Assessment Report of the original authorisation. The conclusions of the RMS are acceptable.

### **2.5.1 The label claim**

The applicant has provided a Dutch label (WG/GA). This has been adapted to our standards.

#### Target species

The applicant claimed efficacy against mosquitoes including the “tjgermug” , *Aedes albopictus*. The claim to control de “tjgermug” , *Aedes albopictus*, has been removed from the label as no specific tests against this species were provided.

#### Use instructions

The instructions that the product needs a 2 hour preheating period to be effective and that the use should not exceed 12 hours were added to the WG/GA. It was also added that the product should not be used in a room that has air-conditioning or is well-ventilated.

## **2.6 Exposure assessment**

### **2.6.1 Description of the intended use(s)**

For the description of the intended use(s) we refer to Product Assessment Report of the original authorisation.

### **2.6.2 Assessment of exposure to humans and the environment**

#### Toxicology:

For the assessment of the exposure to humans we refer to Product Assessment Report of the original authorisation.

SumiOne Liquid Vaporiser contains 0.69% (expressed as a sum of all isomers) metofluthrin as an active substance. Metofluthrin is a new active substance included in the Union List of approved active substances of Regulation 528/2012/EC (RMS UK). SumiOne Liquid Vaporiser is identical to the representative product (S-1264 Liquid) assessed at Annex I inclusion of metofluthrin. The formulation is intended to be used as a repellent against mosquitoes inside the residential premises. SumiOne Liquid Vaporiser is to be used in small-scale electrically heated vaporiser units only. The formulation is intended for non-professional use only. If the product is used 12 hours per day, one bottle (45 mL) is sufficient for ca. 60 days.

The acute toxicity studies submitted for SumiOne Liquid Vaporiser have been evaluated in the CAR of metofluthrin and found acceptable. Based on the available studies, SumiOne Liquid Vaporiser does not need to be classified for acute oral (LD50 > 2000 mg/kg bw),

acute dermal (LD50 > 2000 mg/kg bw) and acute inhalation (LC50 12 hours > 0.13 mg/L) toxicity. SumiOne Liquid Vaporiser is not irritating to skin and eyes. SumiOne Liquid Vaporiser did not show a skin sensitising potential in a Magnusson-Kligman maximisation test and is considered not sensitising to skin.

For other endpoints classification and labelling has been prepared according to the calculation rules in Regulation 1272/2008/EC. The used classification of metofluthrin in the Product Assessment Report is identical to the classification in the CAR of metofluthrin.

The exposure assessment for SumiOne Liquid Vaporiser is identical to the exposure assessment carried out in the CAR of metofluthrin and therefore acceptable. The used values for oral, dermal and inhalation absorption (100%, 53% and 100%) and the derived AELs are in agreement with the values derived for metofluthrin in the CAR. The assessed scenarios are:

Primary exposure:

- the insertion of the SumiOne Liquid Vaporiser bottle into the vaporiser unit and its subsequent removal (adult, acute exposure)

Secondary exposure:

- inhalation exposure to metofluthrin volatilized into the air by the vaporiser unit (adults and children, medium-term exposure)
- inhalation exposure to metofluthrin re-volatilized into the air from surfaces upon which it has condensed (adults and children, medium-term exposure)
- dermal exposure to metofluthrin condensing on body surfaces (adults and children, medium term)
- dermal exposure to metofluthrin due to contact with surfaces on which metofluthrin has deposited (infant crawling over the floor/carpet, medium term exposure)
- dermal exposure to metofluthrin due to breaking of the SumiOne Liquid Vaporiser bottle (infant, acute exposure)
- oral exposure to metofluthrin due to breaking open the SumiOne Liquid Vaporiser bottle and drinking the liquid (infant, acute exposure)
- oral exposure to metofluthrin deposited on food and surfaces on which food is placed (infant, children and adults, medium-term exposure).

SumiOne Liquid Vaporiser does not contain substances of concern for human toxicological risk assessment.

#### Environment:

SumiOne Liquid Vaporiser is supplied as a plug-in electrical vaporiser, with ceramic wick and sealed glass bottle containing the product. The intended usage pattern envisaged for the product is for indoor, amateur use. Thus the UK CA considers the main potential exposure routes for the environment to be:

- 1) Application phase -volatile residues, resulting in;
  - a) direct exposure of the immediate and local air compartment through venting.
- 2) Cleaning phase - disposal of deposited surface residues via cleaning, resulting in;
  - a) direct exposure of a sewage treatment plant (STP) [wet cleaning],
  - b) indirect exposure of surface waters via STP effluent,
  - c) indirect exposure of soil via disposal of STP sludge,
  - d) indirect exposure of birds/mammals via fish and
  - e) direct exposure to landfill [dry cleaning].

From the above, the main route of environmental exposure is considered to be via the sewage treatment plant (STP) from wet cleaning of indoor hard surfaces.

SumiOne Liquid Vaporiser is identical to the representative product (S-1264 Liquid) assessed at Annex I inclusion of metofluthrin in terms of formulation, user, pest and usage

area and packaging. The proposed authorisation holder Sumitomo Chemical (UK) PLC for the product is also the applicant which submitted the metofluthrin dossier accepted for Annex I inclusion under product type 18.

As such, the effects and exposure assessments and the risk characterisation for the environment conducted at Annex I remain valid here and no further data have been submitted, nor additional evaluation done for the purpose of this authorisation. Full details of the information available on the representative product is described in Documents IIA, IIB and IIC of the CAR.

For details on the assessment of the exposure to the environment we refer to Product Assessment Report of the original authorisation (annex 1) and the final draft CAR of June 2008.

## **2.7 Risk assessment for human health**

For the risk assessment for human health we refer to Product Assessment Report of the original authorisation.

Based on the risk assessment, no adverse effects from exposure to metofluthrin are expected for non-professional users due to the application of SumiOne Liquid Vaporiser (loading into and removal of the bottle from the vaporiser unit). Additionally, the applicant has proposed the following safety precautions to be carried on the label, to which the RMS UK has agreed: "Do not touch wick" and "Wash hands after handling". These phrases will be added to the WG/GA.

Based on the risk assessment, no adverse effects from secondary exposure to metofluthrin due to the application of SumiOne Liquid Vaporiser are expected for general public when SumiOne Liquid Vaporiser is used according to the WG/GA. As an additional precautions the following safety phrases are suggested by the applicant and supported by the RMS UK: "Keep out of reach of children" (P102) and "To prevent contamination of food, do not use the unit in kitchens, or other food storage or preparation areas". These phrases will be added to WG/GA.

## **2.8 Risk assessment for the environment**

For the risk assessment for the environment we refer to Product Assessment Report of the original authorisation and the final draft CAR of June 2008.

### Substances of concern

The product contains the active substance metofluthrin 0.69% w/w (expressed as the sum of all isomers – equivalent to 0.5% w/v), and 0.56% w/w (expressed as the RTZ or major isomer - equivalent to 0.41% w/v).

In addition to metofluthrin, SumiOne Liquid Vaporiser contains the following substance of concern:

Paraffins (petroleum) normal C5-20

Classification under Dir 67/548/EEC (CAS 64771-72-8)

Xn, R65: Harmful: may cause lung damage if swallowed

This substance of concern triggers a classification of Xn, R65 in the product which is relevant for the risk to human health. The product does not contain substances which can be considered substances of concern for the environment which means that no assessment of these substances is required for the environmental aspect.

### Major metabolites

With regard to metabolites, 3 major (> 10 %) metabolites 'MFOA-D, TFPA and M7' have been identified. Although as shown in (Document II-A, Section 4.1.1.2.3 'Aerobic degradation in soil' the first 2; MFOA-D and TFPA, are secondary and tertiary metabolites respectively. The structures shown in Section 4.1.1.2.3 (Document II-A of the final draft CAR) strongly suggest that these 2 metabolites are structurally very similar and are sufficiently complex to assume that the chemistry will be very similar to the parent compound, which is also supported by the ecotoxicity studies where degradation was reported. Therefore, the exposure and subsequent risk assessment presented for metofluthrin can be assumed to include any exposure to any subsequent metabolites. However, this does not appear to be the same for M7, nonetheless its DT50 of 1.7 d at 12 °C

suggests that this substance is unlikely to exist in the soil environment to any great extent. This is particularly demonstrated by the PEC values predicted for soil being exceptionally low suggesting that these are unlikely to be significantly different in toxicity. Therefore, the UK CA considers that by using only the initial (worst-case, with no degradation considered) PEC values for the active substance (a.s.), exposure assessment is sufficiently precautionary to account for any metabolites formed in the longer term.

### Exposure assessment

The OECD PT18 ESD recognises 2 types of diffuser; electrical (limited [in time] use) and passive (unlimited use); as the SumiOne Liquid Vaporiser is an electrical plug-in device all relevant defaults, unless stated otherwise, have been taken from the 4th draft PT18 ESD (see Table 1). In order to calculate the environmental exposure during the use (application phase) and post-use (cleaning) phases the following assumptions have been applied by the UK CA in the final draft CAR:

- 1) Only one vaporiser per house.
- 2) No degradation occurs either before or during cleaning of the treated property [assuming that the product has been restricted to use during the hours of dusk to dawn, when mosquitoes are most prevalent and to ensure maximum efficacy, i.e. as no degradation by photo degradation in air].
- 3) Deposition to horizontal surfaces of both 10 % (default - tier 1 assessment) and 3 % (Applicant's data - tier 2 assessment) have been assumed.

### *Deposition to horizontal surfaces*

In the PAR the following reservation by the UK CA regarding assumption no. 3 is made: "it should be noted that floor deposition rate data relating to prallethrin were used in the refined environmental risk assessment of metofluthrin. The applicability of studies on deposition rates for refining the environmental exposure assessment is still under discussion at TM level. The results of the discussion on floor deposition rates and their impact on the environmental risk assessment must be considered during product authorisation of metofluthrin containing products including SumiOne® Liquid Vaporiser."

In the absence of agreed EU guidance for this specific type of product and associated use pattern, the UK CA has proposed an absolute worst-case scenario based on use by amateurs in a domestic setting to define the Predicted Environmental Concentrations (PECs). The assessment presented is considered by the UK CA to contain many gross assumptions resulting in a significant over-estimate of exposure and represents an absolute [if not unrealistic] worst-case scenario. On consideration of the assumptions made in the risk assessment and the limited use".

The Ctgb also has some strong reservations regarding the results obtained in the study of Matoba and Takimoto (1996) included in Doc IIIB, section 6.6-(05) of the final draft CAR as the temperature in the experimental room is quite high (25°C) which will affect the vaporisation rate of the active substance. Furthermore the air inlet is just behind the electric vaporizer which is not the case in real life. The air moves from the air inlet to the air outlet in a straight line and air entering the room from outdoors is not taken into account. Therefore we do not favour the use of a refined percentage for deposition to horizontal surfaces in the exposure assessment.

#### Cleaning methodology

Pyrethroids tend to adhere strongly to very small particles like house dust (Lewis *et al*, 1999), due to their strong hydrophobic properties (metofluthrin: log Pow = 5; log Koc = 3.8). In general when cleaning a room, first a broom or vacuum cleaner is used to remove the dust and then the floor is cleaned with water. Cleaning of floors in bedrooms of households is generally done with vacuum cleaner or increasingly with Swiffer wipes, hardly ever with water. So we estimate that only 25% of the total amount on the floor will be available for emission to waste water.

The remaining 75% will be sorbed to dust particles and removed by dry cleaning by i.e. vacuum cleaner.

In view of the considerations presented above we propose the following input parameter  $F_{ce}$ : 0.25 (cleaning efficiency) for calculating the emission to the floor and local STP and to use the default of 10% for deposition to horizontal surfaces. All input parameters for calculation of the daily emission to the STP are included in Table 1.

**Table 1 Parameters and defaults used in environmental exposure scenarios**

		Adapted Value		Final draft CAR Value		
Parameter					Unit	
Quantity of active in the diffuser	$Q_{AI}$	0.24	S	0.24	[g]	S
Maximal duration of use of the diffuser [h]	$T_{Max}$	720	D	720	[h]	S
Duration of use per day [h]	$T_{Day}$	12	D	12	[h/d]	S
Fraction emitted to the floor, default	$F_{application, floor}$	0.1		0.1	[-]	D
Emission to the floor	$E_{application, floor}$		O		[kg/d]	O
Fraction emitted to waste water	$F_{ww}$	1	S	1	[-]	D
Cleaning efficiency	$F_{ce}$	0.25	S	1	[-]	D
Emission from the treated floor to waste water	$E_{treated, ww}$		O		[kg/d]	O
Number of houses connected to the STP	$N_{house}$	4000	D	4000		D
Factor to correct for the simultaneous use of the product	$F_{simultaneity}$	0.055	D	0.055	[-]	D
Daily emission to the STP	$E_{localSTP}$		O		[kg/d]	O

The formulas to calculate the emission to the floor, from the treated floor to waste water and the daily emission to the STP are given below.

$$E_{application, floor} = Q_{AI} \times T_{Day} / T_{Max} \times F_{application, Floor} \times 10^{-3}$$

Where

$Q_{AI}$  = Quantity of active in the diffuser [g]

$T_{Day}$  = Duration of use per day [12 h]

$T_{Max}$  = Maximal duration of use of devise [720 h]

$F_{application, floor}$  = Fraction emitted to floor during use [0.1]



$$E_{\text{treated,ww}} = E_{\text{application,floor}} \times F_{\text{ww}} \times F_{\text{ce}}$$

Where

$F_{\text{ww}}$  = Fraction emitted to wastewater during cleaning [ 1 ]

$F_{\text{ce}}$  = Cleaning efficiency (how much of the deposited a.s. can be removed in a single cleaning event)

### Risk assessment

The risk assessment is based upon the PEC:PNEC ratio for the compartments of concern. These are extracted from the final CAR for metofluthrin and presented in Table 2. Results are shown for tier 1 (default) assessment with deposition to horizontal surfaces of 10% and for tier 2 assessment (applicant's data) with deposition to horizontal surfaces of 3%.

The risk for groundwater has not been characterised during this risk assessment. This is because the UK CA considers the submitted fate and behaviour profile along with the limited

usage pattern suggest that exposure of the groundwater compartment would not occur.

- Adsorption  $K_{oc}$  = 6184 L/kg (mean value)
- DT50 = 7.4 d (12 °C)

Experience with FOCUS groundwater models suggest compounds with  $K_{oc} < 500$  L/kg and DT50 > 21 d are likely to result in significant groundwater levels (as agreed TM II06).

**Table 2 Risk characterisation (PEC:PNEC) values for metofluthrin as a result of using SumiOne Liquid Vaporiser.**

Compartment	Assessment level	PEC (mg/L)	PNEC (mg/L)	PEC/PNEC
STP	Tier 1	$2.54 \times 10^{-5}$	0.67	$3.79 \times 10^{-5}$
	Tier 2	$7.63 \times 10^{-6}$		$1.14 \times 10^{-5}$
Surface waters	Tier 1	$2.52 \times 10^{-6}$	$1.2 \times 10^{-6}$	<b>2.1*</b>
	Tier 2	$7.56 \times 10^{-7}$		0.63
Sediment	Tier 1	$3.41 \times 10^{-4}$	0.0034	0.1
	Tier 2	$1.02 \times 10^{-4}$		0.03
Soil (local <sub>soil</sub> )	Tier 1 only	$2.60 \times 10^{-5}$	$1.31 \times 10^{-4}$	0.20
Biota (PNEC <sub>avian</sub> )	Tier 1	$3.02 \times 10^{-4}$	1.87	$1.61 \times 10^{-5}$
	Tier 2	$9.07 \times 10^{-5}$		$4.85 \times 10^{-5}$
Biota (PNEC <sub>mammal, food ch</sub> )	Tier 1	$3.02 \times 10^{-4}$	0.33	$9.15 \times 10^{-4}$
	Tier 2	$9.07 \times 10^{-5}$		$2.75 \times 10^{-4}$

Tier 1 = 10 % default deposition value,

Tier 2 = 3 % refinement deposition value

+ lowest PNEC based on limit of solubility for main isomer

\* unacceptable risk

wwt – wet weight

dw – dry weight

These data suggest that the use of metofluthrin in the product SumiOne Liquid vaporiser would be acceptable after adjustment for reduced deposition to horizontal surfaces from the ESD default of 10 % to 3 % as shown by the Applicants data (tier 2). It is also acknowledged that these PEC data are 'initial' values and no degradation has been taken into account. According to the CAR for metofluthrin the risk quotients presented in the above table do present a worst-case scenario as available data suggest that photodegradation (DT50 < 2 h) in air (and likely also on surfaces) is likely to occur during daylight prior to cleaning.

However, the Ctgb does not agree with this argument as photodegradation will not be a relevant degradation route indoors due to the limited presence of sunlight compared to the outdoor situation.

Furthermore the Ctgb also does not agree with the refinement of deposition to the floor of 3% proposed by the applicant. The Ctgb proposes to lower the cleaning efficiency to 25% for calculating the emission to the floor and local STP and to use the default of 10% for deposition to horizontal surfaces. In case tier PECs and PEC/PNECs are recalculated for tier 1 by applying a cleaning efficiency of 25% instead of 100% the risks will be a factor 4 lower than presented in table 2 and thus acceptable.

**Overall conclusion for the aspect environment:** The conclusions in the risk assessment of the RMS are valid regarding the tier 1 assessment and by applying a cleaning efficiency of 25% instead of 100%.

## 2.9 Measures to protect man, animals and the environment

In the Product Assessment Report of the original authorisation measures to protect man, animals and environment were proposed. In the table below the measures are listed and evaluated whether the measures are appropriate for the Dutch legal instructions and directions for use (WG/GA).

Measure	In WG/GA	WG/GA (in Dutch)
For indoor use only	Yes	Toegestaan is uitsluitend het gebruik binnenshuis.
Do not touch the wick	Yes	Raak de lont niet aan.
Wash hands after handling	Yes	Na gebruik handen wassen.
To prevent contamination of food, do not use the unit in kitchens or other food storage or preparation areas.	Yes	Om besmetting van voeding te voorkomen, gebruik het toestel NIET in keukens of andere opslagruimten of in ruimten waar voedsel wordt bereid.
Use only as directed	Yes	De gebruiksinstructies zoals aangegeven in de gebruiksaanwijzing moeten worden aangehouden
Do not use in confined spaces	Yes	Niet gebruiken in besloten ruimtes.
Do not touch the unit with wet hands or metal implements	Yes	Raak de eenheid niet aan tijdens gebruik.
Do not cover the unit during use	Yes	Dek de eenheid niet af.
Remove or cover terrariums, aquariums and animal cages before use	Yes	Verwijder terrariums, aquariums en dierenkooien of dek ze af voorafgaand aan gebruik.
Turn off aquarium air filter before use	Yes	Schakel de luchtfilter van het aquarium uit voorafgaand aan gebruik.
For safety use refill only with correct electrical device	Yes	Houder niet opnieuw vullen of hergebruiken, lege houders veilig verwijderen als chemisch afval.
- Skin contact: wash immediately with plenty of soap and water - eye contact: bathe the eye with running water for 15 minutes - ingestion: do not induce vomiting	No	treatment statements are not included in WG/GA.
This product and its container should not be reused or recycled. Incineration is the recommended method of disposal.	Yes	Houder niet opnieuw vullen of hergebruiken, lege houders veilig verwijderen als chemisch afval.
Eliminate all sources of ignition	Yes	Breng de verdamer niet in contact met stoffen, papier of brandbare materialen.
Do not discharge into drains or rivers	Yes	Middelresten niet op het riool of oppervlaktewater lozen.

### 3 Proposal for decision

The authorisation of SumiOne Liquid Vaporiser is based on mutual recognition of the authorisation of RMS UK. For the evaluation we refer to the product assessment report which has been composed by the RMS conform the Common Principles.

It is expected that the application of SumiOne Liquid Vaporiser according to the use instructions, will be effective and that there will be no harm for the health of humans, for those who use the product, and for the environment.

#### Proposal for the classification and labelling of the formulation

Based on the profile of the substance, the provided toxicology of the preparation, the characteristics of the co-formulants, the method of application and the risk assessment, the following labelling of the formulation is proposed:

The identity of all substances in the mixture that contribute to the classification of the mixture *:			
-			
Pictogram:	GHS08	Signal word:	Danger
	GHS09		
H-statements:	H304	May be fatal if swallowed and enters airways	
	H400	Very toxic to aquatic life	
P-statements:	P101	If medical advice is needed, have product container or label at hand.	
	P102	Keep out of reach of children	
	P273	Avoid release to the environment	
	P301+P330+P331+P310	IF SWALLOWED: rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician.	
	P501	Dispose of contents/container to hazardous or special waste collection point	
Supplemental Hazard information:	-	-	
Child-resistant fastening obligatory?			Yes
Tactile warning of danger obligatory?			Yes