Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Chrysanthemum cinerariaefolium, extract from open and mature flowers of _Tanacetum cinerariifolium_ obtained with hydrocarbon solvents

Product type: 19

ECHA/BPC/314/2021

Adopted

3 December 2021

Opinion of the Biocidal Products Committee

on the application for approval of the active substance *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents for product type 19

In accordance with Article 89(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the application for approval in product type 19 of the following active substance:

Common name:	***Chrysanthemum cinerariaefolium* extract from HCS**
Chemical name:	***Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents**
EC No.:	**289-699-3**
CAS No.:	**89997-63-7**

Existing active substance

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of BPC opinions

Following the submission of an application by Pyrethrum Task Force (PTF) (Botanical Resources Australia Pty Ltd. (BRA), McLaughlin Gormley King Company (MGK)) and SC Johnson & Son Inc. (SCJ) for Pyrethrins and Pyrethroids on 26 April 2006, the evaluating Competent Authority, Ministry of Health, Spain submitted an assessment report and the conclusions of its evaluation to the Commission on 1 September 2010. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Commission organised consultations via the Technical Meeting (TM IV 2012) and the Agency organised consultations via the BPC (BPC-41) and its Working Groups (WG-V-2015, WG-IV-2020 and WG-III-2021). A redefinition was recommended by the Working Group meeting in 2015, and two active substances of two applications were redefined. *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents is one of the new ones as explained in 2.1. The applicants are BRA and MGK, represented by Sumitomo Chemical (UK) Plc, and SCJ.

Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: Spain

The BPC opinion on the application for approval of the active substance *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents in product type 19 was adopted on 3 December 2021.

The BPC opinion was adopted by consensus.

The opinion is published on the ECHA webpage at: http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents in product type 19 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

Initially, Pyrethrins and Pyrethroids were notified as an existing active substance by the Task Force (BRA, MGK and SCJ). Subsequently, a redefinition of the active substance was decided based on the different extraction methods used to get the extract from *Tanacetum cinerariifolium*:

- *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents. This dossier has been submitted by BRA and MGK, represented by Sumitomo Chemical (UK) Plc, and SCJ after the redefinition. The source of the active substance is MGK.

- *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbondioxide. This dossier has been submitted by BRA and MGK, represented by Sumitomo Chemical (UK) Plc, and SCJ. The source of the active substance is BRA.

Given that all applicants share Letter of Access to the studies, an assessment was conducted to check that the sources were equivalent where relevant, and that the extracts used in the studies could meet the specifications of all sources.

This evaluation covers the use of *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents in product type 19, hereafter referred to as *Chrysanthemum cinerariaefolium* extract from HCS. The active substance *Chrysanthemum cinerariaefolium* extract from HCS (synonym: Pyrethrum Extract) is an extract of the flower heads of *Chrysanthemum cinerariaefolium*. It contains, among other constituents, Pyrethrins, which may be divided into the two groups: Pyrethrins I (consisting of pyrethrin 1, cinerin 1, and jasmolin 1) and Pyrethrins II (consisting of pyrethrin 2, cinerin 2 and jasmolin 2).

Chrysanthemum cinerariaefolium extract from HCS as manufactured is a UVCB substance, hence the purity is 100%. The active substance as manufactured includes a solvent, which is added after the extraction of the active substance to standardize the refined extract to 50% (w/w) pyrethrins. The solvent has a slight stabilising effect on pyrethrins and is also added for better handling of the extract. However, *Chrysanthemum cinerariaefolium* extract from HCS remains stable without the solvent, showing only a slight decrease in stability, which is not enough to support the inclusion of the solvent in the composition of the active substance. Reference specifications (dry matter) have been stablished on the extract in the MGK source.

Physico-chemical properties and physical hazards have been evaluated on the active substance as manufactured and on the representative biocidal product and are deemed acceptable for the appropriate use, storage and transportation. However, as the solvent should not be part of the active substance, physico-chemical properties and physical hazards have to be studied on the purified active substance to conclude without doubt that *Chrysanthemum cinerariaefolium* extract from HCS does not meet any physical hazards described in the CLP.

Validated analytical methods are available for the determination of *Chrysanthemum cinerariaefolium* extract from HCS as manufactured and for the analysis of its constituents. Validated analytical methods are also available for the determination of the active substance in air and food/feeding stuffs matrices. Sufficiently validated analytical methods for the determination of residues in soil, drinking water and surface water are missing. Other analytical methods are not required because *Chrysanthemum cinerariaefolium* extract from HCS is not classified as toxic or highly toxic.

There is no harmonised classification and labelling according to the CLP Regulation. A CLH report was submitted on 18 October 2021. The proposed classification and labelling for *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

(Proposed) Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute toxicity 4 Skin sensitisation 1B Short-term (acute) aquatic hazard 1 Long-term (chronic) aquatic hazard 1
Labelling	
Pictogram codes	GHS07 GHS09
Signal Word	Warning
Hazard Statement Codes	H302 H332 H317 H410
Specific Concentration limits, M-Factors	M = 100 (Acute) M = 10 (Chronic)

b) Intended use, target species and effectiveness

Chrysanthemum cinerariaefolium, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents, is intended to be used as a mosquito repellent outdoors for non-professional use only.

Natural Pyrethrins are contact poisons which repel insects by disrupting their nervous system. They are toxic to the insects' sodium channels, the cellular structure that allows sodium ions to enter a cell as part of the process of transmitting a nerve impulse. The pyrethrins included in the *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents have a very high affinity for membrane sodium channels, with dissociation constants of the order of 4×10^{-8} m. They cause the kinetics of the sodium channel to change dramatically, although many other normal functions are continued. The main consequence of their activity is that while the sodium action potentials are only marginally affected, they are followed by a slowly inactivating abnormal "tail" current. This means that the mean channel open time is greatly

extended, which causes stable repetitive firing. This leads to repetitive discharges by the nerve cell which causes repellency at first stage and later on paralysis and death.

The data on *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents and the representative biocidal product Mosquito Coil have demonstrated sufficient efficacy against the target species. Two *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents -based mosquito coils, with 0.6% total pyrethrins (ca 1.2% *Chrysanthemum cinerariaefolium* extract from HCS) each coil, gave between 98% to 100% repellency of mosquitoes over the 4-hour study period in a field situation simulating the use of the mosquito coils protecting people on a covered balcony or veranda of 9 m^2.

Very few cases of insects' resistance to pyrethrins have been discovered, and these have mainly arisen as a result of cross-tolerance conferred by the insects developing resistance to another insecticide. No formation of resistance is expected because some reasons as the application of pyrethrins results in a rapid knockdown and death, pyrethrins are rapidly degradable by sunlight to harmless breakdown products, or that the resistance to pyrethrins is not widespread in the insect world. Only 15 species are involved, which is about 3% of the total number of species known to be resistant to insecticides. In adition, no selection pressure is expected upon the population and development of resistance is not expected when the active substance is used with repellent doses.

c) Overall conclusion of the evaluation including need for risk management measures

Human health

Chrysanthemum cinerariaefolium extract from HCS is harmful by the oral (Acute Tox. 4, H302) and the inhalation routes (Acute Tox. 4, H332). It is not a skin or eye irritant. It is a skin sensitiser (Skin Sens. 1B, H317) classified by changes observed in several *in vitro* and *in vivo* LLNA studies. *Chrysanthemum cinerariaefolium* extract from HCS did not show mutagenicity, carcinogenicity or reproductive toxicity.

Mosquito coil is a green ridged solid coil containing ca 1.2% *Chrysanthemum cinerariaefolium* extract from HCS. Once ignited the coil burns releasing vapour for a period of 5-7 hours.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
Loading	**Primary exposure** Remove the coils from their packaging and place onto the floor before lighting. RMM (instructions for use: 120 days per year – max. 4 months – e.g. summer season)	Non-professional	Acceptable with RMM
Application	**Secondary exposure** Inhalation exposure during and after operation of two coils (adults/toddlers) RMM (instructions for use: 120 days per	Non-professional	Acceptable with RMM

	year – max. 4 months – e.g. summer season)		
Post - application	**Secondary exposure** Inhalation of volatilized residues of BP	General public	Acceptable
Post - application	**Secondary exposure** Dermal and oral exposure from contaminations on surfaces in treated rooms (toddlers) RMM (instructions for use: 120 days per year – max. 4 months – e.g. summer season)	General public	Acceptable with RMM.

Primary exposure to non-professionals placing mosquito coils is considered acceptable. Secondary exposure during burning of mosquito coils is considered acceptable. The risk assessment is not safe using a frequency of use of 150 days per year (max. 5 months) and $AEL_{long\text{-}term}$. These parameters are the most important to take into account. It is acknowledged that this type of exposure is intermittent and using the $AEL_{long\text{-}term}$ is very conservative. However, a concept specific for intermittent exposure does not exist. For this reason, the use of $AEL_{medium\text{-}term}$ (120 days per year – max. 4 months) can be considered more appropriate because of the seasonal use of the product, and the intermittent use over the period.

Secondary (indirect) exposure of the general public via food is acceptable when the RMM 'Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and animals' is included on the label.

In sub-chronic and chronic toxicity studies in mice, rats and dogs, the liver was the main target organ. Furthermore, in a neurotoxicity study in rats given single oral doses, acute neurological disorders and behavioural effects were noted.

Chrysanthemum cinerariaefolium extract from HCS contains pyrethrins and these pyrethrins may cause paresthesia (burning and prickling of the skin without irritation).

Regarding the ED properties of the active substance, the potential for EAS-mediated adversity is considered to have been sufficiently investigated. Overall, there is strong weight of evidence to indicate that pyrethrum flower extract does not affect the EAS-modalities. However, the potential for T-mediated adversity is considered to have not been sufficiently investigated. Overall, there is not sufficient weight of evidence to indicate that pyrethrum flower extract affects the thyroid modality by a mode of action that is specific to the rat and, as such, it cannot be concluded there are no indications of endocrine adversity of relevance to humans

Environment

The active substance *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents results very toxic to aquatic life with long lasting effects.

It is not readily biodegradable and hydrolytically stable in water at pH 7. It is photolytically unstable (less than 1 day). It undergoes rapid degradation in aerobic natural waters and water/sediment systems. Its high adsorption coefficient leads to a fast movement into the sediment.

This substance is unstable in the atmosphere, therefore, it is expected that its concentration in air will be negligible for the scenarios presented in this dossier.

It rapidly degradates in soil under aerobic conditions, and the adsorption/desorption study characterizes it as an immobile compound in soil according to estimated Koc values.

Release to the environment may occur during the use of the biocidal product outdoors. Subsequent receiving compartments in the environment are therefore outdoor air (atmosphere), soil and groundwater. Emissions to surface water are unlikely.

Chrysanthemic acid was detected as the main relevant metabolite (present at >10% AR) in the hydrolysis and aerobic water/sediment tests performed. Pyrethrolone was formed (> 5% in consecutive data) in the aerobic biodegradation in freshwater test. As the PT 19 scenario considers it very unlikely that the a.s. reaches surface water, no assessment of these metabolites was included.

Environmental emissions were calculated using the the ESD for PT19 (ECHA, 2015). This document and the ESD for PT18 (OECD, 2008) consider that diffusers employed outdoors are not that critical with regard to environmental emissions. Nevertheless, an exposure scenario which was proposed by ECHA (AHEE-3_AP4-2, item 4.2) following discussions from the ENV WG-V-2018 has been used. This scenario concerns a diffuser used in outdoor-domestic gardens.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
The product is a mosquito repellent coil to be lit-up in private terrace and gardens.	When the coil is lit-up, the active substance is released to air with subsequent potential deposition to hard surfaces (and subsequently to STP) and soil, being very unlikely to reach surface water. A default value of 1000 m^3 of water volume of a pond as a receiving compartment was selected from the emission scenario “PT8 - Bridge over pond”.	The risk to the environment compartments water, air, soil and groundwater is acceptable. The risk to surface water is acceptable (approach to be completed). The risk of secondary poisoning is acceptable from the use of the active substance in all scenarios (PEC/PNEC below 0.001).

A tier 2 has been applied both for single and repeated use scenarios, as there was risk with repeated use in tier 1. This tier 2 is based on the very low deposition of the active substance onto soil (from experimental study).

An exposure scenario for releases to water was not developed for the use in outdoor residential gardens, since it is expected that most domestic outdoor areas will not have and/or be adjacent to water bodies (such as a pond or a river) and since this exposure route is not as critical and as common as direct emissions to soil. Hence, assessment of the aquatic compartment is not required. Nevertheless, for additional information, an approach with use adjacent to a pond was used.

Predicted environmental concentrations in groundwater are <0.1 µg/L for all scenarios assessed in the tier 2 approach.

Regarding the ED properties, the EATS-modalities were not sufficiently investigated for environment, then it is not possible to reach a conclusion about the Endocrine Disruption properties of *Chrysanthemum Cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents.

Overall conclusion

A safe use both for human health and environment has been identified. There is acceptable risk for non-professionals users both in loading and application steps but some RMMs should be applied. For general public, there is acceptable risk in the post-application step, but in case of Dermal and oral exposure some RMMs are needed. For environment, there is acceptable risk for all compartments assessed (including approach for surface water) both for single and repeated use. Nevertheless, a precautionary RMM is proposed: "the biocidal product containing *Chrysanthemum Cinerariaefolium* extract from hydrocarbon solvents should not be used close to surface water".

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

<table>
<tr><th colspan="2">Property</th><th colspan="2">Conclusions</th></tr>
<tr><td rowspan="3">CMR properties</td><td>Carcinogenicity (C)</td><td>No classification required</td><td rowspan="3">*Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents does not fulfil criterion (a), (b) and (c) of Article 5(1)</td></tr>
<tr><td>Mutagenicity (M)</td><td>No classification required</td></tr>
<tr><td>Toxic for reproduction (R)</td><td>No classification required</td></tr>
<tr><td rowspan="3">PBT and vPvB properties</td><td>Persistent (P) or very Persistent (vP)</td><td>Nor P or vP. Main metabolites Chrysanthemic acid and Pyrethrolone are P</td><td rowspan="3">*Chrysanthemum cinerariaefolium, extract* from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1).</td></tr>
<tr><td>Bioaccumulative (B) or very Bioaccumulative (vB)</td><td>Not B or vB</td></tr>
<tr><td>Toxic (T)</td><td>T</td></tr>
<tr><td>Endocrine disrupting properties</td><td>Section A of Regulation (EU)</td><td>No conclusion can be drawn</td><td>No conclusion can be drawn</td></tr>
</table>

	2017/2100: ED properties with respect to humans		whether *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents fulfils criteria of Article 5(1)(d) or Article 10(1)(e)
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	No conclusion can be drawn	
	Article 57(f) and 59(1) of REACH	No	
	Intended mode of action that consists of controlling target organisms via their endocrine system(s).	No	
Respiratory sensitisation properties	No classification required. *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects other than those related to endocrine disrupting properties	*Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	*Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

Chrysanthemum cinerariaefolium extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents does not meet the exclusion criteria laid down in Article 5(1)(a, b, c and e) of Regulation (EU) No 528/2012. However, endocrine disrupting criteria have not been sufficiently investigated, and a conclusion cannot be reached. Therefore, according to “Note on the principles for taking decisions on the approval of active substances under the BPR”, Chrysanthemum cinerariaefolium extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents might be approved.

Chrysanthemum cinerariaefolium extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents does not meet the conditions laid down in Article 10(1) (a, b, d, e and f) of Regulation (EU) No 528/2012. For the endocrine-disrupting properties as defined in Regulation (EU) No 2017/2100, no conclusion can be drawn on the available data. For reports submitted before 1 September 2013, it is mentioned in the CA meeting note mentioned above that the evaluating Competent Authority has to conclude based on the already available data and/or the data provided by the applicant and, in case the data is insufficient to reach a conclusion, the BPC may conclude in its opinion that no conclusion could be drawn. It is noted that the evaluation of *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum*

cinerariifolium obtained with hydrocarbon solvents for PT 19 was submitted before 1 September 2013. Consequently, no conclusion is drawn whether the active substance meets the conditions laid down in Article 10(1)(a) based on the available data.

The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR", "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR" and "Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment" agreed at the 54th, 58th and 77th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1) (a, b, d, e and f).

2.2.2. POP criteria

The active substance *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents is not listed in Annex I of EC 850/2004.

The vapour pressure of Pyrethrin 1, as a representative member of Pyrethrins, is 6.9E-05 Pa (25°C), its half-life in air is of 76.8 minutes (OH radicals) and 17.13 minutes (O_3), indicating that the criterion for long-range transboundary atmospheric transport potential is not fulfilled.

As reported above, it does not meet criteria for persistence and bioaccumulation. It is very toxic to aquatic organisms.

It cannot be classified as a POP according to the Executive Body Decision 1998/2 on information to be submitted and the procedure for adding substances to annexes i, ii or iii to the protocol on persistent organic pollutants.

Overall, it can be concluded that *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents does not fulfil the criteria for being a persistent organice pollutant (POP).

2.3. BPC opinion on the application for approval of the active substance *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents in product type 19

In view of the conclusions of the evaluation, it is proposed that *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: minimum purity of the active substance evaluated: minimum purity of 100% w/w of *Chrysanthemum cinerariaefolium* extract, from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents

2. The authorisations of biocidal products are subject to the following condition(s):

    a. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for

authorisation, but not addressed in the Union level risk assessment of the active substance.

b. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:

i. non-professional users and the general public.

c. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

The active substance does not fulfil the requirements of Article 28(2)(a), and therefore *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents cannot be included in Annex I of Regulation (EU) 528/2012 because it meets the criteria of Article 28(2) (a) as it is classified as H317 (Skin Sens. 1B) and H400 (Aquatic Acute 1).

2.4. Elements to be taken into account when authorising products

The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:

a. A local risk assessment may be required if the product is classified for skin sensitisation.

b. A quantitative/qualitative exposure and risk assessment for sensitive pet species (e.g. cats, fish, reptiles and amphibians) may be required if the product is used indoors.

c. An advice on the potential of pyrethrins to cause paresthesia should be considered for biocidal products supplied to non-professional users / general public.

d. This active substance shows an intrinsic hazard to bees. As indicated in document “CA-Dec20-Doc.4.1” agreed at the 90th CA meeting, the warning sentence proposed in this document should only be required for products containing active substances for which scientific evidence exists in regard to their hazard (intrinsic) properties to bees, which is the case for this active substance.

e. For products that may lead to residues in food or feed a dietary risk assessment has to be performed at product authorization level.

f. The complete assessment for surface water and sediment will be requested at product authorisation by using the emission scenario for outdoor airspace treatments by repellents.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of substance *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents. However, the following data have to be provided to the Competent Authority Spain as soon as possible but not later than 6 months before the date of approval of the active substance:

1. Physico-chemical tests on the purified active substance: appearance, colour, odour, relative density, surface tension and viscosity.

2. Physical hazards tests on the purified active substance: explosive properties, self-reactive substances and mixtures, flammable liquids, substances and mixtures in contact with water emitting flammable gases, corrosiveness to metals and auto-ignition temperature (liquids).

3. Validated analytical methods for the determination of residues of the active substance in soil, drinking water and surface water.

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