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 supercritical carbon dioxide**

Product type: 18

ECHA/BPC/366/2022

Adopted

22 November2022

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 supercritical carbon dioxide for product type 18

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 18 of the following active substance:

Common name:	***Chrysanthemum cinerariaefolium*, extract from supercritical CO_2**
Chemical name:	***Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with supercritical carbon dioxide***
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 (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 Technical Meeting (TM IV 2012) and the Agency organised consultations via BPC (BPC-41 and BPC-45) and its Working Groups (WG-V-2015, WG-IV-2020, WG-III-2021 and a dedicated/ad hoc ENV WG meeting in 2022). A redefinition was recommended by the Working Group meeting in 2015, and two active substances of the two applications were redefined. *Chrysanthemum cinerariaefolium,* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide is one of the new ones as explained in 2.1. The applicants are BRA, 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 supercritical carbon dioxide in product type 18 was adopted on 22 November 2022.

The BPC opinion was adopted by simple majority of the members present having the right to vote.

The opinion and the minority position including their grounds 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 supercritical carbon dioxide** in product type **18** 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) and, on the other hand, *Chrysanthemum cinerariaefolium* extract was notified as an existing active substance by KPIC. 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 MGK, represented by Sumitomo Chemical (UK) Plc, KPIC 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 carbon dioxide. This dossier has been submitted by BRA, represented by Sumitomo Chemical (UK) Plc, and SCJ, after the redefinition. 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 supercritical carbon dioxide in product type 18, hereafter referred to as *Chrysanthemum cinerariaefolium* extract from supercritical CO_2. The active substance *Chrysanthemum cinerariaefolium* extract from supercritical CO_2 (synonym: Pyrethrum Extract) is an extract of the flower heads of *Chrysanthemum cinerariaefolium*. It contains Pyrethrins, among other constituents, 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 supercritical CO_2 as manufactured is an 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 supercritical CO_2 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 established on the extract in the BRA source.

Physico-chemical properties and physical hazards have been evaluated on the active substance as manufactured and on the representative biocidal products and are deemed

acceptable for the appropriate use, storage and transportation of the active substance as manufactured and biocidal products. However, as the solvent should not be part of the active substance, physicochemical properties (if possible) and physical hazards have to be studied on the purified active substance to conclude without doubt that *Chrysanthemum cinerariaefolium* extract from supercritical CO_2 does not meet any physical hazard classes described in the CLP.

Validated analytical methods are available for the determination of *Chrysanthemum cinerariaefolium* extract from supercritical CO_2 as manufactured and for the analysis of its constituents. Validated analytical methods are also available for the determination of the active substance in soil, water, air and food/feeding stuffs matrices. Other analytical methods are not required because *Chrysanthemum cinerariaefolium* extract from supercritical CO2 is not classified as toxic or highly toxic.

There is no harmonised classification and labelling according to the CLP Regulation. The proposed classification and labelling for *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide 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 supercritical carbon dioxide, is intended to be used by professionals and non-professionals as an insecticide against a wide range of flying and crawling pests except those that are plant parasitic, in various applications sites in- and outdoor. In this dossier, efficacy indoor against mosquitoes and flies is supported. Efficacy against other species is also presented.

It is a contact poison which kills insects by disrupting their nervous system. It is toxic to the sodium channels, the cellular structure that allows sodium ions to enter a cell as part of the process of transmitting a nerve impulse. This leads to repetitive discharges by the nerve cell which causes paralysis and death. Rapid knockdown and death occur within one hour after contact.

Very few cases of insects' resistance to pyrethrins have been discovered, and these have mainly arisen as a result of cross-tolerance conferred by 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 world. Only 15 species are involved, which is about 3% of the total number of species known to be resistant to insecticides. However, at the product authorisation stage, the resistance issue should be addressed by updating the resistance section through a literature review or relevant data to ensure that no new resistance phenomenon has occurred on the target claimed.

The efficacy tests have been performed with products which have pyrethrins and piperonyl butoxide, as a synergist. The representative products are Product A (a non-ready to use, ultra-low volume aerosol which is for use by professionals only in public indoor and outdoor areas), and Product B (an electric vaporizer mat for use by non-professionals in private housings).

Human and environmental risk assessments have been performed considering *Chrysanthemum cinerariaefolium* extract concentrations at the efficacious dose of the representative product:

Product A:

- Indoor space spray application against adult houseflies and mosquitoes: application rate of 1 mg total pyrethrins/m^3.
- Outdoor ground ULV space spray application against adult mosquitoes: application rate of 0.4-0.6 mg total pyrethrins/m^2.

Product B:

- Indoor electric vaporizer mat against *Culex quinquefasciatus* and *Aedes aegypti* mosquitoes: application rate of 3.26 mg total pyrethrins/m^3/8 hrs.

Submitted data are sufficient to demonstrate efficacy of *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide for active substance approval.

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

Human health

Chrysanthemum cinerariaefolium extract from supercritical CO_2 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 supercritical CO_2 did not show mutagenicity, carcinogenicity or reproductive toxicity. 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.

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 that there are no indications of endocrine adversity of relevance to humans.

The tables below summarise the exposure scenarios assessed.

Summary table: human health scenarios – Product A				
Scenario number	**Scenario**	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**

Summary table: human health scenarios – Product A				
1.	Mixing / Loading	**Primary exposure** Loading of the biocidal product to prepare the end-product PPE: protective gloves RMM for low hazard class chemicals (e.g. protective gloves, coverall and face mask)	Professional (trained/PCO) workers	Acceptable with PPE and RMM
2.	Application	**Primary exposure** Application of the end-product as space spray application (mist or thermal fog) in indoor/outdoor areas. PPE: protective gloves, coated coverall RMM for low hazard class chemicals (e.g. protective gloves, coverall and face mask)	Professional (trained/PCO) workers	Acceptable with PPE and RMM
3.	Post - application	**Secondary exposure** Inhalation of volatilized residues of BP	General public	Acceptable
4.	Post - application	**Secondary exposure** Dermal and oral exposure of a toddler after space spray treatment application in indoor areas Specific RMMs: 'Leave room after spraying/fogging process is triggered', 'Do not enter a room until the treated surface is completely dried' and 'Keep children and pets away from treated surfaces'.	General public	Acceptable with RMM
5.	Post - application	**Secondary exposure** Inhalation exposure of an adult re-entering treated rooms Specific RMMs: 'Leave room after spraying/fogging process is triggered', 'Do not enter a room until the treated surface is completely dried' and 'Keep children and pets away from treated surfaces'.	General public	Acceptable with RMM
6.	Post - application	**Secondary exposure** Dermal and oral exposure of a toddler after space spray treatment application in an outdoor area before the fog has disappeared	General public	Acceptable with RMM

Summary table: human health scenarios – Product A				
		Specific RMMs: 'Leave room after spraying/fogging process is triggered', 'Do not enter a place until the fog has disappeared' and 'Keep people and pets away from treated places until the fog has disappeared'.		
7.	Post - application	**Secondary exposure** Inhalation exposure of an adult re-entering in an outdoor area before the fog has disappeared Specific RMMs: 'Leave room after spraying/fogging process is triggered', 'Do not enter a place until the fog has disappeared' and 'Keep people and pets away from treated places until the fog has disappeared'.	General pubic	Acceptable with RMM
8.	Post - application	**Secondary exposure** Persons laundering contaminated work clothing	General pubic	Acceptable

Product A is a non-ready to use (non-RTU) ultra-low volume (ULV) aerosol; designed to target flies and mosquitoes. It is for use by professionals only, as a space spray application in indoor/outdoor areas. Indoor areas: places continuously occupied such as hospital wards, residential nursing homes and prisons (public premises). Outdoor areas: amenity areas and woodlands.

Primary exposure to professional users is acceptable, assuming PPE (gloves and coverall) is worn. (Product A)

Secondary exposure of the general public is acceptable.

Summary table: human health scenarios - Product B				
Scenario number	**Scenario**	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
1.	Loading	**Primary exposure** Loading of a refill unit into electrical devices. RMM for medium hazard class chemicals (Labelling, instructions for use, Childproof closure, Packaging eliminating exposure)	Non-professional	Acceptable with RMM
2.	Application	**Secondary exposure** Inhalation exposure during and after operation of an evaporator (adults/toddlers)	Non-professional / Bystanders	Acceptable

Summary table: human health scenarios - Product B				
		RMM (instructions for use: The biocidal product contains pyrethrins (natural pyrethroids). DO NOT USE if under medical advice NOT to work with such compounds.)		
3.	Post - application	**Secondary exposure** Inhalation of volatilized residues of BP	General public	Acceptable
4.	Post - application	**Secondary exposure** Dermal and oral exposure from contaminations on surfaces in treated rooms (toddlers)	General public	Acceptable

Product B is an electric vaporizer mat that provides protection from mosquitoes for about 8 hours. The vaporizer mat is solely for use by non-professionals, in private housings, during night-time hours.

Primary exposure to non-professional users is acceptable when RMM are implemented.

Secondary (indirect) exposure of the general public is acceptable when an instruction for use to pyrethroids is implemented.

Based on assessment of the scenarios listed above, it is concluded that primary and secondary exposure are acceptable for both biocidal products.

Furthermore, indirect exposure via food to both products 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 in the label.

Finally, indirect exposure of animals is acceptable when the following RMMs are implemented for each product (see table below):

PRODUCT	FIELD OF USE	RMMs
A	Indoor	Contains pyrethrins, may be dangerous/toxic to pets (e.g. cats, fish, reptiles and other poikilothermic animals). Do not apply in rooms where fish tanks and/or terrariums are present. 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. Leave room after spraying/fogging process is triggered. Do not enter a room until the treated surface is completely dried. Keep children and pets away from treated surfaces.
A	Outdoor	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. Contains pyrethrins, may be dangerous/toxic to pets (e.g. cats, fish, reptiles and other poikilothermic animals). Do not apply in places where fish tanks and/or terrariums are present. Leave place after spraying/fogging process is triggered. Do not enter a place until the fog has disappeared. Keep people and pets away until the fog has disappeared.

PRODUCT	FIELD OF USE	RMMs
B	Indoor	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. Keep children and pets away from treated surfaces. Avoid prolonged contact of pets, particularly cats, to treated surfaces. Contain pyrethrins, may be lethal to cats and poikilothermic animals. Cats and poikilothermic animals contact with treated object area must be avoided.

Environment

The active substance *Chrysanthemum cinerariaefolium* extract from supercritical CO_2 is very toxic to aquatic life with long lasting effects and it shows an intrinsic hazard to bees.

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

Releases to the environment may occur during the preparation (relevant to first scenario), application and cleaning steps. To assess the worst-case use of the products, wet-cleaning has been assessed only; therefore, the STP is considered as the main "receiving compartment" for scenario 1 and 2. Subsequent receiving compartments in the environment are therefore outdoor air (atmosphere), surface water, sediment, agricultural soil and groundwater. Emissions to these environmental compartments result from the cumulative emission from the preparation, application and/or cleaning steps, carried out indoors, following treatment with the products. For scenario 3, which is outdoor, the receiving compartments in the environment are outdoor air (atmosphere), surface water and sediment, agricultural soil and groundwater.

Chrysanthemic acid was detected as the main relevant metabolite (present at >10% AR) in the hydrolysis and aerobic water/sediment tests performed. The highest maximum formations in these studies were considered in the risk assessment as a worst-case approach to assess this metabolite. Pyrethrolone was formed (> 5% in consecutive data) in the aerobic biodegradation in freshwater test and it was also assessed.

Environmental emissions were calculated using the Emission Scenario Document for PT18 (OECD 2008), considering recent agreements made at ECHA Working Groups (TAB ECHA, 2018 and WGII2018_ENV_7-3e) and the Rautmann et al. (2001) scenario for fruit crops – late application.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
- Scenario 1: Product A – Indoor spray	-Scenario 1: indoor spray application against target flies and	The risk to the environment compartments water, sediment,

application - air space in large buildings, by professional users.	mosquitoes for use exclusively by professionals in public buildings that are continuously occupied such as hospital wards, residential nursing homes and prisons. This scenario considers a maximum of two applications per site during the fly and mosquito flight period from April to October at a minimum interval between applications of 1 month. Three release pathways are identified: preparation step, application step and cleaning step. Final receiving compartments in the environment are outdoor air (atmosphere), STP, surface water and sediment, agricultural soil and groundwater. Emissions to these environmental compartments result from the cumulative emission from the preparation, application and cleaning steps, carried out indoors, following treatment.	STP, air, soil and groundwater is acceptable. The risk of secondary poisoning is acceptable from the use of the active substance.
- Scenario 2: Product B – Indoor electric diffuser use in households, by non-professional users.	- Scenario 2: indoor electrical vaporizing mat, which comprises a mat heater and a mat vaporizer. In combination with an electrical heater, the solution evaporates from the cardboard and provides protection from mosquitoes for about 8 hours. The vaporizer mat is solely for use by non-professionals, in private housings, during night-time hours. One mat protects rooms of up to 28 m^3. Two release pathways are identified: application step and cleaning step. Final receiving compartments in the environment are outdoor air (atmosphere), STP, surface water and sediment, agricultural soil and groundwater. Emissions to these environmental compartments result from the cumulative emission from the application and cleaning steps, carried out indoors, following treatment.	The risk to the environment compartments water, sediment, STP, air, soil and groundwater is acceptable. The risk of secondary poisoning is acceptable from the use of the active substance.
- Scenario 3: Product A for outdoor use – spray single and multiple application in woodlands and	- Scenario 3: outdoor spray application against target flies and mosquitoes for use exclusively by professionals in woodlands and amenity areas with a buffer	The risk to the environment compartments water, sediment, air, soil and groundwater is acceptable.

amenity areas.	riparian zone of 30 meters from any surface water. This scenario considers a maximum of three applications during the fly and mosquito flight period from April to October at an interval of 60 days. Final receiving compartments in the environment are outdoor air (atmosphere), surface water and sediment, agricultural soil and groundwater.	The risk of secondary poisoning is acceptable from the use of the active substance.

There is acceptable risk to all compartments in all scenarios assessed for the parent substance and the two metabolites Chrysanthemic acid (water and sediment) and Pyrethrolone (in surface water).

Regarding scenario 3, large-scale outdoor use spray application in woodlands and amenity areas, the following should be considered:

- BPR guidance volume IV Part A, section 2.1.5 Effects on arthropods states that "for systemic insecticides exposure to bees should also be quantified. When no data is available, a qualitative assessment should be performed."

- An ENV TAB (Technical Agreements for Biocides[1]) entry 248 has been approved after ENV WG-II-2022 for outdoor large-scale spraying which states that due to the large scale, open and broad application of the relevant biocidal products into the environment in combination with the unspecific insecticidal mode of action of the active substances in these biocidal products, adverse effects on non-target arthropods, ecosystems and/or biodiversity must be assumed. This TAB entry establishes a risk assessment taking into account adverse effects on co-occurring non-target organisms, biodiversity and ecosystems in treated areas. This allows to define clear preconditions for the application of the relevant biocidal products in case of product authorisation and the assignment of necessary precautionary instructions for use and risk mitigation measures in order to reduce the adverse effects on the environment as much as possible.

- Without a sufficient buffer zone, unacceptable risks would be identified for surface waters and sediment. This means that this is a risk mitigation measure which is required under product authorisation.

Hence, a quantitative risk assessment for pollinators (at least for bees) according to the future pollinators guidance for biocides risk assessment[2] should be provided for product authorisation. In case this is not possible, it should be justified and a qualitative risk assessment should be performed.

Overall conclusion

A safe use both for human health and the environment has been identified.

For product A, there is acceptable risk in all scenarios assessed for human health, but some RMMs are needed for the mixing/loading and application steps, for professionals, and in the post-application step for the general public, due to dermal and oral exposure and inhalation.

[1] Available from the ECHA web-site at: Working Groups of the Biocidal Products Committee - ECHA (europa.eu).
[2] Guidance will become available in the near future as a result of the request received by ECHA under Article 75(1)(g) on "Methodology to assess the risk to bees and other non-target arthropod pollinators from the use of biocides".

For product B, there is acceptable risk in all scenarios assessed for human health, but some RMMs are needed for the loading and application steps for non-professional users.

The environmental risk assessment showed acceptable risk to all compartments in scenarios 1 and 2. For Scenario 3, large-scale outdoor use spray application in woodlands and amenity areas should only be allowed under product authorisation if a quantitative risk assessment for pollinators is carried out – including the introduction of risk mitigation measures – and it does not identify unacceptable risks.

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:

Property		**Conclusions**	
CMR properties	Carcinogenicity (C)	Active substance is not classified and does not meet the criteria to be classified as Carc. Cat. 1A or 1B.	*Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Mutagenicity (M)	Active substance is not classified and does not meet the criteria to be classified as Muta. Cat. 1A or 1B.	
	Toxic for reproduction (R)	Active substance is not classified and does not meet the criteria to be classified as Repr. Cat. 1A or 1B.	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	Not P or vP. Main metabolites Chrysanthemic acid and Pyrethrolone are P.	*Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	Not B or vB.	
	Toxic (T)	T	
Endocrine disrupting properties	Section A of Regulation (EU) 2017/2100: ED properties with	No conclusion can be drawn	No conclusion can be drawn whether *Chrysanthemum*

Property		Conclusions	
	respect to humans		*cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide 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 supercritical carbon dioxide 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 supercritical carbon dioxide 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 supercritical carbon dioxide 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 supercritical carbon dioxide 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 supercritical carbon dioxide might be approved.

Chrysanthemum cinerariaefolium, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide 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 supercritical CO_2 for PT 18 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 supercritical carbon dioxide 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. But toxicity criteria for mammals are not fulfilled as it is not classified as carcinogenic, mutagenic, toxic for reproduction or as endocrine disruptors (ED criteria not sufficiently investigated).

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 supercritical carbon dioxide does not fulfil the criteria for being a persistent organic 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 supercritical carbon dioxide in product type 18

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 supercritical carbon dioxide 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 supercritical carbon dioxide.

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. Professional users and general public;

   ii. Surface water and sediment for products applied via large-scale spraying outdoors.

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 supercritical carbon dioxide 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 paraesthesia should be considered for biocidal products supplied to non-professional users / general public.

d. If an unacceptable risk is identified for professional users, safe operational procedures and appropriate organizational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.

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. 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.

g. For products used for outdoor large-scale application a quantitative (or if this is not possible, a qualitative) risk assessment for pollinators using the future guidance to be published by ECHA should be carried out. If the risk cannot be

reduced to an acceptable level by appropriate risk mitigation measures or by other means, this use should not be authorised.

h. Unacceptable risks are identified in case of outdoor large-scale application by spraying to surface water and sediment. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures like introducing a non-sprayed buffer zone, or by other means, these uses should not be authorised.

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 supercritical carbon dioxide. 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 to the eCA (Spain):

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, oxidising liquids, 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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