National Institute for Public Health and the Environment
Ministry of Health, Welfare and Sport

SUBSTANCE EVALUATION CONCLUSION

as required by REACH Article 48

and

EVALUATION REPORT

for

Sepisol Fast Blue 85219

EC No 700-579-6

CAS RN n.a.

Evaluating Member State: The Netherlands

Dated: 7 February 2024

Evaluating Member State Competent Authority

Bureau REACH on behalf of the Ministry of Infrastructure and the National Institute for Public Health and the Environment
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Year of evaluation in CoRAP: 2017

The substance evaluation was terminated without requesting further information from the registrant under an Article 46(1) decision due to change in status of the registration dossier (cease of manufacture in accordance with Article 50(3) of the REACH Regulation).

Further information on registered substances here:

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

DISCLAIMER

This document has been prepared by the evaluating Member State as a part of the substance evaluation process under the REACH Regulation (EC) No 1907/2006. The information and views set out in this document are those of the author and do not necessarily reflect the position or opinion of the European Chemicals Agency or other Member States. The Agency does not guarantee the accuracy of the information included in the document. Neither the Agency nor the evaluating Member State nor any person acting on either of their behalves may be held liable for the use which may be made of the information contained therein. Statements made or information contained in the document are without prejudice to any further regulatory work that the Agency or Member States may initiate at a later stage.

Foreword

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process the Member States perform the evaluation and ECHA secretariat coordinates the work. The Community rolling action plan (CoRAP) of substances subject to evaluation, is updated and published annually on the ECHA web site[1].

Substance evaluation is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the registrant(s) concerning the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. The document consists of two parts i.e. A) the conclusion and B) the evaluation report. In the conclusion part A, the evaluating Member State considers how the information on the substance can be used for the purposes of regulatory risk management such as identification of substances of very high concern (SVHC), restriction and/or classification and labelling. In the evaluation report part B the document provides explanation how the evaluating Member State assessed and drew the conclusions from the information available.

With this Conclusion document the substance evaluation process is finished and the Commission, the registrant(s) of the substance and the Competent Authorities of the other Member States are informed of the considerations of the evaluating Member State. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes. Further analyses may need to be performed which may change the proposed regulatory measures in this document. Since this document only reflects the views of the evaluating Member State, it does not preclude other Member States or the European Commission from initiating regulatory risk management measures which they deem appropriate.

[1] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

Contents

Part A. Conclusion

1. CONCERN SUBJECT TO EVALUATION

The Substance, Sepisol Fast Blue 85219, EC No 700-579-6 (hereafter referred to as the Substance) was originally selected for substance evaluation (SEv) to clarify concerns about:

- (suspected) PBT/vPvB

- wide-dispersive use

2. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Not applicable.

3. CONCLUSION OF SUBSTANCE EVALUATION

The evaluation of the available information on the substance has led the evaluating Member State to the following conclusions, as summarised in the table below.

Table 1. Conclusion and regulatory follow-up action

CONCLUSION OF SUBSTANCE EVALUATION	
Conclusions	**Tick box**
Need for follow-up regulatory action at EU level	
Harmonised Classification and Labelling	
Identification as SVHC (authorisation)	
Restrictions	
Other EU-wide measures	
No need for regulatory follow-up action at EU level	X

4. FOLLOW-UP AT EU LEVEL

Not applicable.

5. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

5.1. No need for regulatory follow-up at EU level

Table 2. Reason for the absence of regulatory follow-up at EU level

REASON FOR REMOVED CONCERN The concern could be removed because	Tick box
Clarification of hazard properties/exposure	
Actions by the registrants to ensure safety, as reflected in the registration dossiers (cease of manufacture)	X

After finalization of the OECD TG 105 study report (thereby fulfilling the initial information request in the SEv decision), the only registrant of the Substance has ceased manufacture in accordance with Article 50(3) of the REACH Regulation and the substance evaluation was terminated. Therefore, as there were no longer any uses within the scope of substance evaluation, the risk based concerns were removed. At the time of finalising this report, there were no other active registrations within the scope of substance evaluation. The evaluating MSCA is of the opinion that the concern for PBT/vPvB remains unverified since (1) in the TG 105 study, the Substance appears to dissociate into its two main components including the component for which there is concern for PBT/vPvB (i.e. Dissociation product 2) and (2) because no additional information was requested to further clarify the concern due to the termination of the substance evaluation process.

The evaluating MSCA recommends that further assessment of the PBT/vPvB hazard be undertaken in the event the registrant reactivate his registration or if new registrations are submitted.

N.B.: Michler's ethyl ketone (4,4'-bis(diethylamino)benzophenone, EC No 202-025-4), a relevant impurity present in the Substance at >1%, was evaluated in a separate Substance Evaluation. This SEv was concluded after all 10 manufacturer's/importers of Michler's ethyl ketone have ceased import/manufacture.

5.2. Other actions

Not applicable.

6. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS (IF NECESSARY)

Not applicable.

Part B. Substance evaluation

7. EVALUATION REPORT

7.1. Overview of the substance evaluation performed

The Substance, Sepisol Fast Blue 85219 (EC No 700-579-6), was originally selected for substance evaluation to clarify concerns about:

- (suspected) PBT/vPvB

- wide-dispersive use

Table 3. Conclusion on the evaluated endpoints

EVALUATED ENDPOINTS	
Endpoint evaluated	**Outcome/conclusion**
PBT/vPvB	Concern inconclusive. The evaluating MSCA concluded that further information was required for one of the dissociation products of the Substance to clarify the concern regarding PBT/vPvB, after the result of the initial dissociation test requested in the SEv. However due to termination of the substance evaluation process (cease of manufacture), no additional information was requested.
Persistency	Based on screening level information and dissociation behaviour the Substance is concluded to be potential P or vP
Bioaccumulation	Based on screening level information and dissociation behaviour the Substance is concluded to be potential B or vB
Toxicity	Based on acute toxicity test results for the Substance as well as its dissociation products in aqueous solution the Substance is concluded to be T

7.2. Procedure

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to suspected PBT/vPvB properties and wide dispersive use, Sepisol Fast Blue 85219 (EC No 700-579-6) was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2017. The competent authority of the Netherlands (hereafter the evaluating MSCA) was appointed to carry out the evaluation in accordance with Article 45(4) of the REACH Regulation on the information in the registration dossier(s) and other relevant and available information.

The evaluating MSCA considered that further information was required to clarify the abovementioned concerns. Therefore, it prepared a draft decision under Article 46(1) of the REACH Regulation to request further information. A request for an *in vitro* gene mutation study in mammalian cells was removed to become part of a separate Substance Evaluation of the suspected mutagenic impurity in the Substance; Michler's ethyl ketone (EC No 202-025-4).

The Member State Committee reached a unanimous agreement on the draft decision and ECHA issued a decision according to Article 52(2) and 51(6) of the REACH Regulation in December 2019.

The information requested in the decision was included in an update of the registration dossier in September 2021. Based on the data presented, the evaluating MSCA concluded that the parent structure in the Substance appears to dissociate in its components:

- Anionic dissociation product 1 [redacted];
- Cationic dissociation product 2 [redacted].

The implication of this would be that further investigation is needed to address the PBT/vPvB concern of specifically dissociation product 2.

In 2022, the registrant has ceased production of the Substance, therefore the Substance Evaluation was concluded.

7.3. Identity of the substance

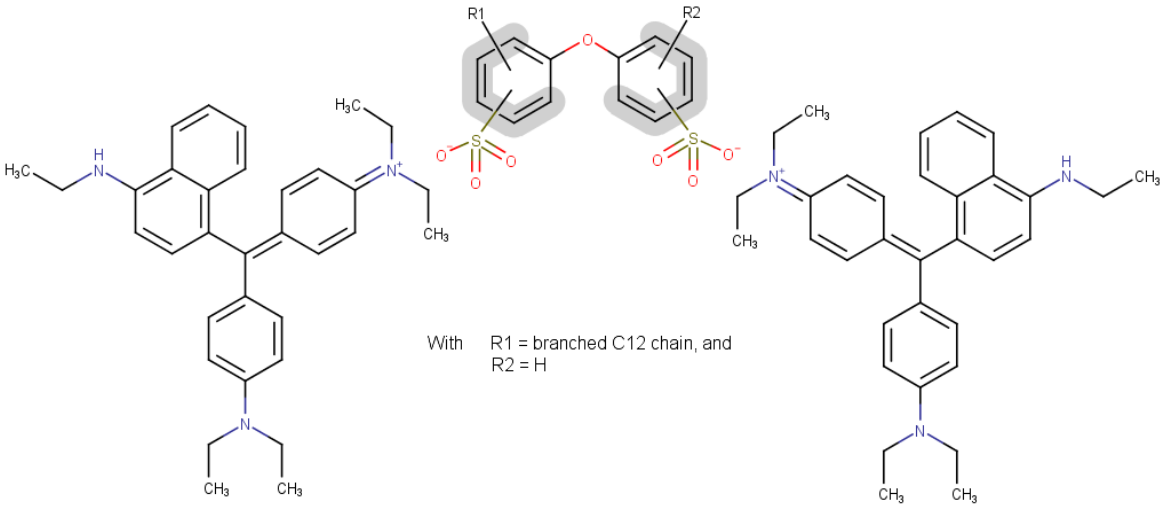
Table 4. Substance identity information

SUBSTANCE IDENTITY	
Public name:	Sepisol Fast Blue 85219
EC number:	700-579-6
CAS number:	n.a.
Index number in Annex VI of the CLP Regulation:	
Molecular formula:	$C_{192}H_{248}N_{12}O_{14}S_4$
Molecular weight range:	$C_{90}H_{114}O_7S_2N_6$ (MW = 1454) and $C_{102}H_{138}O_7S_2N_6$ (MW = 1622)
Synonyms:	Bis[N-(4-{[4-(diethylamino)phenyl][4-(ethylamino)-1-naphthyl]methylene}cyclohexa-2,5-dien-1-ylidene)-N-ethylethanaminium] [mono and bis(dodecanyl, branched)]-(sulfonatophenoxy) benzenesulfonate

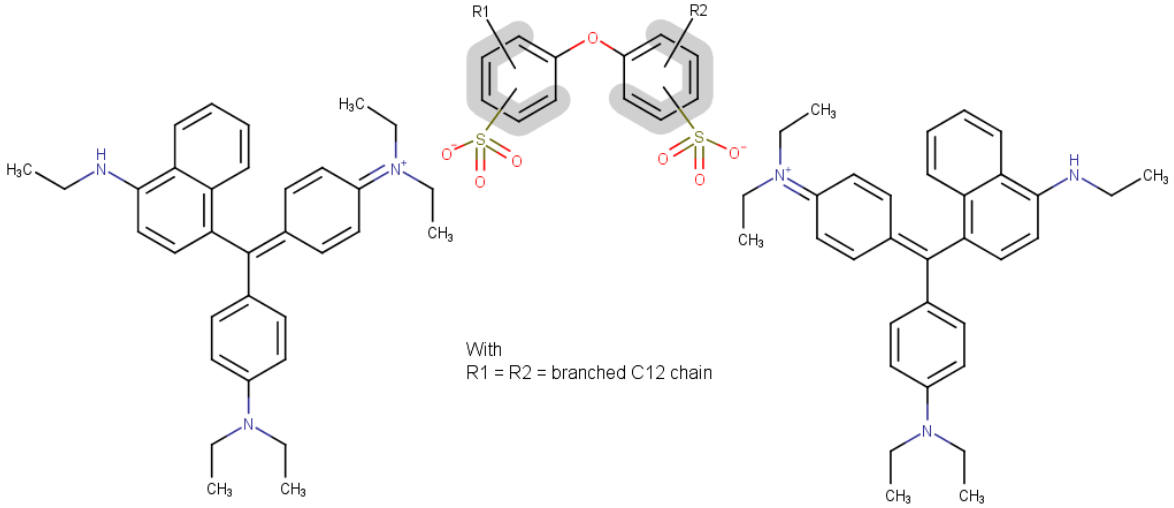
Type of substance ☐ Mono-constituent ☐ Multi-constituent **X** UVCB

Structural formula:

Constituent 1: $C_{90}H_{113}O_7S_2N_6$



Constituent 2: $C_{102}H_{136}O_7S_2N_6$



UVCB substance

Table 5. Other information relevant to the composition of the Substance

Impurity	Typical concentration	Concentration range	Remarks
Sodium chloride (231-598-3)			Unknown or variable content
4,4'-bis(diethylamino)benzophenone (202-025-4)			Unknown or variable content
Water (231-791-2)			Unknown or variable content

7.4. Physico-chemical properties

Table 6. Overview of physicochemical properties

OVERVIEW OF PHYSICOCHEMICAL PROPERTIES	
Property	**Value**
Physical state at 20°C and 101.3 kPa	solid (powder)
Vapour pressure	The test item is an organic salt. The vapour pressure of such compounds is less than the vapour pressure of the corresponding non-ionic form. Vapour pressure of the substance is expected to be negligible/below detection limit. The vapour pressure of the dissociation product 2 component was modeled using Epi Suite 4.00. The highest modelled vapour pressure result (using a number of different SMILES representations of dissociation product 2) is 1.72 x 10 E-16 Pa at 25° Celsius.
Water solubility	ca. 0-0.125 mg/L
Partition coefficient n-octanol/water (Log Kow)	> 7.54
Flammability	Burning time: ca. 1 590 s (burning rate test)
Explosive properties	Not applicable
Oxidising properties	Not applicable
Granulometry	Laser diffraction: 90% of the particles < 268.5 µm; 50% < 69 µm and 10% < 8.7 µm. MMAD < 100 µm.
Stability in organic solvents and identity of relevant degradation products	Not applicable
Dissociation constant	Not applicable / not known. It was deemed necessary to determine the possibility of dissociation in the Substance evaluation.

7.5. Manufacture and uses

7.5.1. Quantities

At the start of the substance evaluation process, the tonnage was reported to be 1-10 tonnes per annum. However, during the data generation phase the only registrant ceased manufacture of the substance in accordance with Article 50(3) of the REACH Regulation and therefore the registration was inactivated.

At the time of finalising this report, there were no active registrations within the scope of substance evaluation.

7.5.2. Overview of uses

Table 7. Overview of uses

USES	Use(s)
Manufacture	Manufacture of dye
Formulation	• Formulation of ink and toners • Mixing or blending in batch processes • Transfer of substance or mixture (charging and discharging) at dedicated facilities • Use as laboratory reagent
Uses at industrial sites	• Use at industrial site leading to inclusion into/onto article • Transfer of substance or mixture (charging and discharging) at dedicated facilities • Transfer of substance or mixture into small containers (dedicated filling line, including weighing) • Use as laboratory reagent
Uses by professional workers	N/a, but evaluating MSCA considers it likely due to presence of the Substance in ink, toners and laboratory reagents
Consumer Uses	N/a, but evaluating MSCA considers it likely due to presence of the Substance in ink, toners and laboratory reagents
Article service life	• Widespread use of articles with low release (indoor) • Other (intended to be released): Use of a ballpoint pen and cartridge

7.6. Classification and Labelling

7.6.1. Harmonised Classification (Annex VI of CLP)

The Substance is not listed on Annex VI of CLP.

7.6.2. Self-classification

The Substance is not notified to the classification and labelling inventory.

In the registration(s):

- Acute Tox. 4; H302: Harmful if swallowed.
- Eye Irrit. 2; H319: Causes serious eye irritation.
- STOT Single Exp. 3; H335: May cause respiratory irritation; respiratory tract; inhalation
- Aquatic Chronic 1; H410: Very toxic to aquatic life with long lasting effects

7.7. Environmental fate properties

See 7.11 PBT and vPvB assessment.

7.8. Environmental hazard assessment

Not evaluated separately. See 7.11 PBT and vPvB assessment.

7.9. Human Health hazard assessment

Not evaluated.

7.10. Assessment of endocrine disrupting (ED) properties

Not evaluated.

7.11. PBT and vPvB assessment

Based on information in the registration dossier and specifically information on one of the possible dissociation products, dissociation product 2, a concern was identified that the Substance may be a PBT or vPvB substance as defined in REACH Annex XIII as detailed below.

The Substance is an ionic complex that potentially forms the anionic dissociation product 1, and the cationic dissociation product 2. For the complex itself there is no PBT/vPvB concern as the molecular weight and log Kow of the complex are too high to give a concern for bioaccumulative behaviour in the environment. However, there is a potential PBT/vPvB concern specifically for the cationic dissociation product 2 as it meets all PBT/vPvB screening criteria (see Table 8).

Table 8. PBT/vPvB relevant properties of the Substance (Sepisol Fast Blue 85219) and its dissociation products: anionic part, dissociation product 1 and cationic part, dissociation product 2.

Properties	Sepisol Fast Blue 85219	Dissociation product 1 (anionic)	Dissociation product 2 (cationic)
Mol. weight	1454-1622 g/mol[1]	496-664 g/mol[1]	479 g/mol[1]
Water solubility	<0.007 mg/L[2]	>1000 mg/L[2] (pH 8.3; OECD105)	20-25 g/L[3]
Log Kow	>7.54[2] (solubility octanol / solubility water) >20 (QSAR estimates KowWIN v1.68 / ClogP v1.5)	<-2.68[2] (pH 4.8; OECD107)	7.00[4] (KowWIN v1.68) 7.67[4] (ClogP v1.5)
Biodegradation	45% ThCO2[2] (28d; OECD301B)	0% ThOD[2] (20d; OECD301D) 21% DOC[2] (28d; OECD302B)	QSAR[5]: - Biowin2: Does not biodegrade fast - BioWin3: Half-life months to years - BioWin6: Not readily biodegradable
Ecotoxicity	0.006 mg/L[2] (EC50-48h; daphnids) >12.6 mg/L[2]	0.65 mg/L[2] (NOEC-168h; daphnids) 3.85 mg/L[2]	0.015 mg/L[3] (EC50-48h; daphnids) 0.03 mg/L[3]

	(NOEC-72h; algae)	(LC50-96h; fish) 100 mg/L[2] (NOEC-3w; algae)	(LC50-96h; fish) 2.91 mg/L[3] (LC50-96h; algae)
PBT/vPvB concern	**No (not B)**	**No (not B, not T based on ecotoxicity)**	**Yes (potential P/vP, potential B/vB, T)**

[1] *One molecule of the Substance Sepisol Fast Blue 85219 dissociates into one anionic molecule of dissociation product 1, and two cationic molecules of dissociation product 2.*

[2] *Substance registration dossier*

[3] *Safety data sheet for chloride salt of dissociation product 2 as supplied in the communication to evaluating MSCA and ECHA [BIMA, 2017]*

[4] *QSAR estimate (KowWin v1.68 as part of EPIWIN, US EPA. 2019. Estimation Programs Interface Suite™ for Microsoft® Windows, v 4.1. United States Environmental Protection Agency, Washington, DC, USA). Multiple values between log Kow 3.9 and 10.8 result from the QSAR estimations based on different structural representations (SMILES) and the software used (KowWin or ClogP). The list of SMILES and structure representations used to generate these values ranging from 3.9 to 10.8 (together with a rationale for selecting the best representation) is given in Table 2 of the Decision on Substance Evaluation for the Substance issued on 16 December 2019.*

[5] *QSAR estimates (BIOWIN v4.10 (September 2010), as part of EPIWIN, US EPA. 2019. Estimation Programs Interface Suite™ for Microsoft® Windows, v 4.1. United States Environmental Protection Agency, Washington, DC, USA). SMILES representations ID nr. 9 and 10 – with and without the chloride anion – have been used as input (see Table 2 in the Substance Evaluation Decision) BioWin2 result with chloride 0.0002; without chloride 0.0003: Does not biodegrade fast, P-screening criterion <0.5. BioWin3 result with chloride 1.5533, without chloride 1.6295: P-screening criterion < 2.7. BioWin6 result with chloride 0.0001, without chloride 0.0001: Not readily biodegradable, P-screening criterion < 0.5. (REACH guidance R11).*

The PBT/vPvB properties of the dissociation product 2 are as follows:

7.11.1. Persistence

QSAR estimations of biodegradability indicate that the substance is very likely to be persistent to biological degradation. The BIOWIN QSAR models, indicated in the REACH Guidance R11 as screening criteria (BioWIN2, 3 and 6), all show likely persistence.

The ready biodegradability test result for the Substance, showing 45% $ThCO_2$ production after 28 days, cannot be indicative for the potential biodegradability of the dissociation product 2 as the dissociation product 1 is added in excess during the formulation of the Substance, and this dissociation product 1 does show some potential to be biologically degraded in the ready biodegradability test in its respective registration dossier.

To determine the persistency of the dissociation product 2 further experimental testing would be needed, starting with a ready biodegradability test (OECD301), and subsequently when no ready biodegradability is observed, a biodegradation simulation study, for example an Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test (OECD TG 309). It should be noted that the NONS-dossier for a closely related substance, the tetrafluorborate salt of dissociation product 2 (*https://echa.europa.eu/nl/registration-dossier/-/registered-dossier/9405/1*) contains a ready biodegradability test that shows 0% $ThCO_2$ production after 28 days.

At present the dissociation product 2 is concluded to be potentially P and/or vP.

When dissociation product 2 is released from the Substance, the Substance is also considered to be potentially P and/or vP.

7.11.2. Bioaccumulation

The screening criterion for bioaccumulation (log Kow >4.5) is met for dissociation product 2. No experimental determination of the log Kow is available, but multiple QSAR estimates show that the most representative structures of the dissociation product 2 have a log Kow well above 4.5, most likely in the range of 7.00 to 7.67.

Although the molecular weight of the Substance well exceeds the 1000 g/mol, therefore making bioaccumulation of the Substance unlikely, the molecular weight of the dissociation product 2 (479 g/mol), its most likely octanol-water partitioning constant and its resistance to biological degradation (metabolization) make dissociation product 2 potentially bioaccumulative or very bioaccumulative

At present the dissociation product 2 is concluded to be potentially B and/or vB.

When dissociation product 2 is released from the Substance, the Substance is also considered to be potentially B and/or vB.

7.11.3. Toxicity

Only acute aquatic toxicity information in available for the Substance and its dissociation products 1 and 2 (see Table 8). Nevertheless, dissociation product 2 shows a 48h-EC50(immobility) of 15 µg/L in Daphnia, and it is therefore likely that, following longer exposure, its chronic NOEC would be < 10 µg/L. The Substance itself also shows a similar 48h-EC50 of 6 µg/L in Daphnia. If the toxicity of the Substance is caused by the dissociation products, it is very likely that dissociation product 2 is causing the effects, as dissociation

product 1 shows acute toxicity at much higher (mg/L range, i.e. 3 orders of magnitude above the toxicity of the Substance) concentrations.

Based on this acute toxicity test data, dissociation product 2 is concluded to be T(eco).

When dissociation product 2 is released from the Substance, the Substance is also considered to be T.

7.11.4. Dissociation behaviour of the Substance

In the dossier of the Substance it was claimed that the Substance does not at all dissociate. However, the specific water solubility study was considered not adequate as the Limit of Detection of the dissociation product was not sufficiently low, and the study was only conducted under one specific condition (i.e. 22ºC, pH not determined), not covering all conditions relevant to the life-cycle of the Substance. Especially the pH is expected to highly influence the dissociation of the Substance.

Besides the water solubility study, some preliminary screening data on solubility and dissociation were provided [BIMA, 2017]. These data indicate that color changes were observed when the Substance was added to water at different pH-values. Color changes were observed at pH=3 and pH=10 and these color changes were faster at higher temperatures (40-50ºC). These color changes were seen as indicators of the presence of a dissociated chromophore. The registrant was requested to perform a new dissociation study with the registered Substance, to determine whether dissociation product 2 is released under the expected conditions of the life-cycle of the Substance, including conditions (elevated temperatures, lower as well as higher pHs) that can be expected during paper recycling, as the Substance is used as ink in pencils.

Results obtained in the OECD TG 105 test

As a first tier test, to investigate whether the Substance will dissociate in its two main components, of which for one (dissociation product 2) a PBT/vPvB concern exists, a Water Solubility in Dependence of the pH and Temperature (Shake Flask Method) study was performed, according to OECD-Guideline No. 105 (1995) and Council Regulation (EC) No. 260/2014, Method A.6.

Prior to commencing the main study, multiple preliminary tests and inconsistent solubility trials were performed. Within these experiments, it was observed that the test item solubility behaviour is complex and therefore difficult to predict. However, the data indicate that the substance has a high tendency to form stable colloidal dispersions, even in buffer solutions and pure water. These dispersions were also eluted from a column elution setup, making this test design (column elution) infeasible. Finally, the only way to remove the colloidal dispersed material was to filter the samples through 0.2 µm PTFE membrane filters. As adsorption of the dissociation product 2 to this filter material was checked negative, this procedure was deemed acceptable.

The solubility and dissociation in the two dissociation products of the Substance was determined at 20 ± 0.5 °C and 40 ± 0.5 °C for pH values of 3, 7 and 10 based on the presence of the two dissociation products. The validity criterion regarding the repeatability could only be met for pH 7 and 10 at 40 °C for dissociation product 2 (and for pH 3 at 40 °C for dissociation product 1); however, under these conditions low concentrations of dissociation product 2 were measured, while at a pH of 3 (for which the validity criterion was failed) a much higher concentration of dissociation product 2 was detected.

The evaluating MSCA considers the results of the test as inconclusive to determine the exact water solubility, although from these results dissociation product 2 is concluded to

be released from the Substance under conditions that are likely in the life-cycle of the Substance.

7.11.5. Conclusions of the PBT/vPvB assessment and related classification and labelling

The results from the solubility/dissociation study indicate that the (potential) PBT/vPvB concern applies for the Substance as the (potential) PBT/vPvP substance dissociation product 2 is released from the Substance. However, in the absence of adequate information to conclude on P and B, no definitive conclusion on its PBT properties can be reached.

7.12. Exposure assessment

Not evaluated.

7.13. Risk characterisation

Not evaluated.

7.14. References

Registration dossier for Sepisol Fast Blue 85219 (List No 700-579-6), European Chemicals Agency. https://chem.echa.europa.eu/

Decision on Substance Evaluation for Sepisol Fast Blue 85219 (List No 700-579-6), NL CA/Bureau REACH, https://echa.europa.eu/documents/10162/274f165b-21d3-200f-1cb2-6073df277ee3

BIMA, 2017. SEV Sepisol Fast Blue 85219 – Feedback (e-mail) to questions of evaluating MSCA. Materials safety datasheets for the starting materials Basic Blue 7 (chloride) and Dowfax 2A1 and the testing report for the preliminary solubility/dissociation testing already undertaken by the testing laboratory contracted by the registrant.

European Commission. 2015. Best Available Techniques (BAT) Reference Document for the Production of Pulp, Paper and Board. Report EUR 27235 EN (p.69).

7.15. Abbreviations

AF	Assessment factor
CAS	Chemical abstracts service
C&L	Classification and labelling
CLP	Classification, labelling and packaging (Regulation (EC) No 1272/2008)
CMR	Carcinogenicity, mutagenicity and toxicity to reproduction
DNEL	Derived no effect level
MSCA	Member state competent authority

OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulative, Toxic
PROC	Process category
TG	Test guideline
TPA	Tonnes per annum
vPvB	Very Persistent and very Bioaccumulative