Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	Sepisol Fast Blue 85219
Chemical Group:	
EC Number:	700-579-6
CAS Number:	-
Submitted by:	The Netherlands
Published:	26/03/2014

Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

Contents

1 IDENTITY OF THE SUBSTANCE

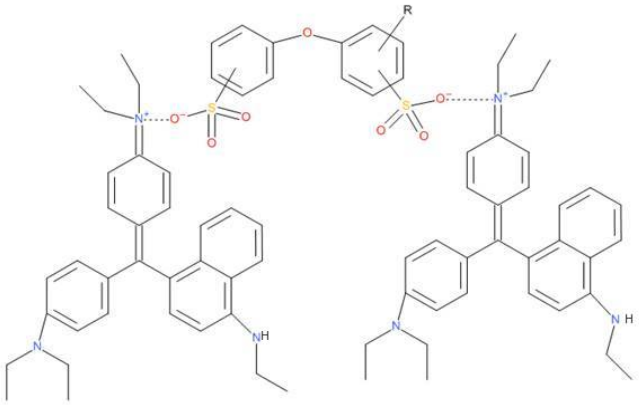
1.1 Other identifiers of the substance

Table 1: Substance identity

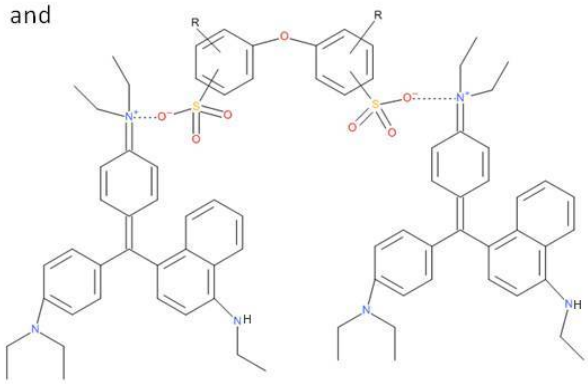
EC name:	unnamed
IUPAC name:	-
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	-
Molecular weight or molecular weight range:	MW = 1454 and MW = 1622
Synonyms/Trade names:	Sepisol Fast Blue 85219

Type of substance ☐ Mono-constituent ☐ Multi-constituent ☒ UVCB

Structural formula:



and



With R being a dodecanyl, branched chain

1.2 Similar substances/grouping possibilities

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2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

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2.2 Self classification

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

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

  There are no notifications for this substance in the CLI.

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

N.A.

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA dissemination site			
☒ 1 – 10 tpa	☐ 10 – 100 tpa	☐ 100 – 1000 tpa	
☐ 1000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	☐ 100,000 – 1,000,000 tpa	
☐ 1,000,000 – 10,000,000 tpa	☐ 10,000,000 – 100,000,000 tpa	☐ > 100,000,000 tpa	
☐ <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☐ Confidential	
☐ Industrial use	☐ Professional use	☒ Consumer use	☐ Closed System
Dye of ink for ballpoint pen and cartridge.			

4 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

4.1 Legal basis for the proposal

☒ Article 44(2) (refined prioritisation criteria for substance evaluation)

☐ Article 45(5) (Member State priority)

4.2 Selection criteria met (why the substance qualifies for being in CoRAP)

☐ Fulfils criteria as CMR/ Suspected CMR

☐ Fulfils criteria as Sensitiser/ Suspected sensitiser

☐ Fulfils criteria as potential endocrine disrupter

☒ Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB

☐ Fulfils criteria high (aggregated) tonnage (*tpa > 1000*)

☒ Fulfils exposure criteria

☐ Fulfils MS's (national) priorities

4.3 Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR ☐C ☐M ☐R	Suspected CMR[1] ☐C ☐M ☐R	☐ Potential endocrine disruptor
☐ Sensitiser	Suspected Sensitiser[1]	
☐ PBT/vPvB	☒ Suspected PBT/vPvB[1]	☐ Other (please specify below)
Exposure / risk based concerns		
☐ Wide dispersive use	☐ Consumer use	☐ Exposure of sensitive populations
☐ Exposure of environment	☐ Exposure of workers	☐ Cumulative exposure
☐ High RCR	☐ High (aggregated) tonnage	☐ Other (please specify below)

[1] CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)
Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)
Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

The UVCB contains two components, both with a log Kow (estimated on the base of solubilities in the dossier) ~4.27. QSAR estimated log Kow (KOWWIN 1.68, by NL not in dossier) values for the cation (identical in both components): 6.50. SMILES used for calculations is the neutral species of the cation structure (constructed from picture of structure in dossier).

For the anion in component 1 log Kow is estimated 4.8, and the anion in component 2 is estimated 11.0. Therefore components of the UVCB seem to be fulfilling the screening B-criterion. No definite B information is present in the dossier. BCFBAF QSAR estimate for the cationic part is 9095 L/kg (NL, not in dossier).

The UVCB substance is not readily biodegradable, showing 45% mineralization after 28 days in an OECD301B (Sturm) test. It is possible that parts of the substance (anions) are completely mineralized and other parts (cation?) are resistant. Further evaluation of the biodegradability is required.

The available (aquatic) toxicity information (acute LC50 daphnia) is 0.0057 mg/l and therefore the substance should be considered T. This is in accordance with the self classification of the notifier. No chronic aquatic toxicity data is available in the dossier.

As the substance fulfills all the screening criteria for PBT, and wide dispersive use can be expected (dye in ink for ballpoints), NL considers this substance a candidate for further evaluation of the PBT properties, and therefore a suitable SEv candidate.

4.4 Other completed / ongoing regulatory processes that may affect suitability for substance evaluation

☐ Compliance check, Final decision	☐ Dangerous substances Directive 67/548/EEC
☐ Testing proposal	☐ Existing Substances Regulation 793/93/EEC
☐ Annex VI (CLP)	☐ Plant Protection Products Regulation 91/414/EEC
☐ Annex XV (SVHC)	☐ Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
☐ Annex XIV (Authorisation)	☐ Other (provide further details below)
☐ Annex XVII (Restriction)	
Please provide further details when relevant.	

4.5 Preliminary indication of information that may need to be requested to clarify the concern

☐ Information on toxicological properties	☒ Information on physico-chemical properties
☒ Information on fate and behaviour	☐ Information on exposure
☒ Information on ecotoxicological properties	☒ Information on uses
☐ Information ED potential	☐ Other (provide further details below)

Dissociation behavior and the phys.chem / ecotox. / fate properties of the individual components and/or their anions/cations need to be evaluated to enable a better PBT assessment.

Whether testing (P, B and/or T) is necessary depends also on the physic chemical properties of the individual components and the dissociation behavior of the UVCB.

4.6 Potential follow-up and link to risk management

☐ Harmonised C&L	☐ Restriction	☒ Authorisation	☐ Other (provide further details)

Use of a PBT substance in consumer products giving wide dispersive use should be avoided and emissions minimized. Authorisation would drive for substitution with non-PBT substance.