baua:
Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin
Federal Institute for Occupational
Safety and Health

Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	1-(4-methyl-2-nitrophenylazo)-2-naphthol
EC Number:	219-372-2
CAS Number:	2425-85-6
Authority:	Germany
Date:	19/03/2019

Cover Note

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

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1 IDENTITY OF THE SUBSTANCE

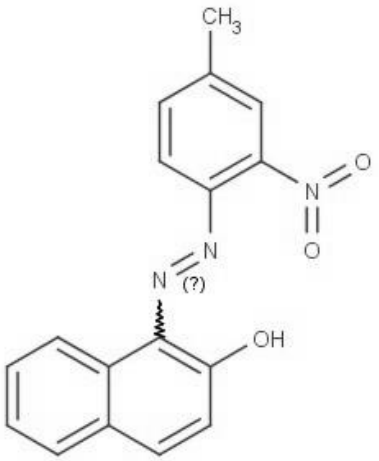
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	1-(4-methyl-2-nitrophenylazo)-2-naphthol
IUPAC name (public):	1-(4-Methyl-2-nitrophenylazo)-2-naphthol 1-[(4-methyl-2-nitrophenyl)diazenyl]-2-naphthol 1-[(E)-2-(4-methyl-2-nitrophenyl)diazen-1-yl]naphthalen-2-ol 1-[2-(4-methyl-2-nitrophenyl)diazen-1-yl]naphthalen-2-ol C.I. Pigment Red 003 C.I. Pigment Red 3 Pigment Red 3
Index number in Annex VI of the CLP Regulation:	N/A
Molecular formula:	$C_{17}H_{13}N_3O_3$
Molecular weight or molecular weight range:	307.30 g/mol
Synonyms:	*SEIKAFAST RED 4R-4016* *Sudacolor Red 417* *C.I. Pigment Red 3*

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

Structural formula:



1.2 Similar substances/grouping possibilities

In the REACH registration dossiers, Pigment Red 3 (CAS: 2425-85-6), Pigment Red 4 (CAS: 2814-77-9) and Pigment Orange 5 (CAS: 3468-63-1) are evaluated together. The category hypothesis is used for read-across between the three pigments for all relevant toxicological endpoints.

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	☐ Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	☒ Compliance check, Final decision
		☐ Testing proposal
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restric -tion	☐ Annex XVII[1]
Harmonised C&L	☐ Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	☐ Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	☐ Dangerous substances Directive Directive 67/548/EEC (NONS)	
	☐ Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment	
	☐ In relevant Annex	
Other processes / EU legislation	☐ Other (provide further details below)	

[1] Please specify the relevant entry.

Further details	Dossier evaluation decision CCH-D-2114381726-39-01/F, deadline for provision of information 28 June 2019.[2]

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

3.1.2 There is currently no Annex VI entry for harmonised C&L for this substance. Self classification

- In the registration:

Not classified

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

Aquatic Acute 1	H400
Aquatic Chronic 1	H410
Aquatic Chronic 4	H413
Eye Dam. 1	H318
STOT SE 3	H335 (respiratory tract)

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

There is currently no proposal for harmonised C&L for this substance.

[2] https://echa.europa.eu/documents/10162/29bae82f-55e7-89a5-1d42-d8d8ab5bd930

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[3]

4.1 Tonnage and registration status

Table: Tonnage and registration status*

☐ Full registration(s) (Art. 10)	☐ Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per 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

* From ECHA dissemination site: the total tonnage band has been calculated by excluding the intermediate uses, for details see the Manual for Dissemination and Confidentiality under REACH Regulation (section 2.6.11): https://echa.europa.eu/documents/10162/22308542/manual_dissemination_en.pdf/7e0b87c2-2681-4380-8389-cd655569d9f0

4.2 Overview of uses

Table: Uses

Part 1:

☒ Manufacture	☒ Formulation	☒ Industrial use	☒ Professional use	☒ Consumer use	☒ Article service life	☐ Closed system

Part 2:

	Use(s)
Uses as intermediate	
Formulation	
Uses at industrial sites	
Uses by professional workers	
Consumer Uses	PC 9a: Coatings and paints, thinners, paint removes PC 18: Ink and toners PC 32: Polymer preparations and compounds
Article service life	Numerous articles relevant for consumers.

[3] *The dissemination site was accessed August 2018.*

5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1. Legal basis for the proposal

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

☐ Article 45(5) (Member State priority)

5.2. 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

5.3. 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[4]	
☐ 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)

[4] 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

Suspected CMR properties:

In the REACH registration dossier, Pigment Red 3 (PR3, CAS: 2425-85-6), Pigment Red 4 (PR4, CAS: 2814-77-9) and Pigment Orange 5 (PO5, CAS: 3468-63-1) are evaluated together. The category hypothesis is used for read-across between the three pigments for all relevant toxicological endpoints. There are at least minor inconsistencies between the three CSR dossiers (e.g. not all studies always referenced).

Data for (germ cell) mutagenicity are inconclusive and positive Ames test results (mainly after reductive cleavage of the Azo bond) indicate a concern for genotoxicity which requires thorough evaluation. Available negative in vitro data and from one in vivo UDS test do not clarify the concern raised from the positive bacterial mutagenicity assays after Prival (hamster S9) activation.

The available studies on carcinogenicity, including two oral carcinogenicity studies with PR3 (key studies) have been only evaluated for repeated dose toxicity, but neither CSR nor registration dossier contain results on carcinogenicity, although there is "limited evidence for carcinogenicity in rats and mice" (IARC)[5] and "some evidence of carcinogenic activity" (according to original NTP study summary). A potential concern for carcinogenicity therefore needs to be clarified.

Testing in reproductive toxicity (fertility and development) relied only on a OECD 421 screening study (with PR3, used for read-across for PR4 and PO5), which is wrongly labelled as two generation study.

Suspected PBT/vPvB properties:

No biodegradation was observed in a screening test on ready biodegradability of Pigment Red 3 (EC 219-372-2). Based on this result, Pigment Red 3 is considered to fulfill the screening criterion for persistence / very high persistence.

The experimental log Pow given in the registration dossier is 3.7 and hence below the screening criterion for bioaccumulation/ very high bioaccumulation. Given the very low water solubility (3.3 μg/l) and the significantly higher log Pow estimations from KOWWIN (6.45)[6], chemicalize (5.52)[7] and COSMOtherm (4.06)[8], the measured log Pow needs to be checked for plausibility. A study on bioaccumulation is available but it is considered to be not reliable as it was conducted at concentrations above water solubility. As the log Pow may be larger than the screening criterion of 4.5, Pigment Red 3 is considered to be potentially bioaccumulative or very bioaccumulative.

Studies are available for short-term toxicity to fish, short- and long-term toxicity to daphnids and toxicity to algae. No effects were observed up to the limit of water solubility.

Exposure

The substance is used as a colorant in inks, paints, pigments and plastics. There are widespread dispersive indoor and outdoor uses by consumers in paints.

[5] IARC Monographs on the Evaluation of Carcinogenic Risks to Humans Volume 57 Occupational Exposures of Hairdressers and Barbers and Personal Use of Hair Colourants; Some Hair Dyes, Cosmetic Colourants, Industrial Dyestuffs and Aromatic Amines, 1993, pp. 259-267.
[6] 2010 U.S. Environmental Protection Agency. KOWWIN v1.68.
[7] Chemicalize 2018. http://www.chemicalize.org/, accessed on 14th August 2018
[8] COSMOtherm C30-1601 (revision 2299), COSMOlogic GmbH & Co KG, http://www.cosmologic.de
F. Eckert and A. Klamt, "Fast solvent screening via quantum chemistry: COSMO-RS approach," AIChE J., vol. 48, no. 2, pp. 369–385, 2002.
COSMOconf 4.0, COSMOlogic GmbH & Co KG, http://www.cosmologic.de

5.4. 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)

CMR concern:

Dossiers lack important information: Two oral carcinogenicity studies are cited but no results are presented on carcinogenicity.

A thorough review of genotoxicity/mutagenicity data is necessary. Detailed study reports have to be made available.In dossiers, an OECD 421 study is labelled as two-generation study, other studies on reproductive toxicity (fertility and development) are lacking.

PBT/vPvB concern:

Refinement of log P_{ow} might be required. In case the substance screens as B/vB, further information on fate and behavior is needed to clarify the PBT/vPvB concern.

5.5. Potential follow-up and link to risk management

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

After evaluation of all necessary data the conclusion will be drawn if a harmonized C&L dossier will be submitted.