



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

Justification Document for the Selection of a CoRAP Substance

- Update -

Substance Name (public name): 1-[(2,4-dinitrophenyl)azo]-2-naphthol

EC Number: 222-429-4

CAS Number: 3468-63-1

Authority: Germany

Date: 22/03/2016

19/03/2019 (1. update)

Cover Note

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

Table of Contents

1	IDENTITY OF THE SUBSTANCE	3
1.1	Other identifiers of the substance	3
2	OVERVIEW OF OTHER PROCESSES / EU LEGISLATION	4
3	HAZARD INFORMATION (INCLUDING CLASSIFICATION)	5
3.1	Classification	5
3.1.1	Harmonised Classification in Annex VI of the CLP	5
3.1.2	Self classification	5
3.1.3	Proposal for Harmonised Classification in Annex VI of the CLP	5
4	INFORMATION ON (AGGREGATED) TONNAGE AND USES	6
4.1	Tonnage and registration status	6
4.2	Overview of uses	6
5.	JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CORAP SUBSTANCE	7
5.1.	Legal basis for the proposal	7
5.2.	Selection criteria met (why the substance qualifies for being in CoRAP)	7
5.3	Initial grounds for concern to be clarified under Substance Evaluation	7
5.4	Preliminary indication of information that may need to be requested to clarify the concern	8
5.5	Potential follow-up and link to risk management	9

1 IDENTITY OF THE SUBSTANCE

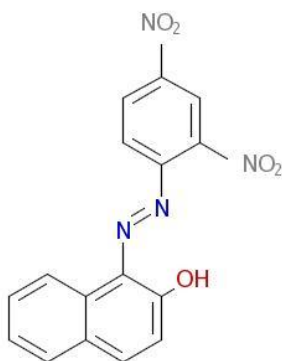
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	1-[(2,4-dinitrophenyl)azo]-2-naphthol
IUPAC name (public):	1-[(2,4-dinitrophenyl)diazanyl]-2-naphthol
Index number in Annex VI of the CLP Regulation:	
Molecular formula:	C ₁₆ H ₁₀ N ₄ O ₅
Molecular weight or molecular weight range:	338.274 g/mol
Synonyms:	C.I. PIGMENT ORANGE 5 SEIKAFAST ORANGE 3064-K 1-[(E)-2-(2,4-dinitrophenyl)diazen-1-yl]naphthalen-2-ol C.I. Pigment Orange 005 Permanent Orange Pigment Orange 5

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

RM OA	<input type="checkbox"/> Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	<input checked="" type="checkbox"/> Compliance check, Final decision
		<input type="checkbox"/> Testing proposal
		<input type="checkbox"/> CoRAP and Substance Evaluation
	Authorisation	<input type="checkbox"/> Candidate List
		<input type="checkbox"/> Annex XIV
	Restri- -ction	<input type="checkbox"/> Annex XVII ¹
Harm onise d C&L	<input type="checkbox"/> Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	<input type="checkbox"/> Plant Protection Products Regulation (EC) No 1107/2009	
	<input type="checkbox"/> Biocidal Product Regulation (EU) 528/2012 and amendments	
Previous legislation	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC (NONS)	
	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	<input type="checkbox"/> Assessment	
	<input checked="" type="checkbox"/> In relevant Annex	
Other process es/ EU legislati on	<input type="checkbox"/> Other (provide further details below)	
Furt her detai ls	Dossier evaluation decision CCH-D-2114381690-46-01/F, deadline for provision of information 28 June 2019. ²	

¹ Please specify the relevant entry.

² <https://echa.europa.eu/documents/10162/0b877ba0-4d0c-6487-1579-11df27ee6434>

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

No harmonised classification is available.

3.1.2 Self classification

- In the registration:
The pure substance is not classified.
The substance with a high content of 1-chloro-2,4-dinitro benzene, CAS-No 97-00-7), is classified as Skin Sens 1 H317 and Expl. Div. 1.1. H201.
- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
Eye Irrit 2 H319
Muta 2 H341 and Carc 2 H351
"not classified"

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

Currently, no proposal for harmonized classification and labeling is available.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES³

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site		
<input checked="" type="checkbox"/> Full registration(s) (Art. 10)	<input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input checked="" type="checkbox"/> 100 – 1000 tpa
<input type="checkbox"/> 1000 – 10,000 tpa	<input type="checkbox"/> 10,000 – 100,000 tpa	<input type="checkbox"/> 100,000 – 1,000,000 tpa
<input type="checkbox"/> 1,000,000 – 10,000,000 tpa	<input type="checkbox"/> 10,000,000 – 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa
<input type="checkbox"/> <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input type="checkbox"/> Confidential

4.2 Overview of uses

Table: Uses

Part 1:

<input checked="" type="checkbox"/> Manufacture	<input checked="" type="checkbox"/> Formulation	<input checked="" type="checkbox"/> Industrial	<input checked="" type="checkbox"/> Professional	<input checked="" type="checkbox"/> Consumer	<input checked="" type="checkbox"/> Article service life	<input type="checkbox"/> Closed system
---	---	--	--	--	--	--

Part 2:

	Use(s)
Formulation	Industrial formulation of non-solid preparations containing pigment (including inks and paints): PROC 5, PROC 8b, PROC 9, PROC 14, PROC 15, PROC 24 Industrial formulation of solid preparations containing pigment (including plastics): PROC 24
Uses at industrial sites	Industrial use of pigment preparations resulting in inclusion into a matrix (including ink, paint, plastics): PROC 5, PROC 6, PROC 7, PROC 8a, PROC 10, PROC 13, PROC 14, PROC 21, PROC 24
Uses by professional workers	Widespread dispersive indoor and outdoor use (professional) resulting in inclusion into a matrix: PROC 5, PROC 8a, PROC 10, PROC 11, PROC 13, PROC 19 Professional removal of matrix, outdoor and indoor (e.g. abrasion) PROC 24
Consumer Uses	PC 9a, 18, 32
Article service life	Removal of matrix (e.g. abrasion), outdoor PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles Removal of matrix (e.g. abrasion), indoor PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles

³ Data taken from ECHA dissemination site (accessed in May 2015)

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 <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR ¹ <input checked="" type="checkbox"/> C <input type="checkbox"/> M <input checked="" type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ⁴	
<input type="checkbox"/> PBT/vPvB	<input checked="" type="checkbox"/> Suspected PBT/vPvB ¹	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input checked="" type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input checked="" type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> 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 C and R properties

Data are lacking for carcinogenicity and reproductive toxicity. A read across was performed with to other azo-dyes. However, the presentation of data is confusing: No data were presented for two oral carcinogenicity studies using a read across compound and only a statement was presented from "an IARC publication" on only limited evidence for carcinogenicity in rats and mice. Testing in reproductive toxicity relied only on a OECD 421 study, labelled as two generation study. Considering the genotoxic properties in the AMES-assay a thorough evaluation is needed.

Worker exposure

As wide dispersive use of these substances by professional workers has to be assumed, this concern needs clarification: Workers may be exposed during transfer operations, during blending in batch processes, spraying of paints and coatings and during manipulation of the substance bound in materials and articles. It is anticipated that exposure of professional workers in the public domain is less well controlled than in industry.

Suspected PBT/vPvB properties

There are no biodegradation studies for Pigment Orange 5 (EC 222-429-4). The registrant proposes read-across to the structurally related substance Pigment Red 3 (EC 219-372-2) and it appears reasonable to assume similar properties for both substances. No biodegradation was observed in a screening test on ready biodegradability of Pigment Red 3. Based on this result, Pigment Red 3 and consequently Pigment Orange 5 are considered to fulfill the screening criterion for persistence / very high persistence.

The experimental log Pow given in the registration dossier is 2.45 and hence below the screening criterion for bioaccumulation/ very high bioaccumulation. Given the very low water solubility (6.3 µg/l) and the significantly higher log Pow estimations from KOWWIN (5.72)⁵, chemicalize (4.94)⁶ and COSMOtherm (3.97)⁷, the measured log Pow needs to be checked for plausibility. A study on bioaccumulation is available for the structurally related substance Pigment Red 3 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 Orange 5 is considered to be potentially bioaccumulative or very bioaccumulative.

There is only one study on the short-term toxicity of Pigment Orange 5 to daphnids. For short-term toxicity to fish, long-term toxicity to daphnids and toxicity to algae the registrant proposes read-across to respective studies on the structurally related substance Pigment Red 3 (EC 219-372-2). All studies mentioned above showed no effects up to the limit of water solubility.

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

<input checked="" type="checkbox"/> Information on toxicological properties	<input checked="" type="checkbox"/> Information on physico-chemical properties
<input checked="" type="checkbox"/> Information on fate and behaviour	<input type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)
Dossiers lack important information: Two oral carcinogenicity studies are cited but no results are presented. In dossiers, an OECD 421 study is labelled as two-generation study, other studies on reproductive toxicity are lacking. Refinement of log Pow might be required. In case the substance screens as B/vB, further	

⁵ 2010 U.S. Environmental Protection Agency. KOWWIN v1.68.

⁶ Chemicalize 2018. <http://www.chemicalize.org/>, accessed on 14th August 2018

⁷ 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>

information on fate and behavior is needed to clarify the PBT/vPvB concern.

5.5 Potential follow-up and link to risk management

<input checked="" type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
--	--------------------------------------	--	--

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