



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-[(2,4-dinitrophenyl)azo]-2-naphthol

**EC Number:** 222-429-4

**CAS Number:** 3468-63-1

**Authority:** DE MSCA

**Date:** 22/03/2016

### 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

<b>EC name (public):</b>	1-[(2,4-dinitrophenyl)azo]-2-naphthol
<b>IUPAC name (public):</b>	1-[(2,4-dinitrophenyl)diazenyl]-2-naphthol
<b>Index number in Annex VI of the CLP Regulation:</b>	
<b>Molecular formula:</b>	C <sub>16</sub> H <sub>10</sub> N <sub>4</sub> O <sub>5</sub>
<b>Molecular weight or molecular weight range:</b>	338.274 g/mol
<b>Synonyms:</b>	C.I. PIGMENT ORANGE 5

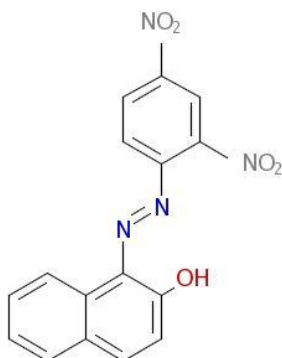
Type of substance

Mono-constituent

Multi-constituent

UVCB

Structural formula:



## 2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

**Table: Completed or ongoing processes**

RMOA	<input type="checkbox"/> Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	<input 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
	Restriction	<input type="checkbox"/> Annex XVII <sup>1</sup>
Harmonised C&L	<input type="checkbox"/> Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	<input type="checkbox"/> Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	<input type="checkbox"/> Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	<input type="checkbox"/> Dangerous substances Directive Directive 67/548/EEC (NONS)	
	<input type="checkbox"/> Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	<input type="checkbox"/> Assessment	
	<input type="checkbox"/> In relevant Annex	
Other processes / EU legislation	<input type="checkbox"/> Other (provide further details below)	

<sup>1</sup> Please specify the relevant entry.

### **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:  
*Additionally, 299 notifiers classify as Eye Irrit 2 H319*  
*Additionally, 23 notifiers classify as Muta 2 H341 and Carc 2 H351*  
*Additionally, 7 notifiers as "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 USES<sup>2</sup>

### 4.1 Tonnage and registration status

**Table: Tonnage and registration status**

<b>From ECHA dissemination site</b>		
<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 use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input checked="" type="checkbox"/> Article service life	<input type="checkbox"/> Closed system
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**Part 2:**

	<b>Use(s)</b>
<b>Formulation</b>	Industrial formulation of non-solid preparations containing pigment (including inks and paints): PROC 5, PROC 8b, PROC 9, PROC 14, PROC 15, Industrial formulation of solid preparations containing pigment (including plastics): PROC 24
<b>Uses at industrial sites</b>	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
<b>Uses by professional workers</b>	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

<sup>2</sup> Data taken from ECHA dissemination site (accessed in May 2015)

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	Professional removal of matrix, outdoor and indoor (e.g. abrasion) PROC 24
<b>Consumer Uses</b>	PC 9a, 18, 32
<b>Article service life</b>	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

## 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 <sup>1</sup> <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 <sup>3</sup>	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB <sup>1</sup>	<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)

<sup>3</sup> 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



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.

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.

**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 type="checkbox"/> Information on physico-chemical properties
<input 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.

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