



Justification Document for the Selection of a CoRAP Substance

Group Name: Phenyl amino anthraquinones

EC	CAS	Substance public name
216-475-4	1594-08-7	1-hydroxy-4-[[4-[(methylsulphonyl)oxy]phenyl]amino]anthraquinone
267-636-0	67905-17-3	N-[4-[(9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthryl)amino]phenyl]acetamide

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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 SUBSTANCES WITHIN THE GROUP

1.1 Other identifiers of the substances within the group

EC name (public)	IUPAC name (public)	Index number in Annex VI of the CLP Regulation	Molecular formula	Molecular weight or molecular weight range	Synonyms
1-hydroxy-4-[[4-[(methylsulphonyl)oxy]phenyl]amino]anthraquinone	4-[(4-hydroxy-9,10-dioxo-9,10-dihydroanthracen-1-yl)amino]phenylmethanesulfonate	NA	C ₂₁ H ₁₅ N O ₆ S	409.4	9,10-Anthracenedione, 1-hydroxy-4- 4-(methylsulfonyl)oxy phenyl amino - 9,10-Anthracenedione, 1-hydroxy-4-[[4-[(methylsulfonyl)oxy]phenyl]amino]- 9,10-Anthracenedione, 1-hydroxy-4-[[4-[(methylsulfonyl)oxy]phenyl]amino]- 4-[(4-hydroxy-9,10-dioxo-9,10-dihydroanthracen-1-yl)amino]phe

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					nyl methanesulfo nate
N-[4-[9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthryl)amino)]phenyl]acetamide	N-{4-[(4-hydroxy-9,10-dioxo-9,10-dihydroanthracen-1-yl)amino]phenyl}acetamide	NA	C ₂₂ H ₁₆ N ₂ O ₄	372.4	Acetamide, N- 4- (9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthracenyl)amino phenyl - Acetamide, N-[4-[(9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthracenyl)amino]phenyl] - Kenawax Blue X3RP Solvent Blue 122

Type of substances

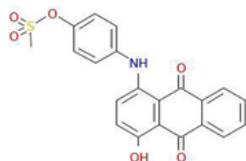
Mono-constituent

Multi-constituent

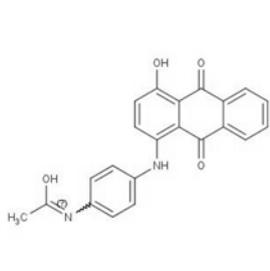
UVCB

Structural formulas:

EC 216-475-4:



EC 267-636-0:



2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

other processes	RMOA	REACH process			Authorisation		Restriction	h C&L	process under other EU legislation		previous legislation		Stockholm convention	other processes EU legislation
		CCH	TPE	SEV	candidate list	Annex XIV			Annex XVII	Annex VI (CLP)	PPP	BPR		
216-475-4	/	/	/	/	/	/	/	/	/	/	/	/	/	Manual screening
267-636-0	/	/	/	/	/	/	/	/	/	/	/	/	/	Manual screening

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

NA

3.1.2 Self classification

- In the registration:

EC Nr	Self-classification	
	Hazard class category code	Hazard statement code
216-475-4	Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H317: May cause an allergic skin reaction H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects
267-636-0	Eye Irrit. 2 Aquatic Acute 1	H319: Causes serious eye irritation H400: Very toxic to aquatic life

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

Both substances are not classified in the C&L inventory by several notifiers.

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

NA

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES¹

4.1 Tonnage and registration status

Table: Tonnage and registration status¹

EC 216-475-4

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 checked="" type="checkbox"/> 10 – 100 tpa	<input 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

EC 267-636-0

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

*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

¹ Dissemination website consulted on 19 July 2018.

4.2 Overview of uses

Table: Uses (in three parts)

Part 1:

Substance: EC 216-475-4						
<input 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
Substance: EC 267-636-0						
<input type="checkbox"/> Manufacture	<input type="checkbox"/> Formulation	<input checked="" type="checkbox"/> Industrial use	<input type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Article service life	<input type="checkbox"/> Closed system

Part 2: Substance1: EC 216-475-4

	Use(s)	Technical function
Uses as intermediate		
Formulation	Industrial formulation of solid preparations containing colorant (including plastics) Use as laboratory reagent Formulation into mixture	
Uses at industrial sites	Textile industrial use-Dyeing Use in laboratory Industrial use of colorant preparations resulting in inclusion into a matrix (including plastics) Use at industrial site leading to inclusion into/onto article	
Uses by professional workers	Treatment of articles by dipping and pouring Textile dyes and impregnating products	
Consumer Uses	Polymer preparations and compounds Colorants and colorants additives	
Article service life	Fabrics, textiles and apparel (outdoor and indoor)	

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Substance2: 267-636-0

	Use(s)	Technical function
Uses as intermediate	Industrial use as intermediate	
Formulation	/	
Uses at industrial sites	Industrial use in ink and toners Dyestuff application Industrial use of laboratory chemicals Industrial use in colouring of wax products Chemical synthesis Industrial use in colouring of polymer products	
Uses by professional workers	/	
Consumer Uses	/	
Article service life	/	

5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE OR GROUP

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 or group 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 type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ²	
<input type="checkbox"/> PBT/vPvB	<input checked="" type="checkbox"/> Suspected PBT/vPvB ¹	<input type="checkbox"/> Other (please specify):
Exposure/risk based concerns		
<input type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input 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)

In the framework of a PBT assessment the grouping of the 2 substances is acceptable as both compounds consist of an anthraquinone core with a phenylamino side chain. The only difference between the two compounds is a different hydrophilic functionality on the phenyl side chain. It is possible that the two parent substances show a somewhat different ecotoxicological profile, but key physico-chemical properties will be similar and once transformation or metabolism takes place identical degradation products are expected. Therefore, grouping of the two substances seems appropriate.

For most endpoints QSAR estimations are given but their reliability remains questionable and degradation products (whose identities are currently unknown) may be very relevant regarding PBT assessment.

Physico-chemical properties.

It is observed that values of key physico-chemical properties are experimentally not exactly determined (water solubility, vapour pressure, log K_{ow} , log K_{oa} , log K_{oc}).

For many endpoints QSAR estimations are presented but it is not clear whether these predictions are reliable enough, certainly when basic phys-chem properties are combined like for log K_{ow} , log K_{oa} predictions.

PBT-assessment:

Definitive information for persistence (simulation studies / half-lives) is not available for both substances. For 1-hydroxy-4-[[4-[(methylsulphonyl)oxy]phenyl]amino]anthraquinone one study (equivalent to OECD 303 A) suggests ready biodegradability while according to another study (DIN 38'49-H-41-1) no biodegradation at all is observed. For N-[4-[(9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthryl)amino]phenyl]acetamide experimental biodegradation studies are not available. Predictions with EpiSuite indicate that depending on the environmental compartment both substances could meet the P and vP-criterion. It is also observed that both substances contain a nitrogen bridge in their chemical structure and the stability of this nitrogen bridge under field conditions is expected to be highly relevant and should be further examined.

Experimental studies on bioaccumulation are not available, nor for aquatic organisms, nor for terrestrial organisms and mammals. In absence of this kind of studies the current screening can only refer to screening B-criteria. In relation to bioaccumulation the log K_{ow} and log K_{oa} -values are important metrics. These values are not experimentally measured. In the registration dossier following log K_{ow} values are reported: for N-[4-[(9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthryl)amino]phenyl]acetamide 4.8 and for 1-hydroxy-4-[[4-[(methylsulphonyl)oxy]phenyl]amino]anthraquinone = 2.49. The log K_{oa} values are also not experimentally measured for these two substances; EpiSuite predicts very high values, i.e. around 20. Based on this, there is serious concern that these substances are bioaccumulative for air-breathers and mammals.

In the registration dossier for N-[4-[(9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthryl)amino]phenyl]acetamide all ecotoxicity studies are waived. For 1-hydroxy-4-[[4-[(methylsulphonyl)oxy]phenyl]amino]anthraquinone some experimental ecotoxicity studies are available. The most relevant study is a test on freshwater algae that resulted in an NOEC-value of 0.001 mg/L. Although the relevance of algae studies can be questioned, this result indicates that the T-criterion is fulfilled for 1-hydroxy-4-[[4-[(methylsulphonyl)oxy]phenyl]amino]anthraquinone. Based on a read-across argumentation, N-[4-[(9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthryl)amino]phenyl]acetamide also potentially meets the T-criterion for the environment.

Therefore, in view of the fact that these substances potentially meet the P/vP criteria, the B/vB criteria (for air-breathers), and the T criterion further analysis of these properties seems appropriate.

² 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

Taking into account wide dispersive use (pigment) and the environmental exposure of both substances, the potential risk for human health and environment cannot be excluded. Therefore, BE CA concluded that the concern regarding persistency and bioaccumulation should be addressed under substance evaluation procedure.

5.4 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 on ED potential	<input type="checkbox"/> Other (provide further details below)
The biodegradation potential will first be further analysed. If the P-character is confirmed, experimental testing on bioaccumulation could be envisaged (potentially via toxicokinetics study).	

5.5 Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
In case that the concerns for persistency and bioaccumulation are confirmed, then an identification of both substances as SVHC according to article 57(d) and/or (e) of REACH would be a potential follow-up action in order to improve RMMs for these substances.			