



## Justification Document for the Selection of a CoRAP Substance

**Group Name:** nitrophenyl azo dyes

EC	CAS	Substance public name
229-419-9	6528-34-3	2-[(4-methoxy-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide
228-768-4	6358-31-2	2-[(2-methoxy-4-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide
229-355-1	6486-23-3	2-[(4-chloro-2-nitrophenyl)azo]-N-(2-chlorophenyl)-3-oxobutyramide

**Authority:** Italy

**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 SUBSTANCES WITHIN THE GROUP

EC/List number	CAS number	Public Substance Name	Type of substance (mono-, multi-constituent, uvcb)	Structure
229-419-9	6528-34-3	2-[(4-methoxy-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide  (PY 65)	mono-constituent substance	
228-768-4	6358-31-2	2-[(2-methoxy-4-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide  (PY 74)	mono-constituent substance	
229-355-1	6486-23-3	2-[(4-chloro-2-nitrophenyl)azo]-N-(2-chlorophenyl)-3-oxobutyramide  (PY 3)	mono-constituent substance	

### 1.1 Similar substances/grouping possibilities

The substances are members of the chemical category of Monoazo Yellow Pigments, which covers seven monoazo pigments with similar chemical structure.

## 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 VI (CLP)	PPP	BPR	NONS		
EC entries							Annex XVII							
229-419-9							tattoo Restriction currently under consideration							
228-768-4		<a href="#">CCH-D-0000002676-67-03/F</a> 07/06/2013 <a href="#">CCH-D-0000003825-69-02/F</a> 14/08/2013					tattoo Restriction currently under consideration							

### **3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)**

#### **3.1 Classification**

##### **3.1.1 Harmonised Classification in Annex VI of the CLP**

All the category members are not currently listed on Annex VI of CLP Regulation ((EC) No 1272/2008).

##### **3.1.2 Self classification**

2-[(4-methoxy-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide (EC 229-419-9; CAS 6528-34-3) (PY 65)

- In the registration:

Not Classified

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

None

2-[(2-methoxy-4-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide (EC 228-768-4; CAS 6358-31-2) (PY 74)

- In the registration:

Not classified

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

Skin Irrit. 2            H315

Eye Irrit. 2            H319

Acute Tox. 5            H303

Lact.                    H362

2-[(4-chloro-2-nitrophenyl)azo]-N-(2-chlorophenyl)-3-oxobutyramide (EC 229-355-1; CAS 6486-23-3) (PY 3)

- In the registration:

Not classified

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

Acute Tox. 4            H302

Eye Dam. 1            H318

### **3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP**

Currently, there is no proposal for harmonised classification for the substances:  
2-[(4-methoxy-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide (PY65)  
2-[(2-methoxy-4-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide (PY74)  
2-[(4-chloro-2-nitrophenyl)azo]-N-(2-chlorophenyl)-3-oxobutyramide (PY3)

## 4 INFORMATION ON (AGGREGATED) TONNAGE AND USES<sup>1</sup>

### 4.1 Tonnage and registration status

**Table: Tonnage and registration status  
from ECHA dissemination site\***

EC	Substance name	Full registration(s) (Art. 10)	Intermediate registration(s) (Art. 17 and/or 18)	Tonnage band (as per dissemination site)
229-419-9	PY 65	10-100T(2), 1-10T(1), 100-1000T(1)	-	100-1000 tpa
228-768-4	PY 74	10-100T(13), 100-1000T(6), 1-10T(8), 1000+T(3)	-	1000-10000 tpa
229-355-1	PY 3	100-1000T(1), 10-100T(5), 1-10T(1)	-	100-1000 tpa

\*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](https://echa.europa.eu/documents/10162/22308542/manual_dissemination_en.pdf/7e0b87c2-2681-4380-8389-cd655569d9f0)

### 4.2 Overview of uses

Only few information are provided in the registration reports of the substances and no exposure scenarios are included according to Article 14.4 and Annex XI section 3 of REACH regulation, because the substances are considered neither as dangerous, nor as PBT/vPvB.

Most common technical function of the substances is:

Colouring agents, pigments

Remarks:

Colouring agents for paints, plastics and inks

- Generally the substances are used in industrial and/or professional settings
- The substances are contained in consumer products
- The substances are contained in articles handled by consumers

#### Table: Uses (in three parts)

##### Part 1:

Substance: 2-[(4-methoxy-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide (EC 229-419-9; CAS 6528-34-3) (PY 65)

<sup>1</sup> The dissemination site was accessed 19 July 2018.

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<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
Substance: 2-[(2-methoxy-4-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide (EC 228-768-4; CAS 6358-31-2) (PY 74)						
<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
Substance: 2-[(4-chloro-2-nitrophenyl)azo]-N-(2-chlorophenyl)-3-oxobutyramide (EC 229-31; CAS 6486-23-3) (PY 3)						
<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

**Part 2:**

Substance1: PY 65 (EC 229-419-9)



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	<b>Use(s)</b>	<b>Technical function</b>
<b>Uses as intermediate</b>		
<b>Formulation</b>	<p>ECHA has no public registered data indicating whether or in which chemical products the substance might be used.</p> <p>Release to the environment of this substance can occur from industrial use: formulation of mixtures and formulation in materials.</p>	<p>This substance is used in the following activities or processes at workplace: transfer of chemicals, mixing in open batch processes, closed batch processing in synthesis or formulation, transfer of substance into small containers, closed processes with no likelihood of exposure, production of mixtures or articles by tableting, compression, extrusion or pelletisation and laboratory work.</p>
<b>Uses at industrial sites</b>	<p>ECHA has no public registered data indicating whether or in which chemical products the substance might be used.</p> <p>Release to the environment of this substance can occur from industrial use: in the production of articles, in processing aids at industrial sites, as an intermediate step in further manufacturing of another substance (use of intermediates), as processing aid, for thermoplastic manufacture, as processing aid and of substances in closed systems with minimal release.</p>	<p>This substance is used in the following areas: formulation of mixtures and/or re-packaging and printing and recorded media reproduction. This substance is used for the manufacture of: plastic products.</p> <p>This substance is used in the following activities or processes at workplace: transfer of chemicals, mixing in open batch processes, production of mixtures or articles by tableting, compression, extrusion or pelletisation, calendering operations, industrial spraying, roller or brushing applications, treatment of articles by dipping and pouring, the low energy manipulation of substances bound in materials or articles and high energy work-up of substances bound in materials or articles (e.g. hot rolling/forming, grinding, mechanical cutting, drilling or sanding).</p>
<b>Uses by professional workers</b>	<p>ECHA has no public registered data indicating whether or in which chemical products the substance might be used. This substance is used in the following areas: printing and recorded media reproduction and building &amp; construction work. This substance is used for the manufacture of: machinery and vehicles.</p> <p>Other release to the environment of this substance is likely to occur from: indoor use and outdoor use.</p>	<p>This substance is used in the following activities or processes at workplace: transfer of chemicals, mixing in open batch processes, roller or brushing applications, non-industrial spraying, treatment of articles by dipping and pouring, hand mixing with intimate contact only with personal protective equipment available and high energy work-up of substances bound in materials or articles (e.g. hot rolling/forming, grinding, mechanical cutting, drilling or sanding).</p>
<b>Consumer Uses</b>	<p>This substance is used in the following products: coating products, inks and toners and polymers.</p> <p>Other release to the environment of this substance is likely to occur from: indoor use and outdoor use.</p>	

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<p><b>Article service life</b></p>	<p>This substance is used in the following activities or processes at workplace: high energy work-up of substances bound in materials or articles, production of mixtures or articles by tableting, compression, extrusion or pelletisation, the low energy manipulation of substances bound in materials or articles, potentially closed industrial processing with minerals/metals at elevated temperature, open transfer and processing with minerals/metals at elevated temperature and hot work operations with metals.</p> <p>Other release to the environment of this substance is likely to occur from: indoor use, outdoor use, outdoor use in long-life materials with low release, outdoor use in long-life materials with high release rate, indoor use in long-life materials with low release rate and indoor use in long-life materials with high release rate.</p> <p>This substance can be found in complex articles, with no release intended: vehicles. This substance can be found in products with material based on: metal (e.g. cutlery, pots, toys, jewellery), wood (e.g. floors, furniture, toys), paper (e.g. tissues, feminine hygiene products, nappies, books, magazines, wallpaper) and plastic (e.g. food packaging and storage, toys, mobile phones).</p>	
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Substance2: PY 74 (EC 228-768-4)

	<b>Use(s)</b>	<b>Technical function</b>
<p><b>Uses as intermediate</b></p>		
<p><b>Formulation</b></p>	<p>This substance is used in the following products: inks and toners, coating products and polymers.</p> <p>Release to the environment of this substance can occur from industrial use: formulation of mixtures and formulation in materials.</p>	<p>This substance is used in the following activities or processes at workplace: transfer of chemicals, mixing in open batch processes, transfer of substance into small containers, closed batch processing in synthesis or formulation, closed processes with no likelihood of exposure and production of mixtures or articles by tableting, compression, extrusion or pelletisation.</p>
<p><b>Uses at industrial sites</b></p>	<p>This substance is used in the following products: inks and toners, polymers, coating products, finger paints, fillers, putties, plasters, modelling clay and paper chemicals and dyes.</p> <p>Release to the environment of this substance can occur from industrial use: in the production of articles, in processing aids at industrial sites, as an intermediate step in further manufacturing of another substance (use of intermediates), as processing aid, as processing aid, of substances in closed systems with minimal release and for thermoplastic manufacture.</p>	<p>This substance is used in the following areas: printing and recorded media reproduction and formulation of mixtures and/or re-packaging. This substance is used for the manufacture of: plastic products, pulp, paper and paper products, rubber products, wood and wood products, chemicals and mineral products (e.g. plasters, cement).</p> <p>This substance is used in the following activities or processes at workplace: mixing in open batch processes, transfer of chemicals, closed batch processing in synthesis or formulation, transfer of substance into small containers, batch processing in synthesis or formulation with opportunity for</p>

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		exposure and production of mixtures or articles by tableting, compression, extrusion or pelletisation.
<b>Uses by professional workers</b>	This substance is used in the following products: inks and toners, coating products, polymers, finger paints and paper chemicals and dyes. Other release to the environment of this substance is likely to occur from: indoor use, outdoor use, indoor use in close systems with minimal release and outdoor use in close systems with minimal release.	This substance is used in the following areas: printing and recorded media reproduction. This substance is used for the manufacture of: plastic products, pulp, paper and paper products, textile, leather or fur, machinery and vehicles and chemicals. This substance is used in the following activities or processes at workplace: transfer of chemicals, roller or brushing applications, mixing in open batch processes, non-industrial spraying, hand mixing with intimate contact only with personal protective equipment available, high energy work-up of substances bound in materials or articles (e.g. hot rolling/forming, grinding, mechanical cutting, drilling or sanding), closed, continuous processes with occasional controlled exposure and treatment of articles by dipping and pouring.
<b>Consumer Uses</b>	This substance is used in the following products: inks and toners, coating products, polymers and finger paints. Other release to the environment of this substance is likely to occur from: indoor use, outdoor use, indoor use in close systems with minimal release and outdoor use in close systems with minimal release.	
<b>Article service life</b>	This substance is used in the following activities or processes at workplace: high energy work-up of substances bound in materials or, production of mixtures or articles by tableting, compression, extrusion or pelletisation, the low energy manipulation of substances bound in materials or articles, potentially closed industrial processing with minerals/metals at elevated temperature, open transfer and processing with minerals/metals at elevated temperature and hot work operations with metal. Release to the environment of this substance can occur from industrial use: industrial abrasion processing with low release rate and industrial abrasion processing with high release rate. Other release to the environment of this substance is likely to occur from: indoor use in long-life materials with low release rate, outdoor use in long-life materials with low release rate, outdoor use in long-life materials with high release rate, indoor use in long-life materials	This substance can be found in complex articles, with no release intended: vehicles, electrical batteries and accumulators and machinery, mechanical appliances and electrical/electronic products. This substance can be found in products with material based on: paper, wood, metal, plastic, fabrics, textiles and apparel, stone, plaster, cement, glass or ceramic, leather and rubber.

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	with high release, indoor use and outdoor use.	
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Substance 3: PY 3 (EC 229-355-1)

	<b>Use(s)</b>	<b>Technical function</b>
<b>Uses as intermediate</b>		
<b>Formulation</b>	<p>This substance is used in the following products: polymers, coating products, inks and toners, fillers, putties, plasters, modelling clay and finger paints.</p> <p>Release to the environment of this substance can occur from industrial use: formulation of mixtures, formulation in materials and in the production of articles.</p> <p>Other release to the environment of this substance is likely to occur from: indoor use.</p>	<p>This substance is used in the following activities or processes at workplace: transfer of chemicals, mixing in open batch processes, transfer of substance into small containers, high energy work-up of substances bound in materials or articles, production of mixtures or articles by tableting, compression, extrusion or pelletisation, the low energy manipulation of substances bound in materials or articles, closed processes with no likelihood of exposure and closed batch processing in synthesis or formulation.</p>
<b>Uses at industrial sites</b>	<p>This substance is used in the following products: coating products, inks and toners, polymers, finger paints and fillers, putties, plasters, modelling clay.</p> <p>Release to the environment of this substance can occur from industrial use: in the production of articles, formulation of mixtures, formulation in materials, in processing aids at industrial sites, as processing aid and for thermoplastic manufacture. Other release to the environment of this substance is likely to occur from: indoor use.</p>	<p>This substance is used in the following areas: formulation of mixtures and/or re-packaging, printing and recorded media reproduction and building &amp; construction work. This substance is used for the manufacture of: plastic products, textile, leather or fur, pulp, paper and paper products, rubber products, mineral products, fabricated metal products, electrical, electronic and optical equipment, machinery and vehicles and furniture.</p> <p>This substance is used in the following activities or processes at workplace: transfer of chemicals, mixing in open batch processes, roller or brushing applications, treatment of articles by dipping and pouring, production of mixtures or articles by tableting, compression, extrusion or pelletisation, the low energy manipulation of substances bound in materials or articles, high energy work-up of substances bound in materials or articles, calendering operations, industrial spraying and transfer of substance into small containers.</p>
<b>Uses by professional workers</b>	<p>This substance is used in the following products: coating products, inks and toners, finger paints, polymers and fillers, putties, plasters, modelling clay.</p> <p>Other release to the environment of this substance is likely to occur from: indoor use and outdoor use.</p>	<p>This substance is used in the following areas: printing and recorded media reproduction and building &amp; construction work. This substance is used for the manufacture of: machinery and vehicles.</p> <p>This substance is used in the following activities or processes at workplace: transfer of chemicals, high energy work-up of substances bound in materials or articles, mixing in open batch processes, roller or brushing applications, non-industrial spraying, hand mixing with intimate contact only with personal protective equipment available and treatment of articles by dipping and pouring.</p>
<b>Consumer Uses</b>	<p>This substance is used in the following products: coating products, inks and toners and polymers.</p> <p>Other release to the environment of this substance is likely to occur from: indoor use (e.g. machine wash liquids/detergents, automotive care products, paints and coating or adhesives, fragrances and air fresheners) and outdoor use.</p>	

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<b>Article service life</b>	<p>This substance is used in the following activities or processes at workplace: high energy work-up of substances bound in materials or articles (e.g. hot rolling/forming, grinding, mechanical cutting, drilling or sanding) and transfer of chemicals.</p> <p>Other release to the environment of this substance is likely to occur from: outdoor use in long-life materials with low release rate, indoor use in long-life materials with low release rate, outdoor use in long-life materials with high release and indoor use in long-life materials with high release.</p>	<p>This substance can be found in complex articles, with no release intended: vehicles. This substance can be found in products with material based on: wood, plastic and paper.</p>
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*Please include non-confidential information on tonnages for the listed uses, where available.*

**Part 3: The potential for exposure is high for**

<b>Substance name</b>	<b>Humans</b>	<b>Environment</b>
PY 65 (EC 229-419-9)	X	X
PY 74 ( EC 228-768-4)	X	X
PY 3 (EC 229-355-1)	X	X

## 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 disruptor
- 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 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 <sup>2</sup>	
<input type="checkbox"/> PBT/vPvB	<input checked="" type="checkbox"/> Suspected PBT/vPvB <sup>1</sup>	<input type="checkbox"/> Other (please specify):
Exposure/risk based concerns		
<input checked="" type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input checked="" type="checkbox"/> Exposure of environment	<input type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input checked="" type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)

<sup>2</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

**Persistence assessment**

A reliable screening test for ready biodegradability for PY 74 according to OECD Guideline 301F, showed a biodegradation rate of 1% in 28 days. Inherent biodegradability was assessed for PY 65 and for another member of the Monoazo Yellow Pigments, PY 1 (EC 2512-29-0), according to OECD Guideline 302C. A biodegradation of 5% and 14% within 28 days was observed in the tests.

Based on the available data, the Monoazo Yellow Pigments are regarded by the Registrants as not readily and not inherently biodegradable, therefore PY 65, PY 74 and PY 3 are considered to fulfill the P criterion.

**Bioaccumulation assessment**

The Monoazo Yellow Pigments show a low solubility in octanol and water, therefore the determination of partition coefficient was calculated measuring the solubility in water and in n-octanol separately. The estimated log  $K_{ow}$  was 2 for PY 74, so that a reduced uptake in aquatic organisms is expected.

For PY 65 and PY 3 the estimated log  $K_{ow}$  were 3.3 and 2.9 respectively. The BCF values were then predicted using different QSAR models, as tests according to OECD 305 are not reliable for substances with low aqueous solubility (1.9 µg/L PY 65 and 7.5 µg/L PY 3). The BCF values ranged between 5 and 213 L/kg, showing a low potential for bioaccumulation.

A low octanol solubility of a substance may indicate reduced bioaccumulation potential. For PY 74 the octanol solubility was 0.74 mg/L and was lower of the critical body burden (CBB) of 0.772 mg/L (0.002 mMol/L × 386 g/Mol), so it can be assumed that the substance has only a limited potential to establish high body burdens and to bioaccumulate.

The octanol solubility of the other two pigments was higher than the one of PY 74, it was 4.1 mg/L for PY 65 and 5.96 mg/L for PY 3. These values were above the related CBBs of the two pigments: 0.772 mg/L (PY 65) and 0.79 mg/L (PY 3). Therefore a build-up to a critical concentration of the substances in lipid cannot be excluded. The only study for toxicokinetic was performed with PY 74 on rat and the findings didn't find evidence of bioavailability of the pigment after oral or dermal application. The conclusion of the study was extended to all the other members of the category by read across. However, some doubts arise that read across is applicable to evaluate the B properties for PY 65 and PY 3 on the basis of the water solubility, octanol solubility and log  $K_{ow}$ .

The potential to bioaccumulate in air-breathing (terrestrial) organisms was also assessed. The octanol-air partition coefficients were above the trigger value of 5 for all three pigments (log  $K_{oa}$  = 7.4, 7.6 and 10 for PY 65, PY 3, PY 74) and the log  $K_{ow}$  were  $\geq 2$ , therefore a potential to biomagnify was expected. The only study reported in the CSR for mammalian toxicokinetic is conducted on PY 74 and is conclusive to exclude the B property for PY 74, but this conclusion can't be readily extended to the other members of the category.

Moreover PY 74 and PY 65 are listed in the tattoo Restriction dossier currently under consideration and data from literature "Metabolism of pigment yellow 74 by rat and human microsomal proteins" (Cui et al.2005), are suggestive that these ink pigments can be metabolized by phase I enzymes (P450s) in metabolites potentially toxic depending on their formulation.

In conclusion, new toxicokinetic studies could be needed to further investigate on the B property of the three Monoazo Yellow Pigments.

**Toxicity assessment**

Based on the available ecotoxicity data, the Monoazo Yellow Pigments are regarded as acutely and chronically non toxic for any aquatic tested species (fish, invertebrates and algae) as well as for microorganisms and soil organisms.

No toxic effects have been observed in either aquatic short- or long-term studies for saturated solutions (nominal concentrations tested were far above the water solubility - NOECs  $\geq$  applied nominal concentrations between 1 and 100 mg/L).

No adverse effects to sewage sludge microorganisms were also found, as resulted from OECD 209-test at the nominal concentration of 1000 mg/L (limit test).

Furthermore, Monoazo Yellow Pigments were regarded as non toxic to soil macro-organisms, based on the results from the reliable study with PY 74 according to OECD 222 at nominal limit concentrations of 1000 mg/kg soil dry weight.

Furthermore, these substances were not classified by the Registrants for environmental toxicity nor as CMR or STOT RE according to CLP. Neither definitive nor screening criteria for T appear to be met.

Based on these available data, the Registrants concluded that the Monoazo Yellow Pigments are considered not fulfilling the T criterion.

However, it is to be noted that the Monoazo Yellow Pigments, being highly insoluble (with water solubility <1 mg/L, in the range of 1.9-7.6 µg/L for YP 3, YP 65 and YP 74), are to be regarded as difficult substances for aquatic toxicity testing as well as for Toxicity criterion assessment. In the available aquatic toxicity studies no analytical determination was carried out (no NOEC or ECx values can be calculated) and the derivation of PNEC values is not possible, including any quantitative determination of hazard assessment. Then, it is to be noted that since no toxicity effects are observed in any test system at exposure nominal concentrations up the water solubility and no most sensitive of the three taxonomic groups can be identified, a conclusive hazard assessment for these substances to the aquatic organisms cannot be fully addressed.

Therefore, in the context of the suspected PBT concern, depending on the outcomes of P and B assessment, the T criterion could then be further investigated. For the above considerations on ecotoxicological data and as recommended for poorly water soluble substances, further information including aquatic chronic toxicity data (such as toxicity testing on sediment organisms) could be needed to substantiate the conclusions on Toxicity properties assessment.

#### **Conclusion on PBT assessment**

The available information are:

- Conclusive for P property
- Not conclusive for B property
- depending on the outcomes of P and B assessment, the T criterion could then be further investigated

#### **Exposure assessment**

The Monoazo Yellow Pigments are used by consumers and by professional workers (widespread uses) as colouring agents for paints, plastics and inks. The potential for releases to the environment is likely to occur from: indoor use and outdoor use.

Other potential releases to the environment are likely to occur from industrial use: in the production of articles, formulation of mixtures and formulation in materials. Moreover, releases can occur during the article service life in long-life materials.

#### **Risk considerations**

The Monoazo Yellow Pigments pose a concern as suspected PBT substances, that need to be further examined and clarified under SEV. The substances have wide dispersive uses, therefore a potential risk for human health and for the environment is expected. The requested information under CoRAP process would lead to improvement of Risk management Measures for the nitro phenyl azo pigments.



**5.4 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 checked="" 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)

New toxicokinetic studies could be needed to further investigate on the B property of the three Monoazo Yellow Pigments.

Information on ecotoxicological properties could be needed, since depending on the outcomes of P and B assessment, the T criterion could then be further investigated.

**5.5 Potential follow-up and link to risk management**

<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input checked="" type="checkbox"/> Other (provide further details)
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In case a PBT concern was confirmed, because the uses are wide dispersive, a risk management option analysis (RMOA) could be necessary to decide on a potential regulatory RMO.