Annex XV report

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

Substance Name: 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone

EC Number: 404-360-3

CAS Number: 119313-12-1

Submitted by: Austria, in cooperation with Slovakia

Date: August 5th 2019

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TABLES

ABBREVIATIONS

AAAPs	Alkylaminoacetophenones
AC	Article category
BDMD	2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone
C&L	Classification & Labelling
MMMP	2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one
PC	Product category
PI	Photoinitiator
SVHC	Substance of very high concern
SU	Sector of use
UV	Ultraviolet

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Substance name: 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone

EC number: 404-360-3

CAS number: 119313-12-1

- The substance is proposed to be identified as a substance meeting the criteria of Article 57 (c) of Regulation (EC) No 1907/2006 (REACH) owing to its classification in the hazard class toxic for reproduction category 1B[1].

Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation

2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone is covered by index number 606-047-00-9 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class toxic for reproduction category 1B (H360D: May damage the unborn child).

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification in the hazard class:

- Toxic for reproduction category 1B in accordance with Article 57 (c) of REACH.

Registration dossiers submitted for the substance: Yes

[1] Classification in accordance with section 3.7. of Annex I to Regulation (EC) No 1272/2008.

PART I

Justification

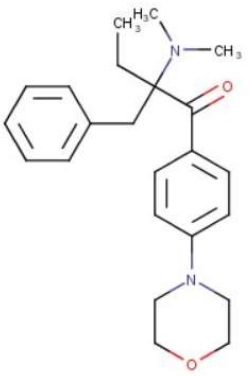
1. Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	404-360-3
EC name:	2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone
CAS number (in the EC inventory):	119313-12-1
CAS number: **Deleted CAS numbers:**	119313-12-1
CAS name:	1-butanone, 2-(dimethylamino)-1-[4-(4-morpholinyl)phenyl]-2-(phenylmethyl)-
IUPAC name:	2-benzyl-2-(dimethylamino)-1-[4-(morpholin-4-yl)phenyl]butan-1-one
Index number in Annex VI of the CLP Regulation	606-047-00-9
Molecular formula:	C23H30N2O2
Molecular weight range:	ca. 366.5
Synonyms:	Omnirad 369, Genocure BDMM, CG 25-369; IRGACURE 369; TK 11-319, Speedcure BDMB, Photoinitiator-369, Doublecure 369, Chivacure 169

Structural formula:



(source: European Chemicals Agency, http://echa.europa.eu/**)**

1.2 Composition of the substance

Name: 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone

Description: solid (particulate/powder)

Substance type: multi-constituent

The substance includes a stereocentre and is regarded as a multi-constituent substance including the two main constituents:

(2S)-2-benzyl-2-(dimethylamino)-1-[4-(morpholin-4-yl)phenyl]butan-1-one and
(2R)-2-benzyl-2-(dimethylamino)-1-[4-(morpholin-4-yl)phenyl]butan-1-one

There are no impurities relevant for the identification of the substances as SVHC.

1.3 Identity and composition of degradation products/metabolites relevant for the SVHC assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of the REACH Regulation.

1.4 Identity and composition of structurally related substances (used in a grouping or read-across approach)

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of the REACH Regulation.

1.5 Physicochemical properties

Table 2: Overview of physicochemical properties

Property	Description of key information	Value [Unit]	Reference/source of information
Physical state at 20°C and 101.3 kPa	Slightly yellowish powder	Solid	ECHA dissemination site: 02.07.2019
Melting/freezing point	Capillary method	113.2 °C[a]	ECHA dissemination site: 02.07.2019
Boiling point	Decomposed at >275°C before boiling	Not applicable[b]	ECHA dissemination site: 02.07.2019
Vapour pressure	Extrapolated based on thermogravimetry (Diffusion controlled evaporation)	≤0.0000006 Pa at 25°C[c]	ECHA dissemination site: 02.07.2019
Density	Air comparison pycnometer method using Helium > 99.8 % as test gas	1210 kg/m³ at 20°C	ECHA dissemination site: 02.07.2019
Water solubility	Flask method	5.9 mg/L at 20°C[d]	ECHA dissemination site: 02.07.2019
Partition coefficient n-octanol/water (log value)	Shake-flask method	2.91 at 25°C[e]	ECHA dissemination site: 02.07.2019

(a) QSAR-model MPBPWIN (v1.44) predicts a melting point of 190°C (weighted value)
(b) QSAR-model MPBPWIN (v1.44) predicts a melting point of 457°C
(c) QSAR-model MPBPWIN (v1.44): Selected VP: 7.97×10^{-7} Pa (Modified Grain Method)
(d) QSAR-model WSKOW (v1.42) predicts a water solubility of 7.163 mg/L
(e) QSAR-model KOWWIN (v1.69) predicts a logPow of 4.50

2. Harmonised classification and labelling

2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone is covered by Index number 606-047-00-9 in part 3 of Annex VI to the CLP Regulation (13th ATP) as follows:

Table 3: Classification according to Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index No	Chemical Name	EC No	CAS No	Classification		Labelling			Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)		
606-047-00-9	2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	404-360-3	119313-12-1	Repr. 1B Aquatic Acute 1 Aquatic Chronic 1	H360D H400 H410	GHS09 GHS08 Dgr	H360D H410			

3. Environmental fate properties

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of the REACH Regulation.

4. Human health hazard assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of the REACH Regulation.

5. Environmental hazard assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of the REACH Regulation.

6. Conclusions on the SVHC Properties

6.1 CMR assessment

2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone is covered by index number 606-047-00-9 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class toxic for reproduction category 1B (H360D: May damage the unborn child).

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification in the hazard class:

- Toxic for reproduction category 1B in accordance with Article 57 (c) of REACH.

6.2 PBT and vPvB assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of the REACH Regulation.

6.3 Assessment under Article 57(f)

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of the REACH Regulation.

Part II

7. Registration and C&L notification status

7.1 Registration status

Table 4: Registration status

From the ECHA dissemination site[2]	
Registrations	☒ Full registration(s) (Art. 10) ☐ Intermediate registration(s) (Art. 17 and/or 18)

7.2 CLP notification status

Table 5: CLP notifications

	CLP Notifications[3]
Number of aggregated notifications	13
Total number of notifiers	154

8. Total tonnage of the substance

Table 6: Tonnage status

Total tonnage band for the registered substance (excluding the volume registered under Art 17 or Art 18)[4]	100 - 1,000 t/pa

[2] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.100.600 *(accessed 03/07/2019)*
[3] C&L Inventory database, http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database (accessed 03/07 2019)
[4] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.100.600 *(accessed 03/07/2019)*

9. Information on uses of the substance

Table 7: Uses (according ECHA dissemination site; July, 2019)

	Use(s)	Registered use	Use likely to be in the scope of Authorisation
Uses as intermediate	-	No	-
Formulation or repacking	Formulation of mixtures in closed and open systems Manufacture of inks and surface coatings based on acrylates polymerised by exposure to UV radiation PC 1: Adhesives, sealants PC 7: Base metals and alloys PC 9a: Coatings and paints, thinners, paint removers PC 9b: Fillers, putties, plasters, modelling clay PC 9c: Finger paints PC 18: Ink and toners PC 32: Polymer preparations and compounds	Yes	Yes
Uses at industrial sites	Industrial application of mixtures containing the substance Manufacture of inks and surface coatings based on acrylates polymerised by exposure to UV radiation Use as ink and specialist surface coatings PC 1: Adhesives, sealants PC 7: Base metals and alloys PC 9a: Coatings and paints, thinners, paint removers PC 9b: Fillers, putties, plasters, modelling clay PC 9c: Finger paints PC 18: Ink and toners PC 32: Polymer preparations and compounds SU 0: Other: C20.3 - manufacturing: manufacture of paints, varnishes and similar coatings, printing ink and mastics SU 0: Other: C26 - manufacturing: manufacture of computer, electronic and optical products SU 7: Printing and reproduction of recorded media SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment	Yes	Yes
Uses by professional workers	Professional use of mixtures containing the substance (widespread use) PC 7: Base metals and alloys PC 9a: Coatings and paints, thinners, paint removers PC 9b: Fillers, putties, plasters, modelling clay	Yes	Yes

	PC 18: Ink and toners PC 32: Polymer preparations and compounds SU 0: Other: C32 - manufacturing: other manufacturing SU 22: Professional uses: Public domain (administration, education, entertainment, services, craftsmen)		
Consumer uses	-	No	-
Article service life	Articles containing no or very limited registered substance AC 1: vehicles AC 2: machinery, mechanical appliances, electrical/electronic articles AC 7: metal articles	Yes	No

2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone is used as photoinitiator in polymer production. It belongs to the chemical group of alkylaminoacetophenones (AAAPs), which are mainly used in acrylate- and methacrylate-based formulations. Photoinitiators are applied in the UV curing process where free radicals are generated by the energy of UV-light for the formation of polymeric materials. The main applications of the substance are in high speed inks such as flexo, offset litho and UV ink jet (Green, 2010).

The substance is registered under REACH and is imported into the EU, formulated and used in industrial and professional applications. There is no manufacture of the substance in the EU.

10. Information on structure of the supply chain

According to ECHA dissemination site (brief profile, accessed July, 2019) 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone has 22 active registrations under REACH, 1 joint submission and 8 individual submissions. Active registrants are located in 7 different Member States.

The substance has a high number of C&L notifications. 13 aggregated notifications with a total number of 154 notifiers are listed at ECHA dissemination site (accessed July, 2019).

According to information from dissemination site the substance is used at least in seven different sectors, seven product categories and three article categories (see Chapter 9).

This substance is used at industrial sites, in formulation or re-packing, by professional workers, and in articles. There is no manufacture in the EU and the number of industrial and professional sites using the substance is not known.

11. Additional information

11.1 Substances with similar hazard and use profiles on the Candidate List

Not relevant.

11.2 Alternatives

2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone belongs to the chemical group of alkylaminoacetophenones (AAAPs) and has a maximum UV absorption at 320 nm. AAAPs are mainly used in acrylate- and methacrylate-based formulations.

AAAPs in general are very efficient in producing radicals and lead to very fast curing (type I photoinitiators). They have become almost high-volume commodity chemicals. According to literature they are used in high-speed offset and flexo inks, UV ink-jet, etch resists, printing plates and solder masks. Due to their yellowing effect they have only limited use in very clear coatings (Green, 2010).

There are several potential alternatives available (RadTech conference, 2018) and the harmonised classification as Repr 1B has already led to a move towards alternative substances, especially in printing inks. However, specific alternatives have to be determined use by use, in view of the specific properties needed (wavelength, moisture sensitivity, O_2-inhibition, yellowing, pigments, etc.).

Chemical alternatives to 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone may be the structural similar substances within the group of AAAPs, namely:

- 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one (EC 400-600-6)
- 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one (EC 438-340-0)
- 2-benzyl-2-dimethylamino-1-(4-piperidinylphenyl)-1-butanone (CAS 119312-76-4)

While 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl] butan-1-one (EC 438-340-0) and 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one (EC 400-600-6) have a similar hazard profile as the substance of concern, only limited information on irritating properties is available for 2-benzyl-2-dimethylamino-1-(4-piperidinylphenyl)-1-butanone (CAS 119312-76-4), as the substance is not registered. The wavelength of maximum absorption is similar (see Table 8). There are indications that the photoinitiator 2-benzyl-2-dimethylamino-1-(4-piperidinylphenyl)-1-butanone even performs better than 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one in varnishes (ABRAFATI conference, 2017).

Polymeric versions within the group of AAAPs may also be used as alternatives. They are a reaction product of a low molecular weight photoinitiator and a polymeric backbone:

- A MMMP-3 structure [polymeric version of 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one (MMMP) with a ε-caprolactone tail]
- Polyethylene glycol di(β-4-[4-(2-dimethylamino-2-benzyl)butaonylphenyl]piperazine)propionate [polymeric version of 2-benzyl-2-dimethylamino-4'-piperazinobutyrophenone]
- A BDMD-3 structure [polymeric version of 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone (BDMD) with a ε-caprolactone tail].

The information on toxicity of these substances is limited as they are not registered. The MMMP-3 structure and BDMD-3 structure have low acute toxicity (LD_{50} > 2000 mg/kg bw day) and no or slightly irritating properties[5].

Polymeric photoinitiators are promoted to have a low migration potential due to their relatively high molecular weights and restricted movement in the matrices. Low migration is also due to the fact that one or both photoinitiator moieties can cross link into the growing polymer chain during cure, effectively locking the photoinitiator *in situ*. A drawback is that products tend to have high viscosity (ABRAFATI conference, 2017).

Alpha hydroxyl ketones have a similar UV absorption as AAAPs:

- 2-hydroxy-1-[4-[4-(2-hydroxy-2-methylpropanoyl)phenoxy]phenyl]-2-methylpropan-1-one (EC 472-110-0)
- 2-hydroxy-1-(4-(4-(2-hydroxy-2-methylpropionyl)benzyl)phenyl)-2-methylpropan-1-one (EC 444-860-9)
- 1-propanone, 2-hydroxy-2-methyl-1-[4-(1-methylethenyl) phenyl]-, homopolymer
- Mixture mainly based on 2,3-dihydro-6-(2-hydroxy-2-methyl-1-oxopropyl)-1,1,3-trimethyl-3-[4-(2-hydroxy-2-methyl-1-oxopropyl)phenyl]-1H-indene; 2,3-dihydro-5-(2-hydroxy-2-methyl-1-oxopropyl)-1,1,3-trimethyl-3-[4-(2-hydroxy-2-methyl-1-oxopropyl)phenyl]-1H-indene (EC 402-990-3).

It is noted that the classification of these substances varies widely (see **Table 8**).

Possible alternatives can also be found in the group of acyl phosphine oxides, a highly reactive group of photoinitiators:

- Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (EC 278-355-8)
- Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinate (EC 282-810-6)
- Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide (EC 423-340-5)

Other possible alternatives may be

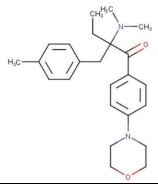
- 1-[4-(4-benzoylphenylsulfanyl)phenyl]-2-methyl-2-(4-methylphenylsulfonyl)propan-1-one (EC 429-040-0)
- 4, 4'-bis (diethylamino) benzophenone (EC 202-025-4)
- Polymeric acylphosphine oxide, based on Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinate (polymeric type I Photoinitiator, no further information available)
- 3-ketocoumarin[6] (efficient type II photoinitiator, no further information available).

Blended products may also be an option to obtain the best total cure under defined conditions according to industry (RadTech conference, 2018).

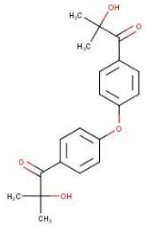
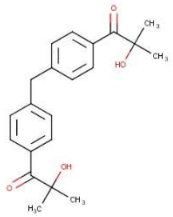
Basic information on the toxicity of possible alternative products has been listed in Table 8. Some substances already have a harmonised classification, for others the toxicological database is rather limited, and the results of a first check in the OECD toolbox have been included in the table.

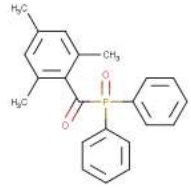
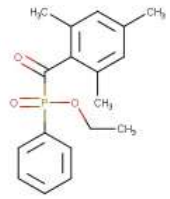
[5] https://radtech.org/proceedings/2004/papers/080.pdf
[6] https://radtech.org/proceedings/2018/Photoinitiator/Morone-Marika_Second-generation-3-ketocoumarin-photoinitiators--oligomeric-and-zero-migration-photoinitiators-for-LED-curing.pdf

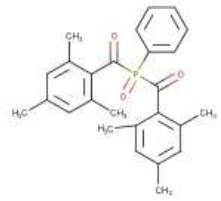
Table 8: Alternatives, their classification and recommendation by industry (RadTech conference, 2018).

Name, chemical structure, identity	**Classification (harmonised in bold)**	**Wavelength of maximum absorption (Green, 2010)**	**Recommendation (RadTech conference, 2018)**
EC 400-600-6 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one CAS 71868-10-5	**Repr. 1B, H360FD** **Acute Tox. 4 *, H302** **Aquatic Chronic 2, H411**	303	Not recommended due to classification as Reprotoxic 1B.
EC 438-340-0 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one CAS 119344-86-4 	Repro 2, H361 Aquatic Chronic 1, H410 Aquatic Chronic 4, H413	320	A very close alternative, by chemical structure. High risk in the longer term with regards to read across of classifications. CMR 2 classed material may give restrictions within company policies or end users specifications. SNUR[7] listed. (1)
EC 827-771-3 2-benzyl-2-dimethylamino-1-(4-piperidinylphenyl)-1-butanone CAS 119312-76-4	Skin Irrit 2, H315 Eye Irrit 2, H319 STOT SE 3, H335 [OECD toolbox: The substance is not in the applicability domain of QSARs; structural alerts for DNA-binding, Micronucleus test and high cramer classification; high structural similarity with 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone]	333	A very close performance and chemical match to 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone. However, there is a considerable risk in the longer term with regards to read across of classifications. (2)
Polyethylene glycol di(β-4-[4-(2-dimethylamino-2-benzyl)butaonylphenyl]piperazine)propionate piperazino based aminoalkylphenone CAS 886463-10-1	[information on polymer structure insufficient for assessment via OECD toolbox]	325	A good performance match, based on similar chemistry to 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone (it is an alpha amino ketone), so there may be some future

[7] SNUR=Significant New Use Rule, under the US Toxic Substances Control Act (TSCA)

			risk for read across. It is a polymer (as classified under REACH) and is a viscous liquid. (1)
MMMP-3 structure [polymeric version of 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one (MMMP) with a ε-caprolactone tail]	[information on polymer structure insufficient for assessment via OECD toolbox]	305	-
BDMD-3 structure [polymeric version of 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone (BDMD) with a ε-caprolactone tail]	[information on polymer structure insufficient for assessment via OECD toolbox]	315	-
EC 472-110-0 2-hydroxy-1-[4-[4-(2-hydroxy-2-methylpropanoyl)phenoxy]phenyl]-2-methylpropan-1-one CAS 71868-15-0 	Aquatic chronic 2, H411 Aquatic chronic 3, H412	275	A close performance match with better cure performance in dense colours. SNUR listed. (1)
EC 444-860-9 2-hydroxy-1-[4[4-(2-hydroxy-2-methyl-propionyl)-benzyl]-phenyl]-2-methyl-propan-1-one CAS 474510-57-1 	**STOT RE 2, H373** **Aquatic acute 1, H400** **Aquatic Chron. 1, H410**	315	A close performance match. Also suitable for pastel shades. SNUR listed. (1)
EC 402-990-3 A mixture mainly based on: 2,3-dihydro-6-(2-hydroxy-2-methyl-1-oxopropyl)-1,1,3-trimethyl-3-[4-(2-hydroxy-2-methyl-1-oxopropyl)phenyl]-1H-indene; 2,3-dihydro-5-(2-hydroxy-2-methyl-1-	Repr. 2, H361	330	A good performance match. Also suitable for lighter shades, but with certain limitations in dark dense colours. CMR 2 classed material

oxopropyl)-1,1,3-trimethyl-3-[4-(2-hydroxy-2-methyl-1-oxopropyl)phenyl]-1H-indene CAS 163702-01-0			may give restrictions within company policies or end users specifications (2)
1-Propanone, 2-hydroxy-2-methyl-1-[4-(1-methylethenyl) phenyl]-, homopolymer CAS 115055-18-0	Repr. 2 Aquatic chronic 4, H413	325	A good performance match. Also suitable for lighter colours, but limitations in dark dense colours. CMR 2 classed material may give restrictions within company policies or end users specifications (1)
EC 278-355-8 Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide CAS 75980-60-8 	**Repr. 2, H361f** Skin Sens 1B, H317 Skin Irrit 2, H315; Eye Irrit 2, H319 Aquatic acute 1, H400 Aquatic chronic 1, H410 Aquatic chronic 2, H411 Aquatic chronic 3, H412 Aquatic chronic 4, H413	275, 379	Technically an interesting possibility. Low yellowing means it is suitable for pastel colours. CMR 2 Classed material may give restrictions within company policies or end users specifications (2)
EC 282-810-6 Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinate CAS 84434-11-7 	Repr. 2, H361 STOT RE 2; H373 Skin Sens 1B, H317 Aquatic acute 1, H400 Aquatic chronic 2, H411 Aquatic chronic 3, H412 Aquatic chronic 4, H413	230, 275, 370	A good technical possibility, and suitable for lighter shades. Some limitations in dark dense colours. Reactivity is lower than 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone. (1)
EC 423-340-5 Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide CAS 162881-26-7	**Skin Sens. 1, H317** **Aquatic Chronic 4; H413**		An interesting possibility as it provides good in depth cure performance, thus more suitable for thicker films. It may have it limits in certain colours. (1)

			
EC 429-040-0 1-[4-(4-benzoylphenylsulfanyl)phenyl]-2-methyl-2-(4-methylphenylsulfonyl)propan-1-one CAS 272460-97-6	**Eye Dam 1, H318** **Aquatic chronic 4, H413**	315	A close performance match which can be used in certain applications as 1:1 replacements. A Type II photoinitiator. (1)
EC 202-025-4 4, 4'-bis (diethylamino) benzophenone CAS 90-93-7	Carc 2, H351 Skin Irrit 2, H315 Eye Irrit 2, H319 STOT SE 3, H335 Aquatic acute 1, H400 Aquatic chronic 1, H410 Aquatic chronic 2, H411 Aquatic chronic 4, H413	248, 374	This is an interesting choice for blended solutions to boost cure and reduce cost. Strongly yellowing, however. (2)

* structural formula source: European Chemicals Agency, https://echa.europa.eu/
(1) Alternate photoinitiators for sensitive applications
(2) Alternate photoinitiators for non-sensitive applications

11.3 Existing EU legislation

2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone is harmonised classified as Repr. 1B according to Regulation (EC) No 1272/2008 (Index number 606-047-00-9).

In the EU there are no occupational exposure limits available.

Legislation on printing inks: Currently there is no specific harmonised legislation in the EU on printing inks. Some photoinitiators have a specific migration limit set in the EU legislation on plastic material and articles to come into contact with foodstuff (EU No 10/2011); 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone is not listed. However printing inks have to fulfil the general requirements according to EC No 1935/2004 (framework regulation on materials and articles intended to come into contact with food). According to Article 3 materials and articles shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could endanger human health (Lago, 2015).

11.4 Previous assessments by other authorities

A CLH dossier focusing on environmental hazards has been prepared by Germany and discussed in RAC in 2017. The result was to retain the classification as Aquatic Acute 1, H400 and Aquatic Chronic 1, H410.

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