

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-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one

EC Number: 400-600-6

CAS Number: 71868-10-5

Submitted by: Austria, in cooperation with Slovakia

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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 |

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-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one

EC number: 400-600-6

CAS number: 71868-10-5

- 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 1B¹.

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

2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one is covered by index number 606-041-00-6 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 (H360FD: May damage fertility. 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

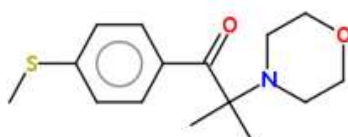
1. Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance identity

| | |
|---|---|
| EC number: | 400-600-6 |
| EC name: | 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one |
| CAS number (in the EC inventory): | 71868-10-5 |
| CAS number: Deleted CAS numbers: | |
| CAS name: | |
| IUPAC name: | 2-methyl-1-[4-(methylsulfanyl)phenyl]-2-(morpholin-4-yl)propan-1-one |
| Index number in Annex VI of the CLP Regulation | 606-041-00-6 |
| Molecular formula: | C ₁₅ H ₂₁ NO ₂ S |
| Molecular weight range: | 279.4 |
| Synonyms: | Omnirad 907 Irgacure 907 Speedcure 97 GENOCURE*PMP UV 907 IHT-PI 907 |

Structural formula:



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

1.2 Composition of the substance

Name: 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one

Description: solid (particulate/powder)

Substance type: mono-constituent

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 | White to light beige powder | Solid | ECHA dissemination site: 07.05.2019 |
| Melting/freezing point | Measured, using photocell detection | 74.6°C* | ECHA dissemination site: 07.05.2019 |
| Boiling point | Decomposed before boiling (decomposition at >190°C) | Not applicable | ECHA dissemination site: 07.05.2019 |
| Vapour pressure | Extrapolated value measurement by thermogravimetry (diffusion controlled evaporation) | 0.0002 Pa at 25 °C | ECHA dissemination site: 07.05.2019 |
| Density | Measured by the air comparison pycnometer method | 1210 kg/m ³ at 33 °C | ECHA dissemination site: 07.05.2019 |
| Water solubility | Flask method | 17.9 mg/L at 20°C** | ECHA dissemination site: 07.05.2019 |
| Partition coefficient n-octanol/water (log value) | Shake flask method | 3.09 at 25°C at pH 7 | ECHA dissemination site: 07.05.2019 |

*QSAR-model MPBPVP v1.43 (Episuite v4.11) predicts a melting point of 133.12°C based on the chemical structure of the substance.

**QSAR-model WSKOW v1.42 (Episuite v4.11) predicts a water solubility of 772.4 mg/L based on the chemical structure of the substance.

2. Harmonised classification and labelling

2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one is covered by Index number 606-041-00-6 in part 3 of Annex VI to the CLP Regulation (10th 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) | | |
| 606-041-00-6 | 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one | 400-600-6 | 71868-10-5 | Repr. 1B Acute Tox. 4 * Aquatic Chronic 2 | H360FD H302 H411 | GHS08 GHS07 GHS09 Dgr | H360FD H302 H411 | | | |

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-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one is covered by index number 606-041-00-6 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 (H360FD: May damage fertility. 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 | <input checked="" type="checkbox"/> Full registration(s) (Art. 10) <input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18) |

7.2 CLP notification status

Table 5: CLP notifications

| | CLP Notifications ³ |
|------------------------------------|--------------------------------|
| Number of aggregated notifications | 12 |
| Total number of notifiers | 518 |

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 | 1000+ t/pa |
|---|------------|

² <https://echa.europa.eu/de/substance-information/-/substanceinfo/100.100.260> (accessed 03/07/2019)

³ C&L Inventory database, <http://echa.europa.eu/web/quest/information-on-chemicals/cl-inventory-database> (accessed 03/07/2019)

⁴ <https://echa.europa.eu/de/substance-information/-/substanceinfo/100.100.260> (accessed 03/07/2019)

9. Information on uses of the substance

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

| | Use(s) | Registered use <i>(If not, specify the source of the information)</i> | Use likely to be in the scope of Authorisation |
|-------------------------------------|--|---|---|
| Manufacture | Industrial manufacture of the photoinitiator | Yes | Yes |
| Uses as intermediate | - | No | - |
| Formulation or repacking | Industrial formulation of preparations containing the photoinitiator Formulation & (re)packing of printer/coating PC 9a: Coatings and paints, thinners, paint removers PC 18: Ink and toners | Yes | Yes |
| Uses at industrial sites | Industrial use of the photoinitiator resulting in inclusion into a matrix, including application in coatings, adhesives, inks, fibre sizing Use as coatings PC 9a: Coatings and paints, thinners, paint removers PC 9b: Fillers, putties, plasters, modelling clay PC 18: Ink and toners SU 0: Other SU 6b: Manufacture of pulp, paper and paper products SU 9: Manufacture of fine chemicals SU 12: Manufacture of plastics products, including compounding and conversion SU 15: Manufacture of fabricated metal products, except machinery and equipment | Yes | Yes |
| Uses by professional workers | Wide dispersive indoor use (professional) of photoinitiator resulting in inclusion into a matrix, including application in coatings, adhesives and inks. | Yes | Yes |
| Consumer uses | - | No | - |
| Article service life | - | No | - |

2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one 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 are in high-speed offset and flexo inks, UV ink-jet, etch resists, printing plates and solder masks (Green, 2010). Uses at industrial sites and by professionals are registered.

10. Information on structure of the supply chain

According to the ECHA dissemination site (brief profile, accessed July, 2019) 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one has 18 active registrations under REACH, 1 joint submission and 4 individual submissions. Active registrants are located in 5 different Member States.

The substance has a high number of C&L notifications. 12 aggregated notifications with a total number of 518 notifiers are listed on the ECHA dissemination site (accessed July, 2019).

According to information from the dissemination site 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one is used in at least five different sectors and three product categories.

The substance is manufactured in the EU, formulated or re-packed and used at industrial sites and by professional workers. 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-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one belongs to the chemical group of alkylaminoacetophenones (AAAPs) and has a maximum UV absorption at 303 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 the 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 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, O₂-inhibition, yellowing, pigments, etc.).

Due to the high similarity in performance and radical forming process to the closely related substance 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone also the alternatives evaluated by industry for that substance are presented here (RadTech conference, 2018).

Chemical alternatives to 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one may be the structural similar substances within the group of AAAPs, namely:

- 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone (EC 404-360-3)
- 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-benzyl-2-dimethylamino-4'-morpholinobutyrophenone (EC 404-360-3) 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 **Error! Reference source not found.**). 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:

- An 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 properties⁵.

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)

⁵ <https://radtech.org/proceedings/2004/papers/080.pdf>

It is noted that the classification of these substances varies widely (see **Error! Reference source not found.**).

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)

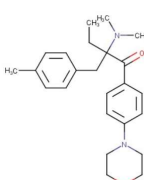
Other possible alternatives may be

- 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-ketocoumarin⁶ (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).

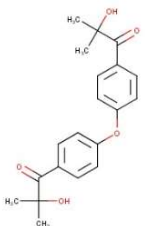
Basic information on the toxicity of possible alternative products has been listed in Table 8. Some substances already have a harmonised classification, for others the toxicological database is rather limited, and the results of a first check in the OECD toolbox have been included in the table below.

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 404-360-3 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone | Repr. 1B, H360D Aquatic Acute 1, H400 Aquatic Chronic 1, H410 | 320 | - |
| CAS 119313-12-1 EC 438-340-0 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one | 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 |
| CAS 119344-86-4 |  | | |

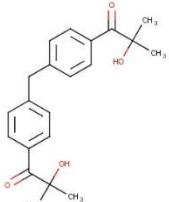
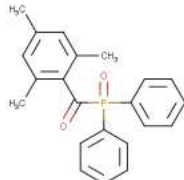
⁶ https://radtech.org/proceedings/2018/Photoinitiator/Morone-Marika_Second-generation-3-ketocoumarin-photoinitiators--oligomeric-and-zero-migration-photoinitiators-for-LED-curing.pdf

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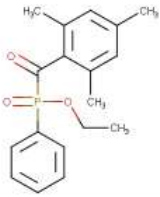
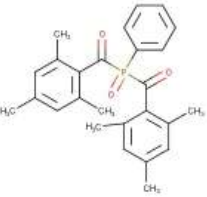
| | | | |
|--|---|-----|---|
| | | | policies or end users specifications. SNUR ⁷ listed. (1) |
| EC 827-771-3 2-benzyl-2-dimethylamino-1-(4-piperidinylphenyl)-1-butanone CAS 119312-76-4 | Skin Irrit 2, H315 Eye Irrit 2, H319 STOT SE 3, H335 [OECD toolbox: The substance is not in the applicability domain 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)p ropionate 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 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 | STOT RE 2, H373 Aquatic acute 1, H400 | 315 | A close performance match. Also suitable |

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

ANNEX XV – IDENTIFICATION OF 2-METHYL-1-(4-METHYLTHIOPHENYL)-2-MORPHOLINOPROPAN-1-ONE AS SVHC

| | | | |
|---|---|----------------------|---|
| <p>2-hydroxy-1-[4[4-(2-hydroxy-2-methyl-propionyl)-benzyl]-phenyl]-2-methyl-propan-1-one</p> <p>CAS 474510-57-1</p>  | <p>Aquatic Chron. 1, H410</p> | | <p>for pastel shades. SNUR listed. (1)</p> |
| <p>EC 402-990-3</p> <p>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-oxopropyl)-1,1,3-trimethyl-3-[4-(2-hydroxy-2-methyl-1-oxopropyl)phenyl]-1H-indene</p> <p>CAS 163702-01-0</p> | <p>Repr. 2, H361</p> | <p>330</p> | <p>A good performance match. Also suitable for lighter shades, but with certain limitations in dark dense colours. CMR 2 classed material may give restrictions within company policies or end users specifications (2)</p> |
| <p>1-Propanone, 2-hydroxy-2-methyl-1-[4-(1-methylethenyl) phenyl]-, homopolymer</p> <p>CAS 115055-18-0</p> | <p>Repr. 2 Aquatic chronic 4, H413</p> | <p>325</p> | <p>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)</p> |
| <p>EC 278-355-8</p> <p>Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide</p> <p>CAS 75980-60-8</p>  | <p>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</p> | <p>275, 379</p> | <p>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)</p> |
| <p>EC 282-810-6</p> <p>Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinate</p> <p>CAS 84434-11-7</p> | <p>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</p> | <p>230, 275, 370</p> | <p>A good technical possibility, and suitable for lighter shades. Some limitations in dark dense colours. Reactivity is lower than 2-benzyl-2-dimethylamino-4'-morpholinobutyrophe none. (1)</p> |

ANNEX XV – IDENTIFICATION OF 2-METHYL-1-(4-METHYLTHIOPHENYL)-2-MORPHOLINOPROPAN-1-ONE AS SVHC

| | | | |
|--|--|---------------------------|--|
|  | | | |
| <p>EC 423-340-5</p> <p>Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide</p> <p>CAS 162881-26-7</p>  | <p>Skin Sens. 1, H317 Aquatic Chronic 4; H413</p> | <p>237 , 275, 380</p> | <p>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)</p> |
| <p>EC 429-040-0</p> <p>1-[4-(4-benzoylphenylsulfanyl)phenyl]-2-methyl-2-(4-methylphenylsulfonyl)propan-1-one</p> <p>CAS 272460-97-6</p> | <p>Eye Dam 1, H318 Aquatic chronic 4, H413</p> | <p>315</p> | <p>A close performance match which can be used in certain applications as 1:1 replacements. A Type II photoinitiator. (1)</p> |
| <p>EC 202-025-4</p> <p>4, 4'-bis (diethylamino) benzophenone</p> <p>CAS 90-93-7</p> | <p>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</p> | <p>248, 374</p> | <p>This is an interesting choice for blended solutions to boost cure and reduce cost. Strongly yellowing, however. (2)</p> |

* 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-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one is harmonised classified as Repr. 1B according to Regulation (EC) No 1272/2008 (Index number 606-041-00-6).

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-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one 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

No assessments performed by any other authority are known.

REFERENCES

References for Part II

- ABRAFATI conference (2017). Photoinitiator basic chemistry. Introduction to formulating and products for LED cure and low migration. Youyuan Wu (IGM Resins USA). Abstract available under: http://www.abrafati2017.com.br/2015/Dados/PDF/Paper_068.pdf
- EU (2006). Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. Official Journal of the European Union, L396: 1-849.
- EU (2008). Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packing of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal of the European Union, L353: 1-1355.
- EU (2011). Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. Official Journal of the European Union, L12, 1-89.
- EU (2004). Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. Official Journal of the European Union, L 338, 4-17.
- Green W. A (2010): Industrial Photoinitiators: A Technical Guide. © 2010 by Taylor and Francis Group, LLC. ISBN: 978-1-4398-2745-1.
- Lago MA, Rodríguez-Bernaldo de Quirósa A, Sendóna R, Bustosb J, Nieto MT, Paseiro P (2015). Photoinitiators: a food safety review. Food Additives & Contaminants: Part A, DOI:10.1080/19440049.2015.1014866.
- Personal communication (2018). email correspondence with lead registrant in July, 2018.
- Personal communication, (2019). email correspondence with lead registrant in July, 2018 and meeting in February, 2019.
- RadTech conference (2018). Presentation on "Transcending regulatory issues: alternates to Omnirad 369" Sandra van Gelder (IGM Resins BV), Elena Bellotti (IGM Resins Italia), Susan E Bailey (IGM Resins USA, Inc), and Dr Stephen R Postle* (IGM Resins USA, Inc). Abstract available under: https://radtech.org/proceedings/2018/Photoinitiator/Postle-Stephen_Transcending-regulatory-issues--alternates-to-Omnirad-369.pdf