

12 April 2023

## Background document for 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone

### Document developed in the context of ECHA's eleventh recommendation for the inclusion of substances in Annex XIV

*ECHA is required to regularly prioritise the substances from the Candidate List and to submit to the European Commission recommendations of substances that should be subject to authorisation. This document provides background information on the prioritisation of the substance, as well as on the determination of its draft entry in the Authorisation List (Annex XIV of the REACH Regulation). Information comprising confidential comments submitted during the consultation or relating to content of registration dossiers which is of such nature that it may potentially harm the commercial interest of companies if it was disclosed, is provided in a confidential annex to this document.*

Information relevant for prioritisation and/or for proposing Annex XIV entries provided during the consultation on the inclusion of 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone in the Authorisation List or in the registration dossiers<sup>1</sup> as well as the MSC opinion<sup>2</sup> were taken into consideration when finalising the recommendation and are reflected in the present document.

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<sup>1</sup> As of the last day of the consultation, i.e. 2 May 2022

<sup>2</sup> Opinion of the Member State Committee on the draft eleventh recommendation of the priority substances to be included in Annex XIV, adopted on 8 February 2023

## 1. Identity of the substance

Identity of the substance as provided in the Candidate List<sup>3</sup>:

Name: 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone  
EC Number: 404-360-3  
CAS Number: 119313-12-1

## 2. Background information for prioritisation

Priority was assessed by using the General approach for prioritisation of SVHCs for inclusion in the list of substances subject to authorisation (ECHA, 2020). Results of the prioritisation of all substances included in the Candidate List by July 2021 and not yet recommended or included in Annex XIV of the REACH Regulation are available in ECHA (2022a).

The prioritisation results of the substances included in the draft 11<sup>th</sup> recommendation have been updated as necessary after the consultation. The updated results are available in ECHA (2023).

### 2.1. Intrinsic properties

2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone was identified as a Substance of Very High Concern (SVHC) according to Article 57 (c) as it is classified in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Toxic for Reproduction, Category 1B, H360D ("May damage the unborn child"), and was therefore included in the Candidate List for authorisation on 16 January 2020, following ECHA's decision ECHA/01/2020.

### 2.2. Volume used in the scope of authorisation

The amount of 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone manufactured and/or imported into the EU is according to registration data in the range of 100 - 1,000 t/y (ECHA, 2022b). All tonnage used in the EU appears to be in the scope of authorisation. Therefore, in conclusion, the volume in the scope of authorisation is estimated to be in the range of 100 - <1,000 t/y.

More detailed information on uses is provided in Annex I.

### 2.3. Wide-dispersiveness of uses

Registered uses of 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone in the scope of authorisation include uses at industrial sites (such as formulation of coatings and inks, use as photoinitiator in UV-curable coatings, inks and adhesives) and uses by professional workers (use as photoinitiator in UV-curable coatings, inks and adhesive).

More detailed information on uses is provided in Annex I.

### 2.4. Further considerations for priority setting

2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone is considered together with 2-methyl-

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<sup>3</sup> For further information please refer to the Candidate List and the respective support document at <https://www.echa.europa.eu/candidate-list-table>.

1-(4-methylthiophenyl)-2-morpholinopropan-1-one as a group, as based on structural similarities and similar uses reported in registrations it appears that 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone could replace 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one in (some of) its uses.

## 2.5. Conclusion

Verbal descriptions and scores			Total score (= IP + V + WDU)	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)		
2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone is classified as toxic for reproduction 1B meeting the criteria of Article 57 (c)  Score: 1	The amount of 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone used in the scope of authorisation is in the range of 100 - 1,000 t/y.  Score: 9	2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone is used at industrial sites and by professional workers.  Score: 10	20	Grouping with 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one

### Conclusion

On the basis of the prioritisation criteria further strengthened by grouping considerations, 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone receives priority among the substances on the Candidate List (see link to the prioritisation results above). Therefore, **2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone is recommended for inclusion in Annex XIV.**

## 3. Background information for the proposed Annex XIV entry

Draft Annex XIV entries were determined on the basis of the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV (ECHA, 2020) and as further specified in the practical implementation document (ECHA, 2020). The draft Annex XIV entries for all the substances that underwent consultation are available in ECHA (2022a).

The final draft Annex XIV entries that ECHA recommends are available in ECHA (2023).

### 3.1. Latest application and sunset dates

ECHA recommends the following transitional arrangements for 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone:

Latest application date (LAD):                      Date of inclusion in Annex XIV plus **24 months**

Sunset date:    18 months after LAD

The LAD slots are set in 3 months intervals (normally 18, 21 and 24 months after inclusion in

Annex XIV).

Allocation of (groups of) substances to LAD slots aims at an even workload for all parties during the opinion forming and decision making on the authorisation applications. All substances can therefore not be set at the same LAD. ECHA proposes to allocate those substances to the “later” LAD slots (21 months or more) for which the available information indicates a relatively higher complexity of supply chain. Groups of substances are considered together.

Based on the assessment performed the supply chain of 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone and 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one (considered as a group) has been concluded as being of higher complexity compared to other substances/groups included in the final recommendation. Therefore, a latest application date of 24 months is recommended.

During the consultation, a comment was received arguing for the longer LAD slot of 24 months due to the time needed to find alternatives (ECHA, 2023).

ECHA made the final LAD allocation using all available relevant information including that received in the consultation.

A summary of the information available is provided in Annex I.

ECHA allocated to the same slot substances considered as a group (see Section 2.4), i.e. the substance 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone was allocated to the same slot as substance 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one.

## 3.2. Review period for certain uses

In its draft recommendation ECHA had seen no ground to include in Annex XIV any review period for 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone.

During the consultation ECHA did not receive comments requesting upfront review periods for specific uses.

ECHA therefore **does not recommend to include in Annex XIV any review periods for uses of 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone.**

## 3.3. Uses or categories of uses exempted from authorisation requirement

### 3.3.1 Exemption under Article 58(2)

In its draft recommendation ECHA had not proposed any exemptions for uses of 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the consultation ECHA did not receive any requests for exemptions for the substance.

ECHA **does not recommend exemptions for uses of 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone** on the basis of Article 58 (1)(e) in combination with Article 58(2) of the REACH Regulation.

### 3.3.2 Exemption of product and process oriented research and development (PPORD)

In its draft recommendation ECHA had not proposed to include in Annex XIV any exemption from authorisation for the use of 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone for PPORD.

During the consultation ECHA did not receive any requests for exemptions from the authorisation requirement for PPORD for the substance.

No PPORD notifications had been submitted by the end of the consultation.

ECHA therefore **does not recommend exempting any use of 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone for PPORD** from authorisation.

## 4. References

ECHA (2019a): [Registry of SVHC intentions until outcome - ECHA \(europa.eu\)](#), filter by substance 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone (EC 404-360-3).

- 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: 203-468-6, CAS Number: 107-15-3.
- Comments on an Annex XV Dossier for identification of a substance as SVHC and responses to these comments. Substance name: 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone, EC Number: 203-468-6, CAS Number: 107-15-3.

ECHA (2019b): [Assessment of regulatory needs - ECHA \(europa.eu\)](#), filter by substance 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone (EC 404-360-3).

- Risk Management Option Analysis Conclusion Document. 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one, 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone.

ECHA (2020): Agreed and applied approaches. 5 March 2020.

[Recommendations for inclusion in the Authorisation List - ECHA \(europa.eu\)](#), filter by substance 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone (EC 404-360-3)

- Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV). Prioritisation approach.
- Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV. General approach.
- Setting Latest Application Dates. Practical implementation document for the Annex XIV entries approach.

ECHA (2022a): ECHA's 11th draft recommendation. 2 February 2022.

[Recommendations for inclusion in the Authorisation List - ECHA \(europa.eu\)](#), filter by substance 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone (EC 404-360-3)

- Prioritisation assessment results of the Candidate List substances assessed - Substances included in the Candidate List by July 2021 and not yet recommended for inclusion in Annex XIV.
- Draft 11th Recommendation of Priority Substances to be included in Annex XIV of the REACH Regulation (List of Substances Subject to Authorisation).

ECHA (2022b): 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone. ECHA's dissemination website on registered substances. Accessed on 2 May 2022.

<https://echa.europa.eu/search-for-chemicals>

ECHA (2022c): WFD - Waste Framework Directive, SCIP Database, [SCIP-Database - ECHA](#)

[europa.eu](https://europa.eu), search by substance 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone (EC 404-360-3)

ECHA (2023): ECHA's final 11<sup>th</sup> recommendation. 12 April 2023.

[Recommendations for inclusion in the Authorisation List - ECHA \(europa.eu\)](#), filter by substance 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone (EC 404-360-3)

- Updated priority assessment results of the substances included in the draft 11th recommendation for inclusion in Annex XIV. 12 April 2023.
- Recommendation of the European Chemicals Agency of 12 April 2023 for the inclusion of substances in Annex XIV to REACH (List of Substances subject to Authorisation).
- "Responses to comments" document. Document compiling the responses to comments from commenting period 02/02/2022 – 02/05/2022 on ECHA's proposal to include 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone in its 11th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).
- "Comments and references to responses" document. Document compiling comments and references to respective answers from commenting period 02/02/2022 – 02/05/2022 on ECHA's proposal to include 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone in its 11th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

## Annex I: Further information on uses

### 1. Detailed information on uses

2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone is used as photoinitiator in polymer production (ECHA, 2019a).

According to Annex XV SVHC report, 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone belongs to the chemical group of alkylaminoacetophenones (AAAPs), which are mainly used in acrylate- and methacrylate-based formulations. The substance is applied in the UV curing process where free radicals are generated by the energy of UV-light for the formation of polymeric materials. The applications are coating products, inks and toners, fillers, putties, plasters, modelling clay, polymers, adhesives and sealants, metals and finger paints, which are largely confirmed in SCIP notifications (ECHA 2019a; ECHA, 2022c). Uses at industrial sites and by professionals are registered.

Article service life (ASL) is reported in a limited number of registrations accounting for low volume. Notifications in the SCIP database (ECHA, 2022c) have been received indicating that this photoinitiator could be contained in polymeric material above 0.1 % (w/w). However, one of the registrants claimed that no or very limited amount of the registered substance is in fact expected in the final articles and provided justification. The substance is reactive and is expected to be consumed during the process. Analytical results presented in the RMOA (ECHA, 2019b) confirm the low residual amounts (well below the concentration limit of 0.1 %) in different article groups. Therefore article service life has not been considered relevant in the priority assessment.

The SVHC report (ECHA, 2019a) concluded that 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, O<sub>2</sub>-inhibition, yellowing, pigments, etc.).

### 2. Structure and complexity of supply chains

The following assumptions were made on the structure and complexity of supply chains associated to uses in the scope of authorisation based on currently available information and were used, together with relevant information from public consultation, to allocate the substance group to a specific LAD slot in the final recommendation. For the purpose of LAD assignment groups of substances are considered together. The information for the group is summarised below.

The substances 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone and 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one are manufactured and/or imported by a limited number of registrants. According to registration information (ECHA, 2022b), the substances are used at more than 100 industrial sites.

The supply chain can be characterised<sup>4</sup> by the following actors: formulators, users at industrial sites and professional workers, as well as articles producers and assemblers (multi-layer assembling chain) (relevant life cycle stages: F, IS, PW, SL (multi-layer)).

The substances seem to be used in the following product categories: Adhesives, sealants, base metals and alloys, coatings and paints, thinners, paint removers, fillers, putties, plasters,

<sup>4</sup> Categories listed here after (life cycle stage, SU, PC and AC) make reference to the use descriptor system described in ECHA's guidance on use description:

[https://echa.europa.eu/documents/10162/17224/information\\_requirements\\_r12\\_en.pdf](https://echa.europa.eu/documents/10162/17224/information_requirements_r12_en.pdf)



modelling clay, finger paints, ink and toners, polymer preparations and compounds (relevant product categories: PC 1, PC 7, PC 9a, PC 9b, PC 9c, PC 18, PC 32).

A number of sectors is relying on the substances in some of their uses including printing and reproduction of recorded media, manufacture of fine chemicals, manufacture of computer, electronic and optical products, electrical equipment, general manufacturing, e.g. machinery, equipment, vehicles, other transport (relevant sector of use categories: SU 7, SU 9, SU 16, SU 17).

Uses of 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone and 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one in the scope of authorisation seem to be relevant for the production of a number of article types such as vehicles, machinery, mechanical appliances, electrical/electronic articles, electrical batteries and accumulators, articles made of stone, plaster, cement, glass or ceramic, fabrics, textile and apparel, leather articles, metal, paper and plastic articles (relevant article categories: AC 1, 2, 3, 4, 5, 6, 7, 8, 13).

Some of the categories mentioned are not explicitly reported in registrations but could be derived from information on uses available in registration dossiers (ECHA, 2022b) and the Annex XV SVHC report (ECHA, 2019a).