2 February 2022

Draft 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 (as of the last day of the consultation, i.e. 2 May 2022 will be taken into consideration when finalising the recommendation and will be reflected in the final background document.

Contents

1. Identity of the substance

Identity of the substance as provided in the Candidate List[1]:

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[2]. 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 is available at *https://echa.europa.eu/documents/10162/17232/prior_results_cl_subst_february_2022_en.pdf*.

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. 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 section 1 of 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 section 1 of Annex I.

[1] For further information please refer to the Candidate List and the respective support document at https://www.echa.europa.eu/candidate-list-table.
[2] Document can be accessed at https://echa.europa.eu/documents/10162/17232/recom_gen_approach_svhc_prior_2020_en.pdf

2.4. Further considerations for priority setting

2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone is considered together with 2-methyl-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, it is proposed to prioritise 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone for inclusion in Annex XIV.

3. Background information for the proposed Annex XIV entry

3.1. Latest application and sunset dates

ECHA proposes the following transitional arrangements:

Latest application date (LAD):	Date of inclusion in Annex XIV plus **18, 21 or 24 months**
Sunset date:	18 months after LAD

ECHA will make the final LAD allocation when finalising the recommendation and will use all available relevant information including that received in the consultation. ECHA will apply the

Annex XIV entries approach[3] and the criteria described in the implementation document[4]. According to these documents, substances for which the available information indicates a relatively high number of uses and/or complex supply chain(s) are allocated to the "later" LAD slots.

A summary of the information currently available is provided in section 2 of Annex I.

The time needed to prepare an authorisation application of sufficient quality has been estimated to require 18 months in standard cases. When setting the LADs ECHA has also to take into account the anticipated workload of ECHA's Committees and Secretariat to process authorisation applications. This is done by allocating the substances proposed to be included in the final recommendation in slots, normally 3, and setting the application dates with 3 months intervals in between these slots (standard LAD slots: 18, 21 and 24 months).

For substances to be included in the 11th recommendation, ECHA sees currently no reason to deviate from these standard LAD slots.

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

3.2. Review period for certain uses

ECHA proposes not to include in Annex XIV any review period for 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone.

In general, ECHA does not propose any upfront specific review periods in its draft recommendations for inclusion in the Authorisation List. Setting review periods in Annex XIV for any uses would require that ECHA had access to adequate information on different aspects relevant for a decision on the review period. Such information is generally not available to ECHA at the recommendation step. It is to be stressed that, in the next step of the authorisation process, i.e. during the decision on whether authorisation is granted based on specific applications by manufacturers, importers or downstream users of the substance, all authorisation decisions will include specific review periods which will be based on concrete case-specific information provided in the applications for authorisation.

3.3. Uses or categories of uses exempted from authorisation requirement

3.3.1 Exemption under Article 58(2)

ECHA proposes not to 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.

According to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses or categories of uses '*provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled*'.

[3] General approach can be accessed at https://echa.europa.eu/documents/10162/17232/recom_gen_approach_draft_axiv_entries_2020_en.pdf/
[4] Practical implementation document can be accessed at https://echa.europa.eu/documents/10162/17232/recom_gen_approach_draft_axiv_entries_impl_doc_2020_en.pdf

ECHA considers the following elements in deciding whether to recommend an exemption of a use of a substance:

- There is existing EU legislation (i.e., rules of law adopted by a European Union entity intended to produce binding effects) addressing the specific use (or categories of use) that is proposed to be exempted;

- The existing EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV; generally, the legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to a group of substances that is clearly distinct from other substances;

- The existing EU legislation imposes minimum requirements for the control of risks of the use. The piece of legislation (i) has to define the minimum standard to be adopted in the interest of public health or the environment and (ii) allows EU Member States to impose more stringent requirements than the specific minimum requirements set out in the EU legislation in question. Legislation setting only a general framework of requirements or the aim of imposing measures or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s), as relevant) are covered by the legislation.

Where interested parties are considering making a request for exemption from authorisation under Art. 58(2) for a particular use, it is strongly recommended that they take into account ECHA's previous responses to Art. 58(2) exemption requests[5]. It is noted that any Art. 58(2) request is assessed case-by-case.

Furthermore, it should be noted that if a use falls under the generic exemptions from authorisation[6], there is no need to propose an additional specific exemption.

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

ECHA proposes not to recommend to include in Annex XIV any exemption from authorisation for the use of 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone for PPORD.

So far, ECHA has not considered it appropriate to recommend specific exemptions for PPORD for any substance. ECHA notes that an operator may use a substance included in Annex XIV for a PPORD activity if that operator has obtained authorisation for that use of the substance in accordance with Articles 60 to 64 of the REACH Regulation.

No PPORD notifications have been submitted for 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone[7].

[5] See analysis of most relevant pieces of legislation e.g. in sections C.2.8 – C.2.12 in https://echa.europa.eu/documents/10162/17232/8th_recom_respdoc_methylpyrrolidone_en.pdf, or in section C.2 in https://echa.europa.eu/documents/10162/17232/9th_recom_respdoc_lead_stabilisers_en.pdf including references given therein

[6] Generic exemptions from the authorisation requirement: https://echa.europa.eu/documents/10162/17232/generic_exempt_auth_2020_en.pdf

[7] As of 1 August 2021.

4. References

Annex XV SVHC report (2019): Proposal for identification of a substance of very high concern on the basis of the criteria set out in REACH Article 57. 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone. Submitted by Austria, in cooperation with Slovakia, August 2019.

https://www.echa.europa.eu/documents/10162/5c1fb9d7-14f9-7687-16bd-ecf62f008525

ECHA (2021): 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone. ECHA's dissemination website on registered substances. Accessed on 1 August 2021.

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

RMOA (2019): Risk Management Option Analysis Conclusion Document. 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one, 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone.
https://www.echa.europa.eu/documents/10162/2002bf57-d0e2-d6aa-e088-73002d530d9

Annex I: Further information on uses

1. Detailed information on uses

2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone is used as photoinitiator in polymer production (Annex XV SVHC report, 2019).

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 (Annex XV SVHC report, 2019; ECHA, 2021). Uses at industrial sites and by professionals are registered.

Article service life (ASL) is reported in registrations (vehicles, machinery, mechanical appliances, electrical/electronic articles, metal articles). Information in the SCIP database (ECHA, 2021), seem to indicate that this photoinitiator could be contained in the polymeric material above 0.1 % (w/w). However, the substance is reactive and according to the RMOA (2019), the residual amounts detected in different article groups are considered as very low (well below the concentration limit of 0.1 %) and therefore article service life is not considered relevant in the priority assessment.

The SVHC report (2019) 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, O2-inhibition, yellowing, pigments, etc.).

2. Structure and complexity of supply chains

The following assumptions are made based on currently available information and will be used, together with any relevant information from consultation, to allocate the substance group to a specific LAD slot in the final recommendation.

Substance is manufactured and/or imported by a limited number of registrants. According to registration information (ECHA, 2021), the substance is used at more than 100 industrial sites.

The supply chain can be characterised[8] 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)). There is no manufacture in the EU/EEA.

The substance seems to be used in the following product categories: Adhesives, sealants, base metals and alloys, coatings and paints, thinners, paint removers, fillers, putties, plasters, modelling clay, finger paints, ink and toners (relevant product categories: PC 1, PC 7, PC 9a, PC

[8] 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

9b, PC 9c, PC 18).

A number of sectors is relying on the substance 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 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, metal, wood and plastic articles (relevant article categories: AC 1, 2, 7, 11, 13). These are confirmed in SCIP notifications.

Some of the categories mentioned are not explicitly reported in registrations but could be derived from information on uses available in registration dossiers (ECHA, 2021), the Annex XV SVHC report (2019) and/or the SPIN database.