Regulatory Management Option Analysis (RMOA)

Authority: Austria

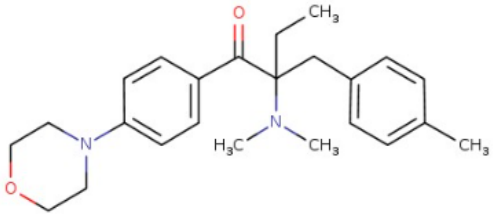
Date: May 2023

Substance name: 2-(dimethylamino)-2-[(4-methylphenyl) methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one

EC number: 438-340-0

CAS number: 119344-86-4

General structure:



Revision history

Version	*Date*	*Description*
1	May 2023	Final RMOA

Contents

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Foreword

The purpose of the assessment of regulatory needs of a group of substances is to help authorities conclude on the most appropriate way to address the identified concerns for a group of substances or a single substance, i.e. the combination of the regulatory risk management instruments to be used and any intermediate steps, such as data generation, needed to initiate and introduce these regulatory measures.

An assessment of regulatory needs can conclude that regulatory risk management at EU level is required for a (group of) substance(s) (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. While the assessment is done for a group of substances, the (no) need for regulatory action can be identified for the whole group, a subgroup or for single substance(s).

The assessment of regulatory needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is voluntary, i.e., it is not part of the processes defined in the legislation but aims to support them.

The assessment of regulatory needs can be applied to any group of substances or single substance, i.e., any type of hazards or uses and regardless of the previous regulatory history or lack of such. It can be done based on different level of information. A Member State or ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, more extensive set of information can be available, e.g. assessment done under REACH/CLP or other EU legislation, or can be generated in some cases (e.g. further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

The responsibility for the content of this assessment rests with the authority that developed it. It is possible that other authorities do not have the same view and may develop further assessment of regulatory needs. The assessment of regulatory needs does not yet initiate any regulatory process but any authority can consequently do so and should indicate this by appropriate means, such as the Registry of Intentions.

For more information on Assessment of regulatory needs please consult ECHA website[1].

[1] https://echa.europa.eu/understanding-assessment-regulatory-needs

Glossary

AAAPs	Alkylaminoacetophenones
ARN	Assessment of regulatory needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
CSR	Chemical safety report
DEv	Dossier evaluation
DNEL	Derived no effect level
ED	Endocrine disruptor
MSC	Member State Committee
NOAEL	No observed adverse effect level
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
PI	Photoinitiator
RMOA	Regulatory management options analysis
RAC	Committee for Risk Assessment
RRM	Regulatory risk management
SEv	Substance evaluation
SVHC	Substance of very high concern

1 Overview of the substance

The substance 2-(dimethylamino)-2-[(4-methylphenyl) methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one (EC 438-340-0) belongs to the group of Alkylaminoacetophenones (AAAPs), very reactive photoinitiators.

Based on information from registration dossiers the substance is typically used for the formulation of UV inks/printing inks/coatings and inks. The photoinitiator is broken by UV-light into reactive parts which initiate the polymerization process "curing process"). Industrial and professional uses as well as article service life are registered.

Under ideal conditions, a photoinitiator will be totally consumed in the photo-polymerization reaction, however, suboptimal reaction conditions may result in residual concentrations of unreacted photoinitiator in articles, therefore migration is of potential concern. Alternatives have to be determined use by use, in view of the specific properties needed, however, alternatives seem to be available for several applications.

EC 438-340-0 is a classified reproductive toxicant. Furthermore, aquatic acute and chronic toxicity have been confirmed recently. The substance also screens as P/vP, however, no conclusion on B can be drawn based on the available data.

2 Justification for the need for regulatory risk management action at EU level

Based on currently available information, there is a need for EU regulatory risk management –Authorisation, due to the known reproductive toxicity of the substance with likely exposure of industrial and professional users and consumers when used as photoinitiator for inks and toners.

For human health hazards, EC 438-340-0 will be harmonized classified as Repr.1B, H361 Df soon, based on the RAC opinion 06/2022. The formal inclusion in Annex VI of CLP is expected after the next ATP[2].

For environment, EC 438-340-0 will be harmonized classified as Aquatic Acute 1 and Aquatic Chronic 1 soon, based on the RAC opinion 06/2022. The substance screens as P and vP but no conclusion on the B criterion can be drawn.

The substance is imported into the EU at medium tonnages (100-1000 tpa). Based on the information reported in registrations considerable exposure potential can be assumed during industrial and professional use. Also consumer exposure during article service life cannot be excluded due to potential migration.

The substances EC 400-600-6 and 404-360-3, two similar alpha-amino acetophenones, have already been identified as SVHC (reproductive toxicity), are on the candidate list for authorisation and have been added to the opinion of the MSC on the draft 11th recommendation of the priority substances to be included in Annex XIV. Consequently, authorisation is also proposed for EC 438-340-0 in order to follow a group approach and to avoid regrettable substitution.

[2] The substance is listed in CARACAL Document CA/06/2023: "List of entries to be included in Annex VI of CLP (RAC opinions 2022)" as presented at CARACAL-48, 28-29 March 2023.

3 Conclusions and actions

EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
EC 438-340-0 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one	Known hazard for reproductive toxicity	Known hazard for aquatic toxicity Inconclusive hazard for PBT/vPvB for ED	Photoinitiator; used for coatings and inks (I, P, A)	Need for EU RRM: SVHC identification Justification: Reproductive toxicity, same regulatory strategy as for similar AAAP-photoinitiators	**First step:** SVHC identification **Next steps (if hazard confirmed):** Authorisation

Annex 1: Harmonised classifications and self-classifications reported by registrants

Data consulted on 2 March 2023

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
438-340-0	119344-86-4	2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one	Final RAC Opinion (06/2022) Repr. 1B H360Df Aquatic Acute 1 H400 Aquatic Chronic 1 H410	Repr. 2 H361d Aquatic Chronic 1 H410	Repr. 2 H361 [122 out of 124] Aquatic Chronic 1 H410 [29 out of 124] Aquatic Chronic 4 H413 [1 out of 124]

Annex 2: Overview of uses based on information available in registration dossiers

Data consulted on 2 March 2023

Main types of applications	EC/ List 438-340-0	Technical function
UV inks for digital printing/printing inks/coatings and inks	F, I, **P, A**	Photoinitiator
Application of coatings and inks	I, **P, A**	Photoinitiator

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; P, C and A are highlighted in red to indicate widespread use with potential for exposure/release

Annex 3: Overview of completed or ongoing regulatory risk management activities

Data consulted on 2 March 2023

EC / List number	RMOA	Authorisation		Restriction	CLH	Actions not under REACH / CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
438-340-0	ARN (ECHA) RMOA (Austria) - ongoing	-	-	-	Ongoing RAC opinion 06/2022	-