Risk Management Option Analysis Conclusion Document

Group name: Alkylaminoacetophenones (AAAPs)

EC	CAS	Name
400-600-6	71868-10-5	2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one
404-360-3	119313-12-1	2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone

Authority: CA Austria, in cooperation with CA Slovakia

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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Please provide a brief overview of completed/ongoing processes (including RMOA) and EU legislation relevant for the substance.

other processes	**Evaluation**			**Authorisation**		**Restriction**	**harm C&L**	**process under other EU legislation**		**previous legislation**		**Stockholm convention**
Identity	CCH	TPE	SEV	Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	PPP	BPR	NONS	RAR	POPs
Omnirad 907 EC 400-600-6	2010/11/12 (closed)	-	-	-	-	-	10th ATP completed (CLH IND; DE)	-	-	-	-	-
Omnirad 369 EC 404-360-3	2010/13 (closed) 2018 (closed, no action)	2013 (closed, Repro Tox)	-	-	-	-	13th ATP completed (CLH IND)	-	-	-	-	-

Occupational Safety and Health legislation: No occupational exposure limits available.

Regulations for printing inks: Currently there is no specific harmonized 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 (EC No 10/2011); above mentioned substances are 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), Article 3 where 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[2]).

[2] 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.

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	
Harmonised classification and labelling	
Identification as SVHC (authorisation)	x
Restriction under REACH	
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	
No action needed at this time	

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

Omnirad 907 and 369 exhibit reproductive toxicity and have harmonised classifications as Repr 1B; H360FD (907) and Repr 1B; H360D (369) respectively.

The two substances are used as photoinitiators in polymer production. They 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 coatings, paints, thinners, ink and toner and in the manufacture of electronic products. Uses at industrial sites and by professionals are registered.

Considering the life cycle stages of the substances, inhalation and dermal exposure to the substances as such (powder) are possible during and after the manufacturing process of the substances until they are incorporated into the matrices. Omnirad 907 and Omnirad 369 reveal low vapour pressures. Therefore, inhalation exposure via gaseous release is not considered to be a concern, whereas inhalation of dust and dermal contact with substances is of concern depending on the activity and RMM applied.

Wide dispersive consumer uses are not registered, however due to the uses in printing inks, coatings etc. exposure of consumers to unreacted residuals migrating from articles cannot be excluded. This is further supported by measurements in different article groups and indoor air, although partly very low and for indoor air outside Europe.

Overall, even though it is impossible to substantiate an unacceptable risk without higher tier exposure assessment, clear concerns for risk at workplace remain to be controlled by further measures.

3.1 Identification as a substance of very high concern, SVHC (first step towards authorisation)

Omnirad 907 and 369 fulfil the SVHC Roadmap 2020 criteria that have been defined for selecting substances that are relevant for identification as SVHC and thus it is in principle desirable to substitute these substances on a long term perspective.
Omnirad 907 and 369 have harmonised classifications as toxic for reproduction (category 1B) and therefore meet the criteria for inclusion in Annex XIV to REACH (Regulation (EC) No 1907/2006) set out in Article 57(c) of that Regulation. They are registered in high tonnages and with wide dispersive uses within the scope of authorisation.

Omnirad 907 and 369 are used as photoinitiators. A wide range of chemicals is on the market sharing this technical function. There are several potential (at first sight less hazardous) alternatives available. However, specific alternatives have to be determined use by use, in view of the specific properties needed (wavelength, moisture sensitivity, O_2-inhibition, yellowing, etc.) and may come from the group of AAAPs or from other groups of PIs.

The harmonized classification as Repr 1B already has led to a move towards alternative substances, especially in printing inks, as for example demonstrated by the recommendations in the EuPIA exclusion list. However, exemptions from this EuPIA voluntary restriction initiative may be applied for. Also for Omnirad 369 such an application is available. This shows that market self-regulation is not sufficient, even though alternatives are available for many applications.

The authorisation process provides incentives for the development of safer alternatives. Until substitution is achieved, the authorisation process aims at ensuring the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable (REACH Article 55). Therefore, the identification of the two substances as SVHC with subsequent eventual inclusion in Annex XIV is considered a particularly appropriate measure in order to further stimulate substitution.

It is acknowledged that further data generation would be necessary to fully rule out that the two substances exhibit PBT/vPvB properties and to further clarify the concern for endocrine disruption. However, due to the clear human health concern already identified (Repr 1B) and the high substitution potential for the two substances, it is rather recommended to await the impact of the risk reduction measures as proposed in the RMOA, which could potentially result in a withdrawal of these substances from the market.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

Follow-up action	Date for follow-up	Actors
Annex XV SVHC dossiers for Omnirad 907 and Omnirad 369	August / 2019	CA Austria, in cooperation with CA Slovakia