



**RISK MANAGEMENT OPTION ANALYSIS
CONCLUSION DOCUMENT**

for

**1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one
(3-benzylidene camphor)**

EC No 239-139-9

CAS No 15087-24-8

and

**(±)-1,7,7-trimethyl-3-[(4-
methylphenyl)methylene]bicyclo[2.2.1]heptan-2-one (4-
methylbenzylidene camphor)**

EC No 253-242-6

CAS No 36861-47-9

Member State: Germany

Dated: June 2015

Disclaimer: Please note that this RMOA conclusion was compiled on the basis of available information and may change in the light of new information or further assessment.

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 2020¹.

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 other 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>

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

The RMOA process on 3-benzylidene camphor (3-BC) and 4-methylbenzylidene camphor (4-MBC) was started on 23.09.2014 (PACT inclusion date). The draft RMOA has been presented at the Risk Management Expert Meeting 26./27.02.2015 and completed in April 2015.

3-BC is listed in the REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products, in Annex VI: List of UV-filters allowed in cosmetic products with a maximum concentration in ready for use preparations of 2%. However, the Scientific Committee on Consumer Safety (SCCS) of the European Commission concludes in its opinion on 3-benzylidene camphor² published in 2013 that even a use of this substance up to 2% in cosmetic products is not safe, owing to clear evidence of embryo-toxicity at 50 mg/kg bw/day and above in a developmental toxicity study.

In February 2015, the Standing Committee on Cosmetic Products has approved the removal of 3-BC from Annex VI and the inclusion into Annex II (list of substances prohibited in cosmetic products) of Regulation (EC/1223/2009).

4-MBC is also listed in the REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products, ANNEX VI: List of UV filters allowed in cosmetic products with a maximum concentration in ready for use preparations of 4%. The Scientific Committee on Consumer Products concluded in its opinion adopted in 2008 that 4-MBC can be considered safe for use in finished cosmetic products (whole body application) at a concentration of up to 4%³.

Beside these regulations regarding the use of both substances in cosmetic products no other legislative process is ongoing.

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	X
Harmonised classification and labelling	
Identification as SVHC (authorisation)	x
Restrictions	
Other EU-wide measures	
No need for regulatory follow-up action	

² http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_134.pdf

³ http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_141.pdf

3. FOLLOW-UP AT EU LEVEL

3.1 Need for follow-up regulatory action at EU level

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

According to the available hazard data 3-benzylidene camphor fulfils the criteria for Article 57 (f) because it is a substance with endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment which gives rise to an equivalent level of concern to those of other substances listed in points [(a) to (e)] of Article 57 of the REACH regulation.

The available hazard data demonstrate an endocrine mediated mode of action of 3-BC unfold adverse effects on the (sub)population level. Thus, there is strong evidence from high quality studies pointing to endocrine mediated adverse effects in various fish species. Additionally, screening data indicate a significant bioaccumulation potential of the substance.

These effects are severe with regard to the type of effects and the concentrations causing the effects. Evidence from several test data show that effects of 3-benzylidene camphor fit to those of other active compounds showing estrogenic activity, which are considered serious for the environment due to the type of effects. Effects remain manifest even after exposure has ceased and the fact that exposure during sensitive life stages may change the endocrine feedback system resulting in effects during the entire life.

Although no chronic test for an environmentally relevant species is available for 4-methylbenzylidene camphor (4-MBC), the highly similar chemical structure (MoA), which allows for setting up a one-to-one read-across scenario from the data available for 3-BC, and the available *in vitro* literature data for 4-MBC give raise for the same concern. Hence, 4-MBC is also considered to fulfil the criteria for Article 57 (f) because it is a substances with endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment which gives rise to an equivalent level of concern to those of other substances listed in points [(a) to (e)] of Article 57 of the REACH regulation.

Both substances have not been registered yet, although preregistrations indicated registrations in 2010 and 2013. The number of individual notifications in ECHA's C&L Inventory database⁴ leads to the conclusion that 3-BC and 4-MBC are commercially relevant inside Europe.

Regarding the use in cosmetics it is expected that 3-BC will no longer be used due to the approved removal from Annex VI and inclusion into Annex II of Regulation (EC/1223/2009). Since the Scientific Committee on Consumer Products considers the use of 4-MBC to be safe for human health up to a maximum concentration in ready for use preparations of 4%, it is not expected that the substance will be removed from Annex VI of the Cosmetics Regulation and it is assumed that the use of 4-MBC will continue or even increase when used as a substitute for 3-BC.

There are indications that 3-BC and 4-MBC are also used for other applications than cosmetics. Although it is expected that 3-BC will no longer be used in cosmetics it cannot be excluded that other uses will lead to environmental emissions of both substances.

For certain UV filter substances regulatory activities have been initiated or they are subject to substance evaluation due to environmental concerns which need to be clarified. With respect to that it can be expected that 3-BC and 4-MBC might gain more

⁴ <http://echa.europa.eu/information-on-chemicals/cl-inventory-database> (last accessed 11.05.2015)

importance in the near future functioning as alternatives to strictly regulated UV filter substances. Thus, even if currently not registered, 3-BC and 4-MBC might be registered, used and released in higher amounts when regulatory measures for common UV filter chemicals enter into force.

From these uses described above continuous and wide dispersive emissions to the environment are very likely and monitoring data show the presence of both camphor substances in the aquatic environment and humans.

Article 57 (f) enables the identification of substances with endocrine disrupting properties, when there is scientific evidence of probable serious effects to human health or the environment. According the current assessment of the German CA 3-benzylidene camphor and 4-methylbenzylidene camphor fulfil the criteria of Article 57 (f) owing to their endocrine disrupting properties in the environment. In contrast to CMR substances, no specific classification e.g. under the CLP regulation is available for endocrine disrupting substances. For ED effects on mammals leading to cancer or reproductive toxicity a harmonised classification as 'Carcinogen' or 'Reprotoxicant' is possible if data are available to prompt a harmonised classification. This is not valid for ED properties in the environment. Thus, identification of 3-BC and 4-MBC as SVHC would be the only available possibility to achieve an EU-wide agreement about their environmentally active endocrine disrupting properties. The inclusion in the candidate list would trigger the obligation to inform downstream users as of Article 33, if the substances are present in an article at a concentration > 0.1 %.

Furthermore, according to Article 7 (2) any producer or importer of articles shall notify ECHA if a substance is present in those articles in quantities totalling over one tonne per producer or importer per year and the substance is present in those articles above a concentration of 0.1%. An identification of 3-benzylidene camphor and 4-methylbenzylidene camphor as environmentally relevant SVHC and inclusion into the Candidate List would be a strong signal to enterprises manufacturer, importer and downstream user to substitute both substances in all uses that may result in environmental exposure.

In conclusion, identification of 3-BC and 4-MBC as SVHC would be the only measure to achieve an EU-wide agreement on their hazardous properties. It would transparently inform consumers and industry about the endocrine disrupting properties and would be a strong signal for substitution. Moreover, legally binding measures would be needed to minimize emissions and enforce substitution.

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 intention	Actor
Annex XV dossier for SVHC identification of 3-BC and 4-MBC	August / 2015	Germany