Risk Management Option Analysis Conclusion Document

Group Name: MEKO, its oxime alternatives and the respective oxime-releasing silanes in paints, coatings and sealants

EC-No.	CAS-No.	Name
MEKO and its oxime alternatives		
202-496-6	96-29-7	Butanone oxime (MEKO)
204-820-1	127-06-0	Acetone oxime
484-470-6	623-40-5	2-Pentanone oxime (MPKO)
203-298-2	105-44-2	4-Methylpentan-2-one oxime (MIBKO)
202-874-0	100-64-1	Cyclohexanone oxime (CHOX)
Butanone oxime-releasing silanes		
245-366-4	22984-54-9	Butan-2-one O,O',O''-(methylsilylidyne)trioxime (MOS)
218-747-8	2224-33-1	Butan-2-one O,O',O''-(vinylsilylidyne)trioxime (VOS; OS 2000)
251-882-0	34206-40-1	Butan-2-one O,O',O'',O'''-silanetetrayltetraoxime (TOS)
433-360-6	34036-80-1	2-Butanone-O,O',O''-(phenylsilylidyne)trioxime (OS 9000)
Acetone oxime-releasing silanes		
611-631-1	58190-57-1	2-Propanone, 2,2',2''-[O,O',O''-(ethylsilylidyne)trioxime] (EAC3)
460-110-3	797751-43-0	A mixture of: propan-2-one-O,O'-(methoxymethylsilandiyl)dioxime; propan-2-one-O-(dimethoxymethylsilyl)oxime; propan-2-one-O,O',O''-(methylsilantriyl)trioxime (Wasox-MMAC2)
458-680-3	797751-44-1	A mixture of: propan-2-one-O,O'(methoxyvinylsilandiyl)dioxime; propan-2-one-O-(dimethoxyvinylsilyl)oxime; propan-2-one-O,O',O''-(vinylsilantriyl)trioxime (Wasox-VMAC2)
MPKO-releasing silanes		
484-460-1	37859-55-5	2-pentanone,O,O',O''-(methylsilylidyne)trioxime (OS 1600)
700-810-0	58190-62-8	2-Pentanone, O,O',O''-(ethenylsilylidyne)trioxime (OS 2600)

700-833-6	1170315-90-8	2-Pentanone, O,O',O''-(phenylsilylidyne)trioxime (OS 9600)
942-139-8	1170315-92-0	Pentan-2-one O,O',O'',O'''-silanetetrayltetraoxime (OS 3600)
MIBKO-releasing silanes		
421-860-7	156145-64-1	2-Pentanone-4methyl-,O,O',O''-(ethenylsilylidyne)trioxime (OS 2200)

Authority: German CA

Date: 15.07.2021

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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 assess whether further regulatory management measures are needed.

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. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Butanone oxime (MEKO)

MEKO was included in the CoRAP and the SEv by the German competent authority (German CA). The SEv was completed in 2014 and subsequently a CLH proposal was prepared by the German CA. On this basis, ECHA's Risk Assessment Committee (RAC) adopted an opinion to classify MEKO as Carc. 1B, H350, in September 2018. Furthermore, several additional endpoints were addressed in the RAC opinion, resulting in a proposal for harmonised classification of MEKO as Acute Tox. 3, H301; Acute Tox. 4, H312; Skin Sens. 1B, H317; Eye Dam. 1, H318; Skin Irrit. 2, H315; STOT SE 3, H336; STOT SE 1, H370 (upper respiratory tract) and STOT RE 2, H373 (blood system). The corresponding inclusion into Annex VI of the CLP Regulation entered into force with the 15th ATP of the CLP regulation in August 2020. It shall apply from 1 March 2022.

Acetone oxime

Acetone oxime was investigated in a SEv by the Austrian competent authority (Austrian CA) in 2016, with the outcome to initiate a CLH process for harmonised classification of the substance as Carc. 1B, H350, among other hazard classes. The Austrian CA submitted a first draft of a proposal for the harmonised classification of acetone oxime for Accordance Check on 21 December 2020. The Austrian CLH-Dossier for Acetone oxime has been resubmitted after Accordance Check on the 8th of April, 2021. The public consultation started on 05.07.2021 and is open until 03.09.2021.

2-Pentanone oxime (MPKO), 4-methylpentan-2-one oxime (MIBKO), and cyclohexanone oxime (CHOX)

MPKO, MIBKO, and CHOX are registered under REACH. So far, no EU processes were initiated for these substances.

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:	
Substance evaluation or compliance check	X
Harmonised classification and labelling	X
Identification as SVHC (authorisation)	
Restriction under REACH	X
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

The identified group of oximes used in paints and coatings consists of five substances and their respective silane derivatives. At least one of those oximes, MEKO (and likely acetone oxime), exhibits hazardous properties fulfilling SVHC criteria. Moreover, there are widespread professional and consumer uses of these oximes and their silane derivatives in paints and coatings as well as in silicone sealants. Especially, exposure to oximes released from sealants poses a risk from applications for the professional user and for the consumer. For the three remaining, structurally and functionally related substances in this group, MIBKO, MPKO and CHOX, data is available indicating that STOT RE classification (and potentially classification for additional hazard classes) is warranted according to CLP. Furthermore, because of their use as alternatives for MEKO, the concern remains that these substances might pertain similar carcinogenic properties as MEKO, as it was already suggested for acetone oxime as well.

Possible regulatory options for all five substances and their silane derivatives are discussed in the following.

3.1 Substance evaluation

Substance evaluation (SEv) can give the opportunity to close data gaps and clarify uncertainties by requesting further information on the hazardous properties of the substance and subsequently performing a proper risk assessment.

There are indications from the public consultation that the longer alkyl chain length of the substances MPKO, MIBKO and CHOX might lead to a lower or even no carcinogenic potential. However, the German CA received no data to validate this information during the public consultation. On the contrary, the available data rather indicate that these three oximes exhibit a similar hazard pattern as MEKO at similar exposure levels, which warrant classification for STOT RE and potentially for carcinogenicity and other endpoints as well.

A SEv could be a measure to request the necessary information and clarify the carcinogenic properties of the alternative substances MPKO, MIBKO and CHOX. Currently, however, the German CA is of the opinion that requesting the necessary data to clarify the carcinogenic concern (i.e. chronic animal studies with each of the substances) for MIBKO and CHOX is not proportional, when considering the rather low tonnage band at which MIBKO and CHOX are registered. Thus, currently SEv is not envisaged for these two oximes. In contrast to this, MPKO is registered at an aggregated tonnage of >1000 tpa, which is indicative of MPKO currently being the main substitute for MEKO (and acetone oxime). Thus, SEv is considered the next relevant action for MPKO, in order to gain vital information on its carcinogenic potential. The tonnage bands of the other substances, MIBKO and CHOX, are monitored closely. In case the tonnage band of any of these two substances will increase significantly (e.g. due to substitution of MEKO), the German CA reserves its right to reassess the data and to reconsider SEv as an option for these two substances as well.

3.2 Harmonised classification and labelling

Harmonised classification, especially regarding CMR properties, can have direct effects for the use of hazardous substances at the workplace and for the use by consumers.

The entry of MEKO in Annex VI of CLP as Carc. 1B, H350 (which will apply as of March 2022), triggers classification and labelling obligations for mixtures containing the

substance in concentrations of more than 0.1 %. The same would apply for acetone oxime if it was classified accordingly. Similarly, the German CA intends to prepare CLH proposals for MEKO-releasing silanes as Carc. 1B due to the release of the carcinogenic oxime, MEKO. Accordingly, the German CA intends to propose the identical harmonised classification that will be decided for acetone oxime in the near future for the acetone oxime-releasing silanes.

Regarding the other three oximes, MPKO, CHOX and MIBKO, the available toxicological information for these substances per se is considered insufficient to conclude on their carcinogenic properties in order to be able to propose an equivalent harmonised classification as for MEKO or acetone oxime, i.e. Carc. 1B, H350. However, these oximes appear to have similar effects on the haematopoietic system when compared to MEKO and acetone oxime, respectively. The German CA, therefore, intends to assess within the planned SEv, whether a subsequent harmonised classification of MPKO for the hazard class STOT RE and potentially also other hazard classes (including STOT SE 1/2, H370/371; STOT SE 3, H336) could be successful. Additionally, during the SEv the German CA intends to assess whether a harmonised classification of MPKO with regard to its assumed carcinogenic properties may be reasonable (e.g. classification as Carc. 1B, H350). For the other two oximes, MIBKO and CHOX, outcomes of the SEv for MPKO will be awaited, in order to consider appropriate relevant (regulatory) actions, e.g. additional SEv or the preparation of CLH dossiers. Potential risks from MPKO-, and MIBKO-releasing silanes due to oral and dermal exposure will be addressed in more detail in a follow-up RMOA. However, if the respective oximes were classified as (suspected) carcinogens, respective classification of their silane derivatives would be aspired, too.

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

At least one oxime, namely MEKO, meets the criteria for identification as SVHC according to Art. 57a. Acetone oxime might fulfil this criterion as well, if the proposal for harmonised classification by the Austrian CA is confirmed by RAC. So far, the other three oximes, MIBKO, MPKO and CHOX, do not formally meet any SVHC criteria at present.

The release of oximes such as MEKO from silicone-sealants, which was identified in this RMOA as a potential risk for workers and consumers, would not fall under the scope of authorisation of MEKO itself, but would imply additional, individual SVHC identification and authorisation processes.

Authorisation of MEKO is seen as a disproportionate regulatory measure at the moment. The German CA will revisit this option after confirmation of the carcinogenic potential of the other oximes and respective oxime-releasing silanes by harmonised classification.

3.4 Restriction under REACH

In this RMOA, the German CA has identified risks for the worker and the consumer, especially regarding the use of silicone-sealants: Release of MEKO from silicone-sealants poses a risk to workers, exceeding existing national limit values at the workplace (in Germany). Moreover, continuous release of MEKO over a longer period of time (range of days/weeks) after application raises a major concern regarding consumer safety. The identified risks would require regulatory action on a Union-wide level.

A restriction under REACH could efficiently address the risks of released MEKO and other carcinogenic oximes and respective oxime-releasers from silicone-sealants in order to protect workers and bystanders (consumers) equally. Similarly, restricting the use of MEKO and other carcinogenic oximes as well as their silane derivatives in paints and coatings would provide a Union-wide, harmonised safety level for workers. Thus, a restriction could address the two specific uses, where MEKO and alternative oximes are applied/used directly or are released by silane compounds through hydrolysis.

Further details and conditions of a restriction, e.g. alternatives and the socioeconomic impact, need to be carefully weighed to adequately consider the protection aims regarding both, workers and consumers.

At present, the German CA considers a restriction under REACH as an appropriate regulatory measure. A restriction could address the identified risks for workers from the use of MEKO and MEKO-releasers, as well as other oximes and their respective oxime-releasers that may be classified as carcinogens in the future.

3.5 Other Union-wide regulatory measures

Derivation of a binding occupational exposure limit value (BOELV) under the Carcinogens and Mutagens Directive (CMD)

Fulfilling the criteria as carcinogen, MEKO falls under the CMD. Thus, derivation of a European harmonised binding occupational exposure limit value (BOELV) could be warranted.

Derivation of a BOELV may draw greater attention to this problem at the workplace in a Union-wide manner. However, it can be expected that the use of other oximes as substitutes will increase even after setting a BOELV for MEKO. Because of their structural similarity it might even be possible that these oximes can be used together in the same mixture. As not only MEKO is in the focus for the need of regulation, a group approach addressing the other oximes as well would be necessary.

The other oximes currently do not fulfil the criteria to fall under the CMD, as they do not have a harmonised classification as Carc. or Muta., Category 1 A/B. At present, the data basis is not sufficient for derivation of acceptable cancer risk levels. Therefore, the German CA does not consider a BOELV setting as efficient regulatory measure for the group of oximes and oxime-releasing silanes at present.

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 (ROI).

Follow-up action	Date for follow-up	Actor
SEv for MPKO	2022	German CA
CLH proposal for MPKO, MIBKO, cyclohexanone oxime (depending on outcome of SEv)	Depending on SEv	German CA

CLH proposal for oxime-releasing silanes (depending on outcome of CLH proposal for single oximes and outcomes of follow-up RMOA on oxime-releasing silanes)	Depending on CLH proposal for single oximes and outcome of follow-up RMOA on oxime-releasing silanes	German CA
Restriction	Depending on the other follow-up actions	German CA