



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Risk Management Option Analysis Conclusion Document

Substance Name: Toluene

EC Number: 203-625-9

CAS Number: 108-88-3

Authority: Dutch National Institute for Public Health and the Environment

Date: June 2020

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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 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 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

The subject of this RMOA is the use of toluene containing thinners, currently used by the general public for thinning of paint for spraying purposes.

Toluene is on Annex XVII of REACH, and therefore its uses are subject to REACH restriction. Restriction entry 48 states that toluene "Shall not be placed on the market, or used, as a substance or in mixtures in a concentration equal to or greater than 0,1% by weight where the substance or mixture is used in adhesives or spray paints intended for supply to the general public". The original concern concerned spray painting and was identified in the EU risk assessment report (EU-RAR). Spray painting was identified as one of the exposures that led to an unacceptable risk.

In 2013 a report on the substance evaluation by the Finnish CA was published. It was concluded that no new information has become available since the EU-RAR of 2003, which would change conclusions for the reproductive toxicity. All together no new information was requested from the registrant, but the registrant was recommended to justify the long-term inhalation DNEL derivation for workers or to use the results from the RAR to derive long-term inhalation DNEL for workers. Overall, it was recommended that the Commission Scientific Committee on Occupational Exposure Limits (SCOEL) takes into account results from the EU risk assessment from 2003 and prepares a review on whether there is a need to update the recommendation on IOEL values for toluene. The effectiveness of the current restrictions was not evaluated.

In 2015 the Danish CA presented an analysis of the most appropriate risk management option (RMO) for Toluene. This report proposed the following risk management options:

1. The Danish EPA will initiate an assessment of existing data to make a decision on inclusion in the Candidate List under REACH based on its neurotoxic effects.
2. Denmark supports the conclusions in the 2013 substance evaluation report that the Commission Scientific Committee on Occupational Exposure Limits (SCOEL) takes into account results from the EU risk assessment from 2003 in the current review on IOEL values for toluene.

The DK analysis mentioned the existing restriction for toluene but did not evaluate whether the restriction covers the full concern of toluene exposure through paint spraying.

The Danish RMOA was based on the concern for emissions of toluene from children's room-related products. It was concluded that these emissions do not generally occur at levels causing concern for chronic neurotoxic effects in children. Considering the risk reduction measures already implemented and on their way in the EU, the analysis concludes that no further regulation for toluene is required for the time being.

2. CONCLUSION OF RMOA

It is concluded that extending the scope of entry 48 to either more paints or paint-thinner combinations is most likely not an effective measure to address the concerns at hand, namely the misuse of non-spray paints in spray applications. Alternatively it is suggested to start the dialogue with paint manufacturers, manufacturers of spraying appliances, branches and retailers on the possibility to adapt the formulation of non-spray paints as such that its thinning will not lead to a risk for the general public when sprayed and to raise awareness on the concern for toluene exposure to discourage thinning of non-spray paint with toluene containing thinner. When adaptation of the formulation is a possibility one should consider to reframe the restriction to restrict the bringing on the market of toluene containing-paints for consumer use.

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

3. NO ACTION NEEDED AT THIS TIME

Table: SVHC Roadmap 2020 criteria

	Yes	No
a) Art 57 criteria fulfilled?	Possibly (equivalent level of concern)	
b) Registrations in accordance with Article 10?	X	
c) Registrations include uses within scope of authorisation?	X	
d) Known uses <u>not</u> already regulated by specific EU legislation that provides a pressure for substitution?	possibly	

The substance of concern is already regulated for consumer uses through Restriction entry 48.

One of the Dutch inspection authorities, The Netherlands Food and Consumer Product Safety Authority (NVWA), has indicated that toluene containing thinners are being used by the general public for thinning of paint for spraying purposes. This may result in toluene concentrations in homemade spray paint exceeding 0.1% as laid down in the restriction entry 48. Entry 48 applies to the use of toluene in adhesives or spray paints intended or supply to the general public.

The home thinning of paint for spraying is common practice and described in the manuals of paint sprayers. Thinners without toluene are available on the market but are not always used. Other thinners may contain up to 15% of toluene and there are even

thinners for which the MSDS indicates 50 to 100% of toluene. The packaging of these high toluene content thinners provides no information that these thinners should not be used for thinning of paint for spraying purposes.

The manuals of paint sprayers recommend a dilution of 10% (Bosch) or refer to specifications of the material (paint) manufacturer (Wagner). Thinning of paint for spraying purposes with 10% of any thinner that contains more than 4% of toluene results in the exceedance of the margin of safety identified in the EU RAR from 2003 that led to the Annex XVII restriction entry 48 for toluene.

In addition to the above, there is also the possibility that a non-spray paint might contain toluene. Their use as spraying paint after thinning with a non-toluene thinner is equal to the concern addressed in the current restriction.

Summary of the current concern

1. Use of homemade spray paint with a toluene concentration >0.1% prepared from the thinning of non-spray paint with toluene containing thinner.
2. Use of homemade spray paint with a toluene concentration >0.1% prepared from toluene-containing-paint after thinning with a non-toluene thinner.

Both concerns are enforcement problems.

Consequently, one risk management option is to adapt entry 48.

Both concerns relate to the misuse of paints for spray-applications that are not intended for that application (unintentional use). Regulating misuse is considered undesirable. Both concerns will also not be addressed by one adaptation of entry 48. The first concern would be addressed by a restriction on marketing of toluene as thinner to the general public. The second concern could be addressed by widening the scope of Restriction Entry 48 to "all paints". These adaptations may remove the present issue with risks stemming from misuse, but may introduce regulating uses that are without an overarching risk to society.

Widening the scope to all paints will not address the issue of an emerging risk after thinning with a toluene containing thinner. The thinners on the market are not impacted by entry 48. Thinners are sold separately from paint and are sold for many different purposes. This implies that in practice there is no control over the combination between paint and thinner used.

On the side of enforcement, the enforcement of "*at home thinning*" requirements may be less straight forward than the restriction currently is. The current restriction relies on the information provided on the SDS. For requirements on the *at home thinning*, enforcement will have to rely on the user-manual or technical datasheets and can no longer simply rely on the content indicated on the packaging.

Furthermore, as the current restriction only involves the supply to the general public, there may be a more wide issue of consumers having access to professional products in the DIY-shops. Further discussion with the Dutch NVWA suggests that there is only limited possibility to further regulate the current practice of using (homemade) spray paints possibly with toluene. Possibly, awareness raising with the help of the paint manufacturers could be used to inform customers about the risk of using toluene rich paints in spraying applications. E.g. suitable kinds of non-toluene thinners could be advised on paint cans and in manuals of spraying appliances. To this extent, it is suggested to open the dialogue with the paint formulators, manufacturers of spraying appliances, branches and retailers to identify the wideness of the concern and identify possible measures to address this.

3.1 Conclusions on the most appropriate (combination of) risk management options

It is concluded that extending the scope of entry 48 to either more paints or paint-thinner combinations is most likely not an effective measure to address the concerns at hand, namely the misuse of non-spray paints in spray applications. Alternatively it is suggested to start the dialogue with paint manufacturers, manufacturers of spraying appliances, branches and retailers on the possibility to adapt the formulation of non-spray paints as such that its thinning will not lead to a risk for the general public when sprayed and to raise awareness on the concern for toluene exposure to discourage thinning of non-spray paint with toluene containing thinner. When adaptation of the formulation is a possibility one should consider to reframe the restriction to restrict the bringing on the market of toluene containing-paints for consumer use.