Risk Management Option Analysis Conclusion Document

Substance Name: *penta-1,3-diene*
EC Number: *207-995-2*
CAS Number: *504-60-9*

Authority: *The Netherlands*
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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

Penta-1,3-diene was evaluated under the OECD HPV-programme. Based on use considerations and health and environmental data, it was concluded that penta-1,3-diene falls into the category of “presently of low concern”.

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)	
Restriction under REACH	
Other EU-wide regulatory measures	X
Need for action other than EU regulatory action	
No action needed at this time	

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

Penta-1,3-diene is selected because of its wide spread use and because of the presence of an impurity classified as Carc. 1B. This impurity is present at concentrations above the generic classification limit (GCL). As a consequence, penta-1,3-diene meets the criteria set by article 57a for SVHC (see also the table below). Main concern relates to the exposure of workers involved in handling the monomer substance.

No worker or consumer DNELs are derived in the registration dossier for penta-1,3-diene.

Based on the information available, exposure of workers and consumers to penta-1,3-diene cannot be excluded. Concern focuses on worker exposure during the handling of the monomer substance. Similarly, exposure to the impurity cannot be excluded. Lower exposure is expected once the substance is polymerized. Because the impurity is expected to polymerize as well, exposure is expected to be lower when handling the polymerized penta-1,3-diene matrix. As a consequence also consumer exposure is assumed to be low.

On the impurity itself, the NL-CA concluded that authorization and restriction were not appropriate RMOs in view of the uncertainties regarding the actual exposure of workers but that a uniform European Occupational Exposure Limit value should be established as a first step to investigate potential risks for workers.

Table: SVHC Roadmap 2020 criteria

	Yes	No
a) Art 57 criteria fulfilled?	X	
b) Registrations in accordance with Article 10?	X	
c) Registrations include uses within scope of authorisation?	X	
d) Known uses not already regulated by specific	X	

EU legislation that provides a pressure for substitution?		

Identification and assessment of risk management options

Compliance check

It is noticed that the registration dossier of penta-1,3-diene does not contain experimental animal or human data which would provide information for any of the specific human health endpoints. For example, for carcinogenicity, the registrant refers to an OECD assessment which states that the substance is "presently of low concern". For the endpoint mutagenicity, the registrant refers to secondary literature showing negative results in an Ames test. Also for reproductive toxicity, no experimental data are provided, Based on this, the registration dossier of penta-1,3-diene should, in relation to its tonnage band of 1000-10000 tpa, be subjected to a compliance check first.

Further, a worker and consumer DNEL is not derived by the registrant. This is also not in accordance with the criteria as described in REACH regulation EU 1907/2006.

The CCH-process is already initiated. Depending on the outcomes of the CCH-process, the possible need for further risk management measures for penta-1,3-diene should be revisited. The risk management options discussed below apply to current situation and available data focusing on penta-1,3-diene and its impurity.

Finally via CCH, when more data will become available, these should be reassessed together with the currently available data. This might result in additional conclusions on potential relevant risk management options to be performed.

Classification and labelling (CLP Regulation)

As a consequence of the impurity, penta-1,3-diene has to be self-classified by industry as Carc. 1B when the concentration of this impurity is above the generic concentration limit (GCL i.e. ≥0.1%). According to the C&L inventory (see also table in section 3.1.4), no self-classifications for Carc. 1B are notified.

This suggests a possible enforcement issue. It is concluded that National Enforcement Authorities and Industry using penta-1,3-diene should be aware that this substance may not correctly be self-classified and should check this on the Safety Data Sheet.

Authorization, restriction and/or placing on the SVHC-candidate lis:

In the absence of a clear risk for workers, the environment or society at large, Restriction is not a possible risk management option for penta-1,3-diene.

Penta-1,3-diene (with its impurity) does meet the criteria for SVHC. Consultation with the registrant indicates that the registrant has no intention of reducing the impurity in penta-1,3-diene to below the GCL. As a consequence, it is expected that the impurity will remain part of penta-1,3-diene if no further measures are taken. Authorization of Penta-1,3-diene is expected effective to warrant the safe use of this

substance in the EU as the applicant(s) should show exposure remains well below the DNEL (though, a compliance issue was observed as no DNELs were derived by the registrant). Nevertheless, it is questioned whether authorization is appropriate at present given that the current concern relates not to the exposure to penta-1,3-diene but to its impurity. The exposure to the impurity is expected to be much lower than the exposure to penta-1,3-diene. The main concern relates to workers involved in the handling of monomers. Both penta-1,3-diene and its impurity act as monomer substance and will react to polymers during processing. Monitoring data on worker exposure to the impurity as a substance suggest very low exposure when handling polymers and negligible exposure for workers in ware houses where the polymer was stored. As an impurity in penta-1,3-diene, the exposure is therefore expected to be even lower.

The appropriateness of Authorization of penta-1,3-diene to manage the concern for its impurity is therefore questioned.

Alternatively, the impurity could be proposed as SVHC with the addition that Authorization should also include this substance as an impurity.

Measures outside REACH: European harmonized OEL

Establishing a uniform European Occupational Exposure Limit value for the impurity can be considered to be a first step to address this problem. By doing this, some of the uncertainties as described in the bullets above can be resolved.

Establishing an OEL for penta-1,3-diene might also be considered. As indicated, concern focuses on worker exposure while handling the monomer substance. A harmonized OEL might be helpful to evaluate the potential risks for workers. However, given the current hazard profile of penta-1,3-diene, setting an OEL for this particular substance isn't concluded a first priority.