Risk Management Option Analysis Conclusion Document

Substance Name: Phenol, alkylation products (mainly in para position) with C12-rich branched or linear alkylchains from oligomerisation, covering any individual isomers and/ or combinations thereof. Exemplary the following substances are covered:

- **Phenol, (tetrapropenyl), derivatives (CAS No. 74499-35-7)**
- **Phenol, dodecyl-, branched (CAS No. 121158-58-5)**
- **Phenol, 4-dodecyl, branched (CAS No. 210555-94-5)**
- **Dodecylphenol, mixed isomers (CAS No. 27193-86-8)**
- **Phenol, tetrapropylene (4-(2,4-dimethyl-3-propylheptyl)phenol, CAS No. 57427-55-1)**
- **Phenol, 4-isododecyl; 4-isododecylphenol (CAS No. 27459-10-5)**
- **p-Dodecylphenol, (CAS No. 104-43-8)**

EC Number: -

CAS Number: -

Authority: Germany

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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

RMOA	☐ Risk Management Option Analysis (RMOA) other than this RMOA	
REACH Processes	Evaluation	☐ Compliance check, Final decision
		☐ Testing proposal
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restri -ction	☐ Annex XVII
Harmonised C&L	☒ Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	☐ Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	☐ Dangerous substances Directive Directive 67/548/EEC (NONS)	
	☐ Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment	
	☐ In relevant Annex	
Other processes/ EU legislation	☒ Other (provide further details below)	

A large portion of phenol, alkylation products (mainly in para position) with C12-rich branched or linear alkylchains from oligomerisation (PDDP) is used to manufacture e.g. calcium salts of alkyl phenol sulfides (phenates). The three following registered substances have been subjected to a Risk Management Option Analysis (RMOA) by the Swedish competent authority in 2018[2]:

[1] Phenol, dodecyl-, sulfurized, calcium salts, CAS No. 68855-45-8, EC No. 701-249-4.
[2] Phenol, dodecyl-, sulfurized, carbonates, calcium salts, CAS No. 68784-25-8, EC No. 701-208-0.
[3] Phenol, paraalkylation products with C10-15 branched olefins (C12 rich) derived from oligomerization, carbonate, calcium salts, overbased, sulfurized, including distillates (petroleum), hydrotreated, solvent-refined, solvent dewaxed, or catalytic dewaxed, light or heavy paraffinic C10-C50, EC No. 701-251-5 (no CAS No. available).

The substances still contain varying amounts of free PDDP. The conclusion document of the RMOA for the calcium phenate group is publically available under the hyperlink given above.

The evaluating MSCA of the above mentioned phenates considers it more appropriate and time-effective to await the outcome of the ongoing phenol, dodecyl-, branched (PDB) substance evaluation process before re-assessing the needs for SVHC identification of the phenates. The potential human health and environmental concerns should be included in an updated assessment of potential risk management measures.

A smaller amount of PDDP is applied in the production of aryl-based zinc dialkyldithiophosphates (ZDDP) substances as lubricant additives. The two following registered substances have been subjected to an interim RMOA by the Swedish competent authority in 2019. The RMOAs are currently still under development[3,4]:

[1] Zinc bis[bis(dodecylphenyl)] bis(dithiophosphate), CAS No. 54261-67-5.
[2] Zinc bis[bis(tetrapropylenephenyl)] bis(hydrogen dithiophosphate), CAS No. 11059-65-7.

PDDP is a common constituent (impurity) in both aryl-based substances.

Considering the ongoing processes on PDB (phenol, dodecyl-, branched, CAS 121158-58-5), the SE-MSCA proposes the aryl-based ZDDPs for SVHC identification, but only after the constituent PDB or PDDP, respectively, is identified as an SVHC on the basis of its reprotoxic and endocrine disrupting properties.

The following table gives an overview of the ongoing or finished processes of aryl-based ZDDP and calcium phenates:

[2] https://echa.europa.eu/documents/10162/1b972670-390d-7acb-e98a-4d0b732ea08a (accessed 02 October 2019)
[3] https://echa.europa.eu/de/rmoa/-/dislist/details/0b0236e18131db29 (CAS No. 54261-67-5, accessed 02 October 2019)
[4] https://echa.europa.eu/de/rmoa/-/dislist/details/0b0236e183aceaec (CAS No. 11059-65-7, accessed 02 October 2019)

Formal /informal processes on aryl-based ZDDP and phenates.

	EC number	Ongoing or finished process (formal or informal)
Aryl-based ZDDP	259-048-8	- RMOA (current) - Testing proposal (terminated)
	234-277-6	- RMOA (current) - Testing proposal
Phenate category	701-249-4*	- RMOA - Reg to update CSR according to 272-234-3 (ongoing)
	701-208-0*	- RMOA - Reg to update CSR according to 272-234-3 (ongoing)
	701-251-5*	- RMOA - SEv (conclusion March 2019)

* main identifier change, old EC No. 272-486-4 /272-233-8 /272-234-3

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
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

With regard to human health, several *in vitro* as well as *in vivo* assays and studies corresponding to levels 2 – 5 of the OECD conceptual framework for testing and assessment of endocrine disruptors (OECD, 2018) are available for PDDP. PDB (phenol, dodecyl-, branched, CAS 121158-58-5) – a specific representative of the UVCB substances in the PDDP group - is classified as Repr. 1B (H360F) as included in the 9th ATP of the CLP Regulation (entry 604-092-00-9). According to the corresponding RAC opinion (Committee for Risk Assessment, Opinion proposing harmonised classification and labelling at EU level of Phenol, dodecyl-, branched [1]; Phenol, 2-dodecyl-, branched; Phenol, 3-dodecyl-, branched; Phenol, 4-dodecyl-, branched; Phenol, (tetrapropenyl) derivatives [2], EC number: 310-154-3 [1], CAS numbers: 121158-58-5 [1], 74499-35-7 [2], Adopted 05 December 2013), this classification implies adverse effects on fertility and sexual function, which cannot be explained by unspecific side-effects of general toxicity. Furthermore, RAC concluded that the available mechanistic information suggests that the observed effects are mediated via weak estrogenic and androgenic activity.

Based on the studies mentioned above it is concluded that PDDP fulfils the WHO/IPCS definition (WHO/IPCS, 2002), referred to also in (OECD, 2018), of an endocrine disruptor for human health.

Furthermore, the observed adverse effects in rats are concluded to be population relevant. Thus, PDDP has to be considered as an endocrine disruptor for the environment. This interpretation was supported by ECHAs Endocrine Disruptors Expert Group and lead the eMSCA to the substance evaluation conclusion that no further environmental testing is necessary to clarify the ED concern for the environment.

The main end uses of PDDP are the preparation of a variety of lubricant additive materials as well as of fuel system cleaners. These additives may contain a significant amount of unreacted PDDP as an impurity. They are used in petrol and diesel-powered road vehicles and marine diesel engines. Thus, a wide dispersive use can be assumed. Lubricant additives are also used as anti-wear and anti-rust substances. The residual concentrations of PDDP in finished gasoline are approx. 390 ppm and in finished diesel engine oil approx. 1520 ppm (in (OECD, 2006) CAS No. 74499-35-7, 57427-55-1, 121158-58-5, 210555-94-5 and 27193-86-8 are covered by the assessment). Up to 95% of the residual PDDP are oxidized. Hence, 5% or more PDDP are not oxidised and presumably released to the environment as an aerosol or as a fluid condensation product. Furthermore, phenol, alkylation products are used as demulsifying agents in oil field applications.

Emissions to the environment of PDDP can occur from industrial manufacture and

formulation of lubricant and fuel additives, blending into finished oils as well as from the use and disposal of used lubricants. A provisional UK environment risk assessment (Brooke, 2007) of para-C12-alkylphenols (dodecylphenol and tetrapropenylphenol) identifies potential environmental risks from production, use as an intermediate and most end-uses of the derivatives and resins (all of which contain some para-C12-alkylphenols as impurities). In the analysis of the phenates, the UK Environment Agency did not see degradation of the phenates as a possible source of PDDP in the environment. The calculated environmental concentrations were however mostly based on (conservative) estimations and it is stated that the risk assessment could be further improved with additional toxicity testing.

The OECD assessment report estimates the annual release of PDDP into the environment in Europe from lubricants containing PDDP additive components at nearly 900 tonnes. Almost all emissions can be allocated to the use and disposal phase (OECD, 2006).

Summing up, for PDDP it is concluded that, beside its reprotoxic effects, the substance fulfils the WHO/IPCS definition of an endocrine disruptor for human health and the environment. Additionally, the available data suggest that PDDP is released to the environment during the use of products and articles containing either residual amounts of the substance (e.g. lubricant additives) or the substance as main compound (demulsifier in oil field applications). Hence, there is a concern for adverse and irreversible effects in the environment that needs to be addressed by regulatory action at EU level.

3.1 Harmonised classification and labelling

PDB as a REACH-registered representative of PDDP is already harmonised classified as reproductive toxicant Cat. 1B., Aquatic acute 1 and Aquatic chronic 1 as well as a sensitizing compound. As there is no possibility to classify a substance as an endocrine disruptor according to CLP, further and refined risk management addressing these endocrine related concerns via (harmonized) classification and labelling is thus not applicable.

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

Identification of PDDP as substance of very high concern (SVHC) based on its endocrine disrupting properties for human health and the environment is considered to be the appropriate first step to efficiently reduce the release of PDDP into the environment. Identification of PDDP as SVHC would create the following regulatory benefits:

- To come to an EU-wide agreement on the endocrine disrupting properties for human health and the environment as well as the SVHC status of PDDP.
- To identify further, still unknown, articles, products and uses via REACH Art. 33 information requirements. This would reduce the uncertainty on relevant uses, especially for products and articles with residual amounts of free PDDP.
- To provide a strong signal to and to put pressure on industry to substitute PDDP in products and articles. Hence, this might already be an effective measure to reduce environmental release of PDDP.

- To address environmental and human health socio-economic aspects in possibly following risk management measures like restriction and /or authorization. Regulation of PDDP solely based on SVHC identification and the harmonized classification of PDB based on its reprotoxic properties is considered to be

underprotective, especially regarding environmental aspects.

Taking into consideration the registered uses where PDDP mainly acts as an intermediate, inclusion of the substance on Annex XIV of REACH subsequent to SVHC identification is not considered to be the most appropriate measure to effectively reduce the environmental release of PDDP. Even though it would be possible to identify all articles and products containing more than 0.1% of PDDP as SVHC substances and regulate these uses via uptake into Annex XIV subsequent to SVHC identification of PDDP, this approach seems to be inefficient and cannot easily be targeted on the environmentally most relevant uses.

Hence, a targeted restriction of environmentally relevant uses and products containing residual amounts of PDDP, like those described in the above cited RMOAs of the SE CA, seems to be a more appropriate approach following SVHC identification to reduce the environmental emissions. The information gained from candidate listing of PDDP might further be beneficial to shape and refine the scope of a restriction proposal.

3.3 Restriction under REACH

As described above, based on the current knowledge, a targeted restriction addressing the environmentally relevant uses and products containing residual amounts of PDDP is considered to be the most appropriate risk management option following SVHC identification. This measure is able to address all products and articles containing residual amounts of free PDDP as well as imported articles and products.

SVHC identification of PDDP based on its endocrine disrupting properties, as described above, prior to a restriction proposal is considered to be the most effective strategy since candidate listing of PDDP will provide further information useful for shaping the scope of a restriction addressing the environment. SVHC identification solely based on the reprotoxic effects of PDB would be too short-reaching since endocrine-related environmental and human health socio-economic aspects would be excluded during preparation and evaluation of a restriction dossier.

3.4 Other Union-wide regulatory measures

Based on the registered uses and the information gathered so far, measures outside the REACH regulation (e.g. under the biocidal and plant protection regulation) are considered to be not applicable or appropriate to reduce the environmental release of PDDP.

4. NEED FOR ACTION OTHER THAN EU REGULATORY ACTION

Not relevant.

5. NO ACTION NEEDED AT THIS TIME

Not relevant.

6. 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	Actor
Annex XV dossier for SVHC identification	12/2020	DE MSCA
Annex XV dossier for restriction	tbd depending on outcome of SVHC identification process	tbd