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CONSULTATION ON DELEGATED ACT

# VCI Position on "Hazardous chemicals – updated rules on classification, labelling and packaging - New hazard classes"

**Summary of key points - Additional information and detailed assessments of the EU Commission's drafts in the following document**

## General comments

- **No need for new CLP hazard classes**: The introduction of new hazard classes is not necessary. A high level of health and environmental protection and improvement of environmental quality are already provided by existing legislation. Nevertheless, we take the opportunity to comment on the new hazard classes in detail, as it seems to be the political will to introduce them regardless of well-founded concerns.

- **Risk management is task of REACH not CLP**: The introduction of new hazard classes intended as selection criteria when extending the generic approach under REACH would result in an unnecessary overlapping of REACH and CLP.

- **Amendments in CLP Regulation concern several regulations**: The legal consequences of the proposed amendments for downstream or other chemical regulations need to be considered.

- **Wording of the criteria/CLP guidelines:** The wording of the criteria and the assessment is vague. The criteria should be specified in the legal text. Further information can be given in CLP guidelines.

- **Transition periods/Guidelines:** Guidelines should be available before the entry into force of the CLP revision, and the transition periods for substances and mixtures in the draft should not start until the updated guidelines are available.

## Measures taken by the EU Commission at UN GHS

- **No compliance with UN GHS on the horizon**: ED, PBT/vPvB and PMT/vPvM are combinations of different effects/multiple endpoints and not separate defined endpoint. The UN GHS (and CLP) does not provide for such an approach.
- **Unilateral changes are not practical**: Any unilateral changes by introducing new hazard classes and categories into the CLP Regulation by the European Union must be avoided. It is of utmost interest for industry to maintain the harmonisation achieved.

## Comments on the proposed criteria for endocrine disruptors

- **Existing hazard classes already address adverse effects:** Adverse effects resulting from endocrine disruptors are already covered by existing CLP hazard classes and result in appropriate risk management measures.
- **IPCS/WHO definition:** We favour that the hazard categories for endocrine disruptors for human health and for the environment are based on the IPCS/WHO definition of 2002.
- **Classification of a mixture:** VCI welcomes the introduction of generic concentration limits triggering classification of a mixture, that are comparable to other existing hazard classes (such as CMRs).

## Comments on the proposed criteria for PBT/vPvB and PMT/vPvM

### General comments - PBT/vPvB and PMT/vPvM

- **Alignment with existing definitions in REACH:** It is to be welcomed that the definition of the P, B and T criteria is mainly based on the already existing definitions in REACH.
- **Impurities of a substance:** For substances, that are not readily or inherently biodegradable a lot of further testing is expected.
- **Hazard communication:** The fact that no pictograms will be used for labelling for PBT/vPvB and PMT/vPvM is welcomed. The wording of the proposed EUH phrases appears inconsistent and not aligned.
- **Extension of the toxicity:** Toxicity assessment should keep consistency with the current REACH criteria. For the presented draft wording we suggest that data from tests on terrestrial and sediment organisms should only be relevant and used if they are already available.

### PMT/vPvM Criteria

- **Log Koc:** The Log Koc as the only criterion for the evaluation of the mobility properties of a substance leads to methodological difficulties. The Koc value does not consider the complex sorption behaviour or the loading or application rate of the chemicals.
- **Ionic and ionisable substances:** For those compounds highly variable adsorption/desorption properties towards soil are observable and the results will therefore be inaccurate.
- **All available information should be considered:** Due to the repeatedly mentioned methodological weaknesses of the individual criterion all available information should be considered (Weight of evidence approach).

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# VCI Position on "Hazardous chemicals – updated rules on classification, labelling and packaging - New hazard classes"

## Background

On 20 September 2022, the European Commission published its proposal[1] for new hazard classes under the Classification, Labelling and Packaging (CLP) Regulation. These new hazard classes are part of the CLP revision and the Chemicals Strategy for Sustainability[2].

The CLP Regulation regulates the classification, labelling and packaging of chemicals and implements the internationally valid Globally Harmonised System (GHS) of the United Nations (UN) in the European Union (EU). The GHS system serves as an internationally consistent basis for classification, labelling and packaging. The primary objective of the CLP Regulation is to inform actors in the supply chain about potential adverse effects of substances and mixtures by classifying them and labelling them appropriately based on this classification.[3]

The Commission intends to implement new hazard classes in the form of a delegated act in the Annexes of the CLP Regulation. According to the Article 53 of the CLP Regulation, this procedure is foreseen for adaptations on technical and scientific progress. The extent to which this is permissible for the hazard classes described here will not be part of the further commentary. Nevertheless, we would like to point out that some Member States have been criticising these proposals through the expert group "Competent Authorities for REACH and CLP" (CARACAL)[4].

In addition to general comments on the new hazard classes under CLP and the introduction of new hazard classes under UN GHS, the VCI will provide concrete detailed assessments of the individual hazard classes in the following.

[1] Have your say, Public consultation – "Hazardous chemicals – updated rules on classification, labelling and packaging" https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13578-Introducing-new-hazard-classes-CLP-revision_en

[2] EU Commission, "Chemicals Strategy for Sustainability - Towards a Toxic-Free Environment", October 2020, https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=COM:2020:667:FIN

[3] CLP-Regulation, https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32008R1272&from=DE

Article 1 (1): The purpose of this Regulation is to ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures and articles [...].

[4] Competent Authorities for REACH and CLP, Follow-up Documents 45th Meeting, https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/50c7fa5c-c542-440e-bdbe-23c58ca6ba41?p=1&n=-1&sort=modified_DESC

## General comments

It is the declared aim of the EU Commission to use the proposed new hazard classes to identify substances that are subject to the so called “generic approach to risk management” which is so far exclusively applied for Carcinogenic, Mutagenic and Reprotoxic (CMR) substances. The “generic approach to risk management” is essentially a hazard-based approach and means the blanket restriction of substances based on their classification without substance-specific risk assessment. Risk management, however, generally is neither in scope of the GHS nor of the CLP regulation. Hazard classification should generally not be used for risk management decisions without additional risk assessment (i.e. no automatism):

- **Risk management is task of REACH not CLP**: The introduction of new hazard classes is proposed to support the identification of substances fulfilling such criteria and that are intended to become subject to the extension of the generic approach to risk management. The aim is to ban the use of substances classified according to these new hazards for the use in consumer products under REACH. This would turn away CLP classes definition from intrinsic hazard properties to random selection criteria to prepare the way for risk management. However, task of UN GHS and the CLP regulation is solely hazard identification - not the definition of other selection or prioritization criteria for risk management. The latter is a core task of REACH insofar as such prioritization is necessary for proper risk management.

Furthermore, the introduction of new hazard classes will not provide additional benefits for achieving the protection goals of the European chemicals policy as the objectives are already covered by existing chemicals legislation:

- **No need for new CLP hazard classes**: We would like to emphasise that the introduction of new hazard classes for endocrine disruptors (ED); persistent, bioaccumulative and toxic (PBT)/very persistent and very bioaccumulative (vPvB) or persistent, mobile and toxic (PMT) and very persistent/very mobile (vPvM) substances is not necessary, since a high level of health and environmental protection and the improvement of environmental quality are already sufficiently provided by existing legislation.

Nevertheless, we take the opportunity to comment, because it seems to be the political will to introduce these hazard classes. We therefore ask the EU Commission to consider the following general aspects in further discussions with the expert groups:

- **Transition periods (substances/mixtures):** Nevertheless, VCI welcomes that different transition periods are foreseen for substances and mixtures which are already on the market when the new regime shall apply and substances and mixtures which will be placed on the market afterwards.

- **Amendments in CLP Regulation concern several regulations**: Consideration of the legal consequences of the proposed amendments for downstream or other chemical regulations (e.g. Plant Protection Products and Biocidal Products Regulations), which are associated with high burden, bureaucracy and costs.

- **Solid test-methods are needed**: As long as no adequate and scientifically sound test-methods are available, the establishment of additional hazard classes within the CLP Regulation would lead to a considerable loss of reputation of this highly recognised regulation. For example, test-methods, such as for polymers, should be developed through the Organisation for Economic Co-operation and Development (OECD) before new CLP hazard classes are made mandatory.
- **Definition of Hazard**: The new hazard classes and criteria do not meet the OECD definition of "hazard"[5], i.e. should be defined exclusively for relevant intrinsic hazardous substance properties.
- **NAMs/Animal testing:** The introduction of new hazard classes would promote a further increase in animal testing for years, although the EU has positioned itself towards a reduction of animal testing and wants to establish alternative methods (NAMs) on a broader basis. At this stage, these are not sufficiently developed, e.g. for identification of endocrine disrupting properties or mode of actions, further test guidelines (including in vitro test methods) need to be available and established internationally at OECD level, which needs more time and funding.
- **Laboratory capacity:** As another direct consequence laboratory capacity is still lacking. In addition, regulatory acceptance by national and EU authorities e.g. European Chemicals Agency (ECHA) needs to be significantly improved, as we currently see some barriers here. Only when these have been cleared can animal-free methods offer a real alternative to current and future animal testing.
- **Wording of the criteria:** The wording of the criteria and the assessment is vague and not scientific based (terms such as "suspected") and therefore, don't reflect appropriate reflection of the current knowledge: This leaves room for interpretation and may lead to unclear results. The chemical industry needs legal certainty and a clear legal frame to operate compliant within chemical legislation. The criteria and all additional data that may be used for classification should be specified in the legal text in as much detail as possible so that misinterpretation and legal problems and ambiguities are prevented. This however does not mean, that other information and data available whose suitability and reliability can be reasonably demonstrated, should not be considered or excluded.
- **CLP guidelines:** Further information, helpful explanations and practical examples, which are not legally binding, should then be given in the CLP guidelines. Regarding these guidelines, all stakeholders, including the chemical industry, should be involved in the adaptation of these texts to the new hazard classes to make these as feasible and explanatory as possible. In particular, further details should be taken into account:

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[5] OECD (2020), OECD Guidelines for the Testing of Chemicals - Test No. 491, June 2020, https://doi.org/10.1787/9789264242432-en

Hazard definition: Inherent property of an agent or situation having the potential to cause adverse effects when an organism, system or (sub)population is exposed to that agent.

- Due to the short time frame of the entry into force, additional useful information should be integrated into the guidelines.
- The final and revised guidelines should be available before the entry into force of the CLP revision, in order to provide guidance to users on the far-reaching adaptations, which is particularly crucial for SMEs.
- In addition, the provided transition periods for substances and mixtures in the draft should not start until the updated guidelines are available.

## Measures taken by the EU Commission at UN GHS

The EU Commission aims at "having a leading role and promoting the implementation of existing international instruments" and to "promote, together with industry, the implementation of the Globally Harmonised System of Classification and Labelling of Chemicals (UN GHS) as the means for identifying chemical hazards".[6] In this context, any unilateral introduction of e.g. new hazard classes without consulting the UN GHS is contradictory. It is of utmost interest for industry to maintain the harmonisation achieved and not to disregard the work of the UN GHS Expert Committee by unilaterally introducing new hazard classes without consulting the UN.

- **Unilateral changes not practical**: It is of utmost interest to industry to maintain the achieved harmonisation. Any unilateral changes by introducing new hazard classes and categories into the CLP regulation by the European Union, must be avoided.

We noticed that the European Commission has presented a draft timetable for discussion at UN GHS level on new hazard classes. Therefore, we urge the European Commission to comply with the GHS and CLP boundaries.

- **Risk management not purpose of UN GHS**: Risk management generally is not in scope of the GHS, and GHS hazard classification should generally not be used for risk management decisions without additional risk assessment (i.e. no automatism). In conclusion, the idea of introducing new hazard classes into the GHS to identify chemicals to be subsequently restricted or banned for certain uses without any risk assessment, is in clear contradiction to the internationally agreed principles of the GHS and therefore cannot be supported.
- **No compliance with UN GHS on the horizon**: ED, PBT/vPvB and PMT/vPvM are combinations of different effects/multiple endpoints. The UN GHS does not provide for such an approach. The scope of the UN GHS is hazard classification and communication. The scope of the UN GHS explicitly excludes any risk management decisions "which generally require some risk assessment in addition to hazard classification". As a conclusion, UN GHS hazard classification is generally not considered to be the sole sufficient basis, i.e. without further risk assessment, to result in risk management decisions, e.g. restrictions or bans of substances.

However, any unilateral implementation of new hazard classes without consultation of the UN GHS beforehand is contradictory in this regard. The stated assumption that the UN GHS may just follow the EU CLP and implement identical criteria is unrealistic and disregards the work of the UN GHS Committee of Experts.

[6] EU Commission, "Chemicals Strategy for Sustainability - Towards a Toxic-Free Environment", October 2020, https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=COM:2020:667:FIN

## Detailed commentary on the proposed criteria for endocrine disruptors

The primary objective of the CLP Regulation is to inform actors in the supply chain about potential adverse effects of substances and mixtures. For data collection, identification, evaluation, and regulation of substances of very high concern (SVHC), e. g. endocrine disruptors, the REACH Regulation provides the right framework. Nevertheless, the European Commission decided to establish a legally binding hazard identification of endocrine disrupters in the CLP regulation and to implement new hazard classes for human health and the environment, although this approach is not appropriate under the CLP Regulation:

- **Mode of actions are not toxicologically defined endpoints:** Endocrine disruption is not a separate toxicologically defined endpoint. Limit values and therefore safe concentration levels for endocrine disruptors can be clearly defined in both toxicological and ecotoxicological studies, so that the usual tools for risk assessment can be applied.
- **Existing hazard classes already address adverse effects:** Adverse effects triggered by endocrine disruptors, such as carcinogenic, reproductive toxic effects or target organ toxicity are already covered by existing CLP hazard classes and result in appropriate risk management measures. For this reason, a separate hazard class for endocrine disruptors is not justified and does not serve the purpose.

The consequences of the introduction of a new CLP hazard scale for endocrine disruptors also lead to multiple hurdles, e.g. in regulation or in practice:

- **Double regulation should be avoided**: The introduction of new hazard classes for endocrine disruptors may result in double classification, which would lead to confusion. Overall, the VCI still considers that for chemicals REACH offers the right and appropriate framework to identify and assess endocrine disruptors as is being done today via Article 57(f).
- **Unnecessary animal testing will increase:** Based on the definition the classification in both categories of endocrine disruptors (“adverse effect”) shall be largely based on evidence from human or animal data. Thus, the performance of animal tests is mandatory. In order to ensure sufficient and appropriate information for identification of endocrine disruptors, the Commission proposes to update the standard information requirements in REACH. Any indication of a possible endocrine Mode of Action (MoA) from in silico calculations or in vitro tests might ultimately result in in vivo tests that consumes hundreds of thousands of additional vertebrates without providing any further value for health or environment.

## Comments on the draft Commission Delegated Regulation and the proposed draft Annex

### Comments on Commission Delegated Regulation

*“(6) […] It has been proven that endocrine disruption can lead to certain disorders in humans, among others birth defects, developmental, reproductive or neurodevelopmental*

*disorders, cancer, diabetes and obesity, and that those disorders have a high and increasing incidence in both children and adults."*[7]

VCI does not agree with this statement in its absoluteness ("it has been proven…"). The causal connection between endocrine disruption and e.g. human obesity or diabetes is at the focus of current public debate but has not been proven as stated by German Federal Institute for Risk Assessment (BfR) or European Food Safety Authority (EFSA)[8]. Exposure must be taken into account.

## Comments on Annex

- **IPCS/WHO definition:** On the positive side, we see that the hazard categories for endocrine disruptors for human health and for the environment are based on the International Programme on Chemical Safety (IPCS)/ World Health Organization (WHO) definition of 2002 and build on criteria already developed for plant protection products and biocidal products. This is important to ensure consistency across Union legislation.

  VCI supports the inclusion of the three elements of the IPCS/WHO definition in the text in both hazard classes for endocrine disruptors. VCI agrees that all three criteria must be fulfilled (the existence of an adverse effect in an intact organism, an endocrine mode of action, and the former being a consequence of the latter).

- **Unclarity in the text:** Some phrases in the text remain unclear, are difficult to interpret and should be defined more precisely, e. g. definition of category 2 ("the evidence […] is not sufficiently convincing").

- **Identification of endocrine disruptors based on existing principles:** Any criteria for endocrine disruptors should include potency as already implemented within the CLP framework e.g., for specific target organ toxicity (Category 1, oral, 90 day <10 mg/kg bw/day; Category 2, oral, 90 day 10-100 mg/kg bw/day). Whereas adversity is part of the hazard identification, aspects such as severity, (ir)reversibility and potency are part of the hazard characterisation. Any criteria for endocrine disruptors, should include those aspects: To decide whether a substance is an endocrine disruptor, consideration must be given to the potency of the substance, the severity of the adverse effects on an intact organism, the reversibility of an adverse effect, and the strength of the scientific data.

- **Classification of a mixture:** VCI welcomes the introduction of generic concentration limits triggering classification of a mixture (0.1% for category 1 and 1% for category 2), that are comparable to what exists in other hazard classes, such as CMRs.

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[7] Have your say, Public consultation – "Hazardous chemicals – updated rules on classification, labelling and packaging" https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13578-Introducing-new-hazard-classes-CLP-revision_en

[8] Bundesinstitut für Risikobewertung (BfR), Questions and answers on endocrine disruptors, March 2022, https://www.bfr.bund.de/en/frequently_asked_questions_on_endocrine_disruptors-50804.html

European Food Safety Authority (EFSA), Endocrine active substances (10.10.2022; 11:12), https://www.efsa.europa.eu/en/topics/topic/endocrine-active-substances

## Commentary on the proposed criteria for PBT/vPvB and PMT/vPvM

The REACH Regulation and other legislation for chemical substances provide very sophisticated protection and define the highest standards worldwide; on the other hand, many substances that could fall under the proposed hazard classes are already (heavily) regulated.

- **Alignment with existing definitions in REACH:** Therefore, it is to be welcomed that the alignment of the criteria for persistent, bioaccumulative and toxic (PBT) and the alignment of the persistent (P) and toxic (T) criteria as part of the PMT assessment for substances and mixtures is mainly based on the already existing definitions in REACH. This is an important point to ensure and further improve consistency across EU legislation.

Nevertheless, we would like to conclude that neither P, bioaccumulative (B) nor mobility (M) or combinations of these parameters are directly linked to any hazard, which should be a prerequisite for a hazard class in the CLP Regulation.

### General comments on the draft Commission Delegated Regulation for the proposed hazard criteria - PBT/vPvB and PMT/vPvM

- **Hazard communication - Pictogram:** The fact that no pictograms will be used for labelling for PBT/vPvB and PMT/vPvM, which would result in confusion on an international level, is welcomed.
- **Hazard communication - EUH phrases:** The wording of the proposed EUH phrases appears inconsistent and not aligned. Especially for PBT and vPvB substances it does not indicate the persistence property at all (EUH440 and 441), which for the PMT and vPvM substances on the other hand is stated explicitly. The mobility criterion however is not being called in the PMT and vPvM phrases EUH450 and 451.
- **Extension of the toxicity:** The draft extends the assessment of the T criterion by including data from tests on terrestrial and sediment organisms. We strongly favor maintaining consistency with the current criteria for the toxicity under REACH. With the draft wording presented, we suggest that these additional data should only be relevant and used if they are already available. The generation of new data, using tests on vertebrates such as birds, should not be an objective of the CLP Regulation for animal welfare reasons.
- **Impurities of a substance:** In the assessment we see some burden in the following statement:

  *“ […] The identification shall also take account of the PBT/vPvB properties of relevant constituents or impurities of a substance and relevant transformation and/or degradation products. […]”*

  For substances, that are not readily or inherently biodegradable a lot of further testing is expected, when all degradation and transformation products require testing for persistence in the simulation tests for each environmental compartment. This is connected to additional burden (e.g. chemical synthesis or isolation of the degradation products) and additional costs and might consume more time. In respect to the still inconsistently defined “More Than One Constituent Substance” (MOCS)-concept or if the substance is characterized as

"unknown or variable composition, complex reaction products or biological materials" (UVCB) and has PBT constituents or impurities >0.1 %, this will also lead to uncertainties in the assessment and further discussions. The same is true for the PMT and vPvM criteria.

## Detailed comments on the draft Commission Delegated Regulation for the proposed hazard criteria - PMT/vPvM

- **Log Koc:** In the application of the Log Koc as the only criterion for the evaluation of the mobility properties of a substance some methodological difficulties that have been raised in the past by ECETOC[9] and others in scientific publications. The limitation of the use of Koc should be recognised and reflected in any hazard criteria that could be used to justify risk management measures of chemicals. The single criterion of a threshold Koc value is too simplistic and does not consider the complex sorption behaviour certain chemicals can undergo in soils and sediments or the loading or application rate of the chemicals.

  Tonnages, emissions, exposure pattern and routes of exposure may be major additional factors at play, which are not yet addressed. These factors should be adequately considered in further risk assessment measures, e.g. under REACH, as we are aware of the fact that the CLP Regulation only refers to intrinsic hazards of substances and their classification and labelling.

- **False results:** Whilst the proposed persistency and mobility (PM) metrics may be adequate for preliminary screening of a large dataset of non-polar chemicals, the P and M criteria alone do not seem to be predictive of the hazard to the water cycle and drinking water and such screening criteria are expected to result in significant false positives and false negatives results. Furthermore, there is evidence that PM substances do not have a higher likelihood than non-PM substance to be detected in surface or groundwater, although the detection of these substances in water sources and the protection of drinking water from these substances was the basis of the definition and implementation of the criteria. There is a very limited number of published scientific articles[10] underlying the PM concept as it will be applied in the upcoming CLP revision. A robust proof of concept is lacking, especially regarding the high error of false-positives PM substances.

- **Ionic and ionisable substances:** For those compounds highly variable adsorption/desorption properties towards soil are observable and the results will therefore be inaccurate – an argument that has been flagged by industry before. Estimations show that 48 % of all under REACH registered substances are (partially) charged at environmentally relevant pH (4-9) and a recent screening for PM substances in surface water

[9] ECETOC, TR 139 - Persistent chemicals and water resources protection, May 2021, https://www.ecetoc.org/publication/tr-139-persistent-chemicals-and-water-resources-protection/

[10] Umwelt Bundesamt, PMT and vPvM substances under REACH (10.10.2022; 11:12), https://www.umweltbundesamt.de/en/PMT-substances

even expected 85 % of the compounds to be charged.[11] Considering the large number of these substances, we advocate robust solutions that go further than the single log Koc criterion and that adequately address the majority of substances.

- **Persistency test methods**: The persistency assessment should not only be based on simulation studies as these are very expensive and laboratory capacities are very limited. There is an urgent need for new or adapted test methods to be allowed for the derivation of degradability/ persistence.

### Weight of evidence approach – For M criteria

As a result of the given arguments, alternative approaches to the simplistic mobility criterion of log Koc, such as leaching indices, screening models and more sophisticated process-oriented leaching models with appropriate scenarios should be considered in the assessment. The legal draft text tries to address this concept by taking all available relevant scientific data together into account in a single weight of evidence determination. In the past communication of the EU Commission on the weight of evidence and its impact and the wording in the current draft there are some discrepancies.

- **Leaching studies vs. log Koc:** In case of the mobility assessment however we understand, that the log Koc still remains the only criterion to conclude whether substances should be considered mobile or not. Other information available, such as adsorption/desorption or data from leaching studies cannot overrule the log Koc in a combined consideration.
- **All available information should be considered:** Due to the repeatedly mentioned methodological weaknesses of the individual criterion, VCI explicitly advocates to consider all available information and data equally, positive as well as negative results, and to emphasize this in the legal text. This also allows to conclude non-mobility for substances, where the log Koc value is in the relevant range, but other scientific data show in an expert judgement, that the substance should not be considered as mobile, especially for ionisable substances and detergents.

[11] Sigmund *et al.*, Sorption and Mobility of Charged Organic Compounds: How to Confront and Overcome Limitations in Their Assessment, Environ. Sci. Technol. 2022, 56, https://doi.org/10.1021/acs.est.2c00570

Contact: Dr. Denis Pahlke
Referent, Dept. Science, Technical and Environmental Affairs
Product Stewardship
P +49 (69) 2556-1637| E pahlke@vci.de

**German Chemical Industry Association**
Mainzer Landstrasse 55
60329 Frankfurt, Germany

www.vci.de | www.ihre-chemie.de | www.chemiehoch3.de

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- The VCI is registered with registration no. R000476 in the Lobbying Register for the Representation of Special Interests vis-à-vis the German Bundestag and the Federal Government.

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