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The impact of information gaps in the supply chain on environmental exposure - case study of a PBT substance

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Dr Maren Krause, Dr Julian Stoesser, Tina Bodenschatz,
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Wörlitzer Platz 1
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Tel: +49 340-2103-0
Fax: +49 340-2103-2285
buergerservice@uba.de
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Abstract: The impact of information gaps in the supply chain on environmental exposure - case study of a PBT substance

The REACH Regulation (EC 1907/2006) ensures chemical safety by requiring rigorous risk assessments before market entry. Safety data sheets (SDS) are vital for communicating safe usage guidelines, yet deficiencies are common, with up to 52% of SDSs found to be inadequate. This project aimed to identify gaps in SDS data by surveying actors across the supply chain with a specific focus on effect related to the environment. The key question driving the project was how far information on emission reduction measures is transferred by the registrants into their SDS and what is communicated along the supply chain. Using octamethylcyclotetrasiloxane (D4) as a case study, a substance with persistent, bioaccumulative, and toxic properties, the study assessed communication effectiveness. Despite a limited response rate, challenges in communication were identified, highlighting the need for improved coordination and transparency. Recommendations targeting both industry and regulatory agencies seek to enhance supply chain communication and address data gaps more effectively.

Kurzbeschreibung: Die Auswirkungen von Informationslücken in der Lieferkette auf die Umweltexposition – Fallstudie einer PBT-Substanz

Die REACH-Verordnung (EG 1907/2006) gewährleistet die Sicherheit von Chemikalien durch die Anforderung konsequenter Risikobewertungen vor Markteintritt. Sicherheitsdatenblätter (SDS) sind entscheidend für die Kommunikation sicherer Verwendungsrichtlinien, jedoch sind Mängel häufig, wobei bis zu 52% der SDS als unzureichend gelten. Dieses Projekt zielte darauf ab, Lücken in den SDB-Daten zu ermitteln, indem die Akteure der gesamten Lieferkette befragt wurden, wobei der Schwerpunkt auf den Auswirkungen auf die Umwelt lag. Die Schlüsselfrage, die das Projekt antrieb, war, inwieweit Informationen über Emissionsminderungsmaßnahmen von den Registranten in ihre SDB übertragen werden und was entlang der Lieferkette kommuniziert wird. Anhand von Octamethylcyclotetrasiloxan (D4) als Fallstudie, einer Substanz mit persistenten, bioakkumulierenden und toxischen Eigenschaften, wurde die Wirksamkeit der Kommunikation untersucht. Trotz einer begrenzten Antwortquote wurden Herausforderungen in der Kommunikation identifiziert, die die Notwendigkeit einer verbesserten Koordination und Transparenz unterstreichen. Empfehlungen, die sowohl die Industrie als auch Regulierungsbehörden ansprechen, zielen darauf ab, die Kommunikation entlang der Lieferkette zu verbessern und Datenlücken effektiver anzugehen.

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List of abbreviations

Abbreviation	Explanation
BAUA	Federal Institute for Occupational Safety and Health
BG	“Berufsgenossenschaft” Employer's liability insurance association
BPR	Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products
CMR	Carcinogenic, mutagenic, toxic for reproduction
CSR	Chemical safety report
D4	Octamethlycyclotetrasiloxane (also known as D4) (CAS No. 556-67-2)
DU	Downstream user (downstream user)
ECHA	European Chemicals Agency
EEA	European Environment Agency
ENES	Exchange Network on Exposure Scenarios
eSDS	Extended safety data sheet
EU	European Union
IHO	Industrieverband Hygiene und Oberflächenschutz
IKW	Industrieverband Körperpflege- und Waschmittel
KIT	Karlsruhe Institute of Technology
LCID	Lead Component IDentification
OC	Operational conditions
OR	Only representative
PBT	Persistent, bioaccumulative, toxic
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency
REF	Reach-EN-Force
RMM	Risk management measures
SDS	Safety data sheet
SIINAS	Indonesian Industry Information System
SME	Small and medium-sized enterprises
SUMI	Safe Use of Mixtures Information
SVHC	Substance of very high concern
UBA	Umweltbundesamt
vPvB	Very persistent, very bioaccumulative

Abbreviation	Explanation
VCI	Verband der Chemischen Industrie
VDL	Verband der deutschen Lack- und Druckfarbenindustrie
VDMI	Verband der Mineralfarbenindustrie

Summary

The REACH Regulation (EC 1907/2006) aims to ensure a high level of protection for the environment by applying the principle of "No data, no market". Chemicals can only be manufactured or marketed if their risk assessment demonstrates their safety. The safety assessment aims to derive safe conditions of use for humans and the environment. The safety data sheet (SDS) serves as a communication tool for safe conditions of use providing safety measures and specifications. However, research projects have shown that up to 52% of SDSs have deficiencies. Downstream users are required to implement suitable risk management measures based on the SDS they receive. The SDS contains environmental information in sections 8, 12, and 15. If the data in the sections is incorrect, this can lead to inadequate risk management measures and thus increased concentrations of substances of high concern (SVHC) in the environment.

The aim of this project was to systematically survey actors throughout the supply chain, including manufacturers, importers and users, about their experiences with supply chain communication and with SDS, in particular to identify any root causes of potential data gaps. These insights should serve as the foundation for refining the guidelines that support users in their processes. A case study of an environmentally relevant substance on ECHA's candidate list for authorisation, which exhibits persistent, bioaccumulative and toxic (PBT) properties and is regulated in several sectors, aimed to evaluate handling of information along the supply chain. The PBT substance octamethylcyclotetrasiloxane (D4) was chosen as an example as it represents a high tonnage chemical with extensively branched supply chains and wide-ranging applications in various sectors . Further its PBT status qualifies it from an environmental assessment perspective as the example deals with the question of what information on emission reduction measures is transferred by the registrants into their SDS and what is communicated along the supply chain. A stakeholder survey was launched and over 300 industry representatives were contacted throughout the different supply chains who could potentially handle data regarding the safety of D4. Despite several attempts to increase the number of responses, only 9 actors responded, leaving the majority of enquiries unanswered. In this context, several associations pointed out that they could not provide feedback on individual substances.

Due to the limited response rate, the study did not reveal systematic issues concerning communication along the supply chain. However, various responses indicated the existence of challenges that must be addressed to establish a more inclusive and transparent communication framework among all stakeholders. Enhancing communication within the supply chain, for both industry and regulatory authorities, requires a concerted effort to improve coordination, transparency, and responsiveness. As such recommendations for possible actions were divided for industry and agency groups.

Zusammenfassung

Die REACH-Verordnung (EG 1907/2006) hat zum Ziel, ein hohes Schutzniveau für die Umwelt zu gewährleisten. Dazu wird der Grundsatz 'Keine Daten, kein Markt' angewendet. Chemikalien dürfen nur dann hergestellt oder vermarktet werden, wenn ihre Sicherheit durch eine Risikobewertung nachgewiesen wurde. Die Sicherheitsbewertung hat das Ziel, sichere Verwendungsbedingungen für Mensch und Umwelt abzuleiten. Das Sicherheitsdatenblatt (SDB) dient als Kommunikationsinstrument für sichere Verwendungsbedingungen, Sicherheitsmaßnahmen und Spezifikationen. Forschungsprojekte haben jedoch gezeigt, dass bis zu 52% der Sicherheitsdatenblätter Mängel aufweisen. Nachgeschaltete Anwender sind verpflichtet, auf der Grundlage des ihnen vorgelegten SDB geeignete Risikomanagementmaßnahmen zu ergreifen. Das Sicherheitsdatenblatt (SDB) enthält in den Abschnitten 8, 12 und 15 Umweltinformationen. Es ist wichtig, dass diese Informationen korrekt sind, da ansonsten unangemessene Risikomanagementmaßnahmen ergriffen werden könnten. Dadurch könnten erhöhte Konzentrationen von besonders besorgniserregenden Stoffen in der Umwelt entstehen. Das Ziel dieses Projekts war es, die Akteure der gesamten Lieferkette systematisch zu ihren Erfahrungen mit der Kommunikation und den Sicherheitsdatenblättern (SDB) zu befragen. Hierbei wurden Hersteller, Importeure und Anwender einbezogen, um insbesondere die Ursachen für mögliche Datenlücken zu ermitteln. Die gewonnenen Erkenntnisse sollten als Grundlage für die Verfeinerung der Leitlinien dienen, die die Anwender bei ihren Prozessen unterstützen. Eine Fallstudie zu einem umweltrelevanten Stoff auf der Kandidatenliste der ECHA, der persistente, bioakkumulierbare und toxische (PBT) Eigenschaften aufweist und in mehreren Sektoren reguliert ist, sollte den Umgang mit Informationen entlang der Lieferkette bewerten. Der PBT-Stoff Octamethylcyclotetrasiloxan (D4) wurde als Beispiel ausgewählt, da es sich um eine Chemikalie mit großen Mengen, weit verzweigten Lieferketten und weitreichenden Anwendungen in verschiedenen Sektoren handelt. Darüber hinaus ist er aufgrund seines PBT-Status aus Sicht der Umweltverträglichkeitsprüfung besonders geeignet, da sich das Beispiel mit der Frage befasst, welche Informationen über Emissionsminderungsmaßnahmen von den Registranten in ihre SDB aufgenommen und welche Informationen entlang der Lieferkette weitergegeben werden. Es wurde eine Umfrage unter Interessenvertretern durchgeführt. Über 300 Vertreter der Industrie in verschiedenen Lieferketten, die potenziell mit Daten über die Sicherheit von D4 umgehen können, wurden kontaktiert. Trotz mehrerer Versuche, die Zahl der Antworten zu erhöhen, antworteten nur 9 Akteure. Die Mehrzahl der Anfragen blieb unbeantwortet. In diesem Zusammenhang wiesen mehrere Verbände darauf hin, dass sie keine Rückmeldung zu einzelnen Stoffen geben können.

Aufgrund der begrenzten Rücklaufquote konnte die Studie keine systematischen Probleme bei der Kommunikation entlang der Lieferkette aufdecken. Allerdings deuten verschiedene Antworten darauf hin, dass es Herausforderungen gibt, die angegangen werden müssen, um einen integrativeren und transparenteren Kommunikationsrahmen für alle Beteiligten zu schaffen. Eine verbesserte Kommunikation innerhalb der Lieferkette erfordert eine konzertierte Aktion zur Verbesserung der Koordination, Transparenz und Reaktionsfähigkeit. Es wurden Empfehlungen für mögliche Maßnahmen nach Industrie erstellt, um dieses Ziel zu erreichen.

1 Background and objectives

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemical commonly referred to as REACH aims to ensure environmental protection by implementing the principle of "no data, no market". This means that chemicals may only be manufactured, formulated, applied or sold if their risk assessment confirms their safety during the lifecycle. Guidelines for the safety assessment of substances are described in Annex I of REACH and standardised registration requirements are available in Annexes VII to X.

The main aim of these assessments is to determine safe conditions of use for humans and the environment. The safety data sheet (SDS) is the main tool for providing measures and specifications to ensure safe use of chemicals and mixtures with detailed requirements in Annex II of REACH. Sections 8, 12 and 15 of the SDS contain important environmental information. Obligations for downstream user arise from Annex XII of REACH.

After receiving an SDS, actors in the supply chain (downstream users) are obliged to identify and implement suitable measures for effective risk management. It is advisable that both suppliers and recipients of SDSs check the availability of the required information. To facilitate this, the European Chemicals Agency (ECHA) and the Forum for Exchange of Information on Enforcement (Forum)[1] have developed a checklist[2]. Downstream users are also encouraged to report any inaccuracies or inconsistencies they find in the SDSs they receive and in case the measures mentioned in the extended safety data sheet (eSDS) do not fit their application, they have to derive their own measures. Although SDSs are not mandatory, suppliers must provide adequate information to enable safe use. Downstream users should receive an SDS if: (i) a substance or mixture is classified as hazardous according to the CLP Regulation, (ii) a substance is persistent, bioaccumulative, and toxic (PBT) or very persistent and very bioaccumulative (vPvB) or (iii) a substance is listed in the candidate list of substances of very high concern (SVHC). However, if a substance or mixture is also sold to the general public, there is no requirement to provide an SDS unless requested by a downstream user or distributor. In cases where a substance is subject to restrictions or authorisations under REACH, all essential details should be provided. For articles containing more than 0.1 mass per cent (w/w) of a SVHC substance from the candidate list, suppliers must provide sufficient information to downstream users and distributors to ensure safe use of the article according to REACH regulation article 33. The detailed "candidate list of substances of very high concern for authorisation" (candidate list) is available on the ECHA website[3] and comprises all substances for which inclusion in Annex XIV of REACH is envisaged. In order to be included in the candidate list, substances must undergo a formal procedure in which it is determined whether they fulfil the criteria for substances of very high concern such as:

- Substances meeting the criteria to be classified as carcinogenic, mutagenic, or toxic for reproduction (CMR) category 1A or 1B according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP)

[1] The Forum for Exchange of Information on Enforcement (Forum) is a network of authorities responsible for the enforcement of the REACH, CLP, and PIC, POP and Biocidal Product regulations in the EU, Norway, Iceland and Liechtenstein.
[2] See downloads on Helpdesk - Sicherheitsdatenblatt - Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (reach-clp-biozid-helpdesk.de) (accessed 2.5.2024)
[3] candidate list of substances of very high concern https://echa.europa.eu/candidate-list-table (accessed 2.5.2024)

- The substance being PBT or vPvB according to REACH Annex XIII
- The substance on a case by case basis, causing an equal level of concern as CMR or PBT/vPvB substances

Research projects have shown that for registered uses, the available substance evaluation data is often overlooked and up to 52% of SDSs have deficiencies (European Chemicals Agency, 2013). The REACH -EN-Force-11 (REF-11) project is currently assessing compliance with the revised Annex II requirements, which came into force in 2023. Users of chemicals often encounter data gaps, incorrect information, or insufficient measures. To remedy this, it is essential to support stakeholders in minimising substance exposure and promoting environmentally sound use.

This report focusses primarily on environmental protection and examines substance-specific data and recommendations, particularly in sections 6, 8, 12 and 15 of the SDS. The data should enable those actors as defined in the REACH Regulation involved in the supply chain to recognise and define safe conditions of use. The project aims to analyse error patterns and systematically identify causes. A case study using the substance octamethlycyclotetrasiloxane (D4) (CAS No. 556-67-2) is intended to shed light on the current approach using an environmentally relevant substance from the ECHA candidate list with PBT properties and various legal restrictions on use. D4 has been chosen as it represents a high tonnage chemical with extensively branched supply chains and wide-ranging applications in various sectors. As such, all actors under REACH handling the substance, whether as a substance, in a mixture, or in articles were thus potential respondents for this project. Furthermore, its chemical properties and in particular the identified environmental hazards trigger a minimization obligation when the substance is listed as a PBT substance on the candidate list.

2 Supply chain communication using the example of D4

This study on supply chain communication was carried out using the substance octamethlycyclotetrasiloxane (CAS No. 556-67-2) (D4) as an example. Specific properties of D4 are not in the focus. The information obligations arising from the environmental relevance due to the high tonnage and wide dispersive use and the PBT status of D4 are relevant for the information collection in the present project. The project is specifically focused on the objective of environmental protection, with particular emphasis on the assessment of environmental exposure.

2.1 Regulatory status of substance D4 under REACH

Octamethylcyclotetrasiloxane (D4, CAS 556-67-2) was identified as a substance of very high concern (SVHC) by the EU Member State Committee on 13 June 2018 and subsequently added to the candidate list for SVHC on 20 June 2018. Substances are only included in this list due to their very serious effects on human health and the environment. In the case of octamethylcyclotetrasiloxane, the reason for inclusion in the candidate list was that it fulfils the criteria as a PBT and very persistent and very bioaccumulative (vPvB) substance according to Annex XIII of REACH (Articles 57d and 57e).

If a substance is on the candidate list, this triggers additional obligations – both along the supply chain and towards consumers – for companies that produce, import, and supply this substance. Companies that manufacture or import the substances must implement measures to minimise discharges into the environment and recommend such measures to their customers.

2.2 Possible uses of D4

Octamethylcyclotetrasiloxane (D4) can be used in various industrial applications as well as consumer products.

In the preparation of the project, the following relevant sectors for the use of D4 were identified:

- Automobile and transport
- Construction
- Electronic and electric appliances
- Paints and varnishes[4]
- Cosmetics[5]
- Leather
- Medicine and medical technology
- Paper and cardboard
- Textile

[4] As part of the project, however, we received feedback from a paint and coatings industry association that, in their experience, D4 is not a priority substance for their members.

[5] D4 was incorporated into Annex II of the EU Cosmetic Regulation N°1223/2009 in May 2019, with the implementation of this inclusion taking place in June 2019. Cosmetic formulations marketed in the EU are prohibited from intentionally including materials listed in Annex II.

- Detergents and cleaning products

Stakeholders asked during the project also stated that D4 is used in the production of silicones.

The supply chain can vary depending on the industry and application. The exact structure also depends on the specific business relationships, geographical locations of the players and the regulatory requirements in the respective regions.

2.3 Actors in the supply chain

There are various players in a supply chain, each of whom has specific tasks and responsibilities. The roles in a typical supply chain can vary depending on the industry and context. The REACH Regulation defines the following actors along the supply chain:

- **Manufacturer** – Within the meaning of the REACH Regulation, any natural or legal person established in the European Union (EU) who manufactures a substance. Manufacturers are subject to registration requirements and obligations to provide information, reporting, and, if applicable, authorization. They may be affected by restrictions.
- **Importer** – Within the meaning of the REACH Regulation, this is any natural or legal person based in the EU who is responsible for the import of a substance. According to REACH, an import is the introduction of substances, mixtures and articles from countries outside the EU by an economic operator based within the European Union. In addition to the member states, the countries of the European Economic Area (EEA) Norway, Iceland and Lichtenstein also belong to the European Community under REACH. Importers are subject to the same obligations as manufacturers under REACH. They are affected by the obligation to register and provide information, potentially reporting requirements, and authorization obligations. They may also be subject to restrictions.
- **Only Representative** (OR) – Within the meaning of the REACH Regulation, a natural or legal person established in the EU who can be appointed by a manufacturer of substances, mixtures or articles established outside the EU. A designated only representative assumes all responsibilities of the importer. The actual importer is considered a downstream user in the context of the REACH Regulation.
- **Distributor** – Within the meaning of the REACH Regulation, this is any natural or legal person established in the EU who merely stores substances or mixtures and places them on the market. This may also include retailers. They are subject to the obligation to provide information and may be affected by restrictions.
- **Downstream user (DU)** – Within the meaning of the REACH Regulation, any natural or legal person established in the EU who uses a substance as such or in a mixture in the course of his industrial or professional activities. This means that all companies that use substances and mixtures in any form could be described as downstream users. Typical downstream users are e.g., formulators who manufacture mixtures from various substances or companies that manufacture products using substances or mixtures. The DU importer plays a special role – as soon as an only representative for a substance is designated within the EU, the actual importers are considered downstream users. They are required to fulfil information obligations, possibly report and seek authorization, and may need to generate substance safety reports. Additionally, they might be subject to restrictions and notification duties.

Using D4 as an example, this could look as follows:

- **Manufacturer**: The substance (D4) is produced by a manufacturer and can be sold directly to various industries.
- **Only representative** (if applicable): If the manufacturer is located outside the EU, an only Representative in the EU can act as an authorised representative to take over the REACH obligations.
- **Importers**: Importers can purchase D4s from manufacturers in other countries and import them into the EU. They are then obliged to fulfil the REACH regulations, including registration with the ECHA.
- **Distributors**: Distributors can purchase D4 in bulk and resell it to various customers, including manufacturers in various industries.
- **Downstream users**: Companies in various sectors, such as the textile industry or the electronics industry, can process D4 further or use it as an ingredient in their end products.

2.4 Regulatory obligations along the supply chain according to REACH

In general, there are several obligations as regards information provision and handling.

Registration Obligation

Any substance manufactured or imported in quantities of at least one tonne per year is subject to the registration obligation. This includes cases where the substance is imported as part of a mixture. Substances already notified under Directive 67/548/EEC ("notified substances") are considered already registered. Substances in articles exceeding one tonne per year must also be registered if they are released under normal conditions of use. Substances subject to registration cannot be manufactured or placed on the market without registration.

Manufacturers and importers must conduct a chemical safety assessment and prepare a chemical safety report (CSR) if the quantity reaches ten tonnes per year and are subject to registration under the REACH Regulation (Article 10).

The CSR outlines specific risk management measures for various applications in which the substance is used. The CSR must contain an exposure assessment and risk characterisation if the substance is classified as hazardous or fulfils the criteria for a PBT substance, as described in REACH Article 14(4). The manufacturer or importer must consider all uses provided by customers, i.e., downstream users, in the substance safety assessment. Guidance on information requirements and chemical safety assessment is available on the ECHA webpage (European Chemicals Agency, 2024a).

Information Obligations

Key information obligations under REACH include the requirement to provide a safety data sheet and information obligations under Article 33 regarding substances in articles.

For all hazardous substances according to Regulation 1272/2008/EC (CLP), manufacturers and importers must provide their customers with an SDS without request. The same applies to hazardous mixtures.

A supplier of articles (e.g., producer or distributor) must inform their recipients according to Article 33 REACH paragraph 1 or consumers can request information according to Article 33 REACH paragraph 2 if a SVHC is present in the article in a concentration above 0.1% by weight. At least the name of the relevant SVHC and, if known to the supplier, indications for safe use

must be provided. Information to commercial customers must be provided without request, while private end consumers must be informed upon request within 45 days.

Notification Obligation

A downstream user must notify the ECHA if they have to prepare a substance safety assessment or if they avail exemptions under Article 37 paragraphs 4 c) or f). This applies if the substance is used below one tonne per year or for product- and process-oriented research and development, provided that risks are controlled to protect human health and the environment.

Reporting Obligation for Classification and Labelling

Manufacturers and importers of substances or mixtures subject to registration or hazardous according to Regulation 1272/2008/EC (CLP Regulation) must report to ECHA, within one month of placing on the market, the identity of the manufacturer or importer, as well as the classification and labelling of the relevant substances. This applies to hazardous substances regardless of quantity and registration obligation, including small quantities. If the relevant information has already been transmitted as part of the registration for registered substances, this reporting obligation is waived. The agency compiles a publicly accessible list of classifications and labels based on this information.

Authorization Obligation

Substances of very high concern – SVHC are subject to authorization if listed in Annex XIV of the REACH Regulation ("List of Substances Subject to Authorization"). An authorization application can be submitted (within a supply chain) by a manufacturer, importer, and/or downstream user to ECHA. In the application, the applicant must demonstrate for their intended uses that the risks associated with handling the substance can be adequately controlled. If the applicant cannot prove this, they must demonstrate that the socio-economic benefits of use outweigh the risks and that no available alternative substances or technologies exist. If alternatives are available, the applicant must submit a substitution plan, including a schedule for proposed actions.

The European Commission makes decisions on authorization applications.

Regulatory obligations differ depending on the role in the supply chain. The following table summarises the registration obligations and obligations to pass on information for the individual players; more information on the obligations in connection with the SDS can be found in the following chapter.

Table 1: Actors in the supply chain and their obligations

Actor in the supply chain	Registration obligations	Communication obligations along the supply chain
Manufacturer	Manufacturers in the EU must register chemicals they produce in quantities of 1 tonne or more per year with the ECHA.[6]	Manufacturers must prepare SDSs and pass them on to their customers, including only representatives, importers and downstream users.[7]

[6] The information requirements for preparing the registration dossier are based on tonnage bands. As soon as a substance is manufactured in quantities of more than 10 tonnes per year, a chemical safety assessment must be carried out. If the substance has PBT or vPvB properties (as in the case of D4), an exposure assessment and risk characterisation must also be carried out.

[7] If exposure scenarios have to be drawn up as part of a registration when preparing the chemical safety report, these must be attached to the corresponding safety data sheets (extended safety data sheet, eSDS).

Actor in the supply chain	Registration obligations	Communication obligations along the supply chain
	The registration dossier of a substance must specify all intended uses of the substance and must be kept up to date.	
Only representative	The only representative acts on behalf of a non-EU manufacturer and assumes the registration obligations in the EU.	The only representative must ensure that all relevant information on the safe use of the chemicals is passed on to downstream users.
Importers	Importers of chemicals in quantities of one tonne or more per year that are not already registered in the EU must register them with the ECHA.	Importers must create their own SDS (if not already available) and pass it on to downstream users.
Supplier (manufacturer/importer or distributor who places a substance or mixture on the market)	Only chemicals that have been properly registered may be sold. The registration must therefore be checked.	Suppliers must make the SDS available to the recipient of a hazardous substance or mixture free of charge.[8] The SDS must be updated immediately as soon as new information on the hazard is available.
Downstream users	-	There are information obligations both for upstream actors in the supply chain (e.g. in the case of new information on hazardous properties) and for all other downstream users following the supply chain. If own formulations are produced, a separate SDS may have to be created and passed on within the supply chain. Downstream users must also use the chemicals in accordance with the instructions and recommendations in the SDS received.

2.4.1 Role of the safety data sheet (SDS)

An SDS is a document that provides information on the properties, hazards and safe handling of a chemical substance or mixture. This makes it possible to take appropriate measures to protect health, labour and the environment for each use. The safety data sheet is therefore the most important means of communication within the supply chain.

The legal requirements for safety data sheets are laid down in Article 31 of the REACH Regulation: [9]

Article 31 – Extract (REACH Regulation)

1. The supplier of a substance or a mixture shall provide the recipient of the substance or mixture with a safety data sheet compiled in accordance with Annex II:

[8] SDSs for non-hazardous mixtures must be made available on request under certain conditions (see next chapter).

[9] Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

(a) where a substance or mixture meets the criteria for classification as hazardous in accordance with Regulation (EC) No 1272/2008; or

(b) where a substance is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII; or

(c) where a substance is included in the list established in accordance with Article 59(1) for reasons other than those referred to in points (a) and (b).

2. Any actor in the supply chain who is required, under Articles 14 or 37, to carry out a chemical safety assessment for a substance shall ensure that the information in the safety data sheet is consistent with the information in this assessment. If the safety data sheet is developed for a mixture and the actor in the supply chain has prepared a chemical safety assessment for that mixture, it is sufficient if the information in the safety data sheet is consistent with the chemical safety report for the mixture instead of with the chemical safety report for each substance in the mixture.

[...]

7. Any actor in the supply chain who is required to prepare a chemical safety report according to Articles 14 or 37 shall place the relevant exposure scenarios (including use and exposure categories where appropriate) in an annex to the safety data sheet covering identified uses and including specific conditions resulting from the application of Section 3 of Annex XI.

Any downstream user shall include relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for identified uses.

Any distributor shall pass on relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for uses for which he has passed on information according to Article 37(2).

8. A safety data sheet shall be provided free of charge on paper or electronically no later than the date on which the substance or mixture is first supplied.

9. Suppliers shall update the safety data sheet without delay on the following occasions:

(a) as soon as new information which may affect the risk management measures, or new information on hazards becomes available;

(b) once an authorisation has been granted or refused;

(c) once a restriction has been imposed.

[...]

The obligation to prepare a safety data sheet applies to manufacturers, formulators or importers who supply a hazardous substance or mixture to downstream users. This is particularly necessary if PBT or vPvB substances are contained, or if a substance is listed in the candidate list for substances subject to authorisation. If a mixture itself does not fulfil the criteria for classification as hazardous, suppliers are obliged to provide the customer with a safety data sheet on request if the mixture contains at least one PBT or vPvB substance or a substance listed in the candidate list in an individual concentration of ≥ 0.1 percent by weight.

If exposure scenarios have to be drawn up as part of a registration when preparing the chemical safety report, these must be attached to the corresponding safety data sheets. An SDS including the exposure scenarios is a so-called extended safety data sheet (eSDS). It consists of a standard SDS with more subsections than the general one, and an additional annex containing one or more exposure scenario(s).

The substance D4 requires an extended SDS. In the following table, the information requirements are listed systematically and linked to importance for the environment.

Table 2: Information requirement in an eSDS with focus on environmental protection

Section	Title	Important information relevant for the environment
1	Identification of the substance/mixture and of the company/undertaking	
2	Hazards identification	
3	Composition/information on ingredients	
4	First aid measures	
5	Firefighting measures	
6	Accidental release measures	The section advises on preventing adverse effects from spills, leaks, or releases on individuals, property, and the environment. It differentiates responses to large and small spills, if different equipment or procedures are necessary, and may reference section 13, "Disposal considerations," as needed.
7	Handling and storage	Section 7 provides information on accidental release. It offers positive guidance on handling and safe storage conditions. Technical measures such as containment and environmental protection measures should be recommended. General occupational hygiene advice, such as dealing with contaminated personal protective equipment and clothing, should also be included. Additional reference may be made to technical fact sheets or industrial sector-specific solutions, if available.
8	Exposure controls/personal protection	This section provides parameters for verifying the successful implementation of prevention and control measures from section 7. It includes national occupational exposure limit values (OELs) and biological limit values for substances or relevant mixture ingredients, as well as air contaminants formed during use. This section also requires information on recommended monitoring procedures, especially for the most relevant substances, and relevant DNELs and PNECs from REACH registration if a chemical safety report is required.
9	Physical and chemical properties	
10	Stability and reactivity	
11	Toxicological information	
12	Ecological information	This section provides information for assessing the environmental impact of the substance or mixture upon release to the environment. Subsections 12.1 to 12.7 offer a concise summary of relevant data, including test data where available, specifying species, media, units, test duration, and

Section	Title	Important information relevant for the environment
		conditions. This data aids in spill handling, waste treatment evaluation, release control, accidental release management, and transport considerations.
13	Disposal considerations	The section covers disposal considerations and precautions for safe waste handling, emphasizing hazardous waste handling compared to the initial product
14	Transport information	
15	Regulatory information	This section informs about applicable EU and national regulations, including authorizations and restrictions, with specific attention to national legislation on occupational safety and health and vulnerable groups' protection.
16	Other information	
Annex		There should be multiple exposure scenarios (ES), each identified by a descriptive "free text" title. Each ES will include "contributing scenarios" outlining safe usage conditions for the environment, workers, and consumers. The environmental section will outline safe daily and annual release limits, as well as environmental risk management measures (RMM), including waste water treatment processes, filters, and air abatement systems, along with their effectiveness.

The supplier must provide the recipient of a hazardous substance or mixture with the safety data sheet on paper or electronically free of charge, at the latest on the day on which the substance or mixture is delivered first. Suppliers must also update the safety data sheet immediately if new information becomes available that may affect risk management measures or if authorisations or restrictions are issued. Updated versions must be made available free of charge to all previous recipients of the previous 12 months.

Downstream users must take into account the risk management measures communicated in the safety data sheet in their risk assessment. If the risk management measures described in the safety data sheet are not sufficient (e.g. because new information on the hazardous properties of a substance is available), this information must be reported back to the supplier in accordance with Article 34 of the REACH Regulation:

Article 34 (REACH Regulation)

Any actor in the supply chain of a substance or a mixture shall communicate the following information to the next actor or distributor up the supply chain:

(a) new information on hazardous properties, regardless of the uses concerned;

(b) any other information that might call into question the appropriateness of the risk management measures identified in a safety data sheet supplied to him, which shall be communicated only for identified uses.

Distributors shall pass on that information to the next actor or distributor up the supply chain.

The exact requirements for the preparation of safety data sheets are regulated in Annex II of the REACH Regulation. According to these provisions, the safety data sheet must be drawn up by a competent person in simple, easily understandable language. Safety data sheets must be kept for at least ten years and access to this information must be granted to employees.

2.4.2 Additional obligations in relation to substances in articles

According to the REACH Regulation, an article is an object which during production is given a specific shape, surface or design which determines its function to a greater degree than does its chemical composition. Articles themselves do not have to be registered under REACH, but additional obligations may arise, particularly if substances on the candidate list are included (as in the case of D4).

2.4.2.1 Registration and notification obligations

Article 7 of the REACH Regulation specifies in section (1) the obligations for registration and in section (2) the obligation to notify substances in articles:

Article 7 (REACH Regulation)

1. Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles, if both the following conditions are met:

(a) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;

(b) the substance is intended to be released under normal or reasonably foreseeable conditions of use.

A submission for registration shall be accompanied by the fee required in accordance with Title IX.

2. Any producer or importer of articles shall notify the Agency, in accordance with paragraph 4 of this Article, if a substance meets the criteria in Article 57 and is identified in accordance with Article 59(1), if both the following conditions are met:

(a) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;

(b) the substance is present in those articles above a concentration of 0,1 % weight by weight (w/w).

For all substances in articles that are produced or imported in the EU in quantities of more than 1 tonne per year, registration is mandatory as soon as the substance is released under "normal" conditions of use. An exception to the registration obligation exists if the substance is already registered for use (European Chemicals Agency, 2017).

As soon as a substance has been included in the candidate list, there are additional notification obligations. As soon as the substance is present in these articles in a concentration of at least 0.1 % (w/w) and is produced or imported at a rate of more than 1 tonne per year, manufacturers or importers must submit information on the presence of candidate list substances in articles to ECHA and the competent authorities of the Member States. Notification is not required for substances in articles that were produced or imported before the substance was included in the candidate list (European Chemicals Agency, 2017).

There is an exemption to the notification obligation if the substance has already been registered for this use. This refers to any registration of this use of the substance in the same or another supply chain.

A further exemption to the notification obligation exists if the manufacturer or importer of articles can exclude exposure of humans or the environment under normal or reasonably foreseeable conditions of use, including disposal. This means that a manufacturer/importer who wants to prove the exclusion of exposure must ensure that the SVHC substance on the candidate list does not come into contact with humans or the environment.

2.4.2.2 Information obligations

Article 33 of the REACH Regulation regulates the obligation to pass on information on substances in articles:

Article 33 (REACH Regulation)

1. Any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

2. On request by a consumer any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

The relevant information shall be provided, free of charge, within 45 days of receipt of the request

This means that once a substance has been included in the candidate list, suppliers of articles containing a substance in a concentration above 0.1 % (w/w) must provide sufficient information to enable the recipient of the article to use the article safely. In this case, the recipients are industrial and professional users and distributors, but not consumers. At the very least, the name of the substance in question must be provided. Consumers can request similar information. The supplier of the article must provide this information free of charge within 45 days (European Chemicals Agency, 2017).

The supplier can only provide this information reliably and on time if it is adequately informed by the parties in its supply chain. This is particularly difficult if the flow of information along the supply chain is delayed, incomplete or incorrect.

This can be particularly problematic in supply chains that utilise the global market and are therefore not fully covered by REACH. European importers should therefore ideally set up a suitable system that enables them to precisely describe and document raw materials, semi-finished products or components from external suppliers internally.

3 Status quo

The REACH Regulation was enacted in 2006 i.a. to improve the protection of human health and the environment from the risks that can arise from chemicals. SDS were based on the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) and were therefore more standardised and globally accepted than the outdated MSDS (Material Safety Data Sheets). Even though the introduction of REACH in the EU has contributed to more standardisation, various research projects indicate that many of the SDS have shortcomings. The results of the individual research projects are summarised in the following chapters.

3.1 EU projects on the status of compliance with the REACH Regulation

The ECHA Forum coordinates various projects aimed at harmonising the enforcement of REACH in the individual Member States and checking the current status of compliance with certain obligations, so-called REACH-EN-FORCE (REF) projects. The REF projects are carried out by inspectors working in the national authorities of the participating Member States and the results are collated by ECHA and the Forum's working group to produce a final report.

Table 3: Overview of all REF projects to date

REF project	Topic
REACH-EN-FORCE-1	Registration, pre-registration and safety data sheets
REACH-EN-FORCE-2	Obligations of downstream users - formulators of mixtures
REACH-EN-FORCE-3	Control and enforcement of compliance with registration obligations by manufacturers, importers and only representatives in close cooperation with customs
REACH-EN-FORCE-4	Restrictions
REACH-EN-FORCE-5	Exposure scenarios, eSDS, Risk management measures (RMM) and operational conditions (OC)
REACH-EN-FORCE-6	Classification and labelling of mixtures
REACH-EN-FORCE-7	Enforcement of registration obligations after the last registration deadline in co-operation with the customs authorities, including verification of the strict control conditions applicable to substances registered as intermediates
REACH-EN-FORCE-8	Enforcement of CLP, REACH and Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR) obligations in relation to substances, mixtures and articles sold online
REACH-EN-FORCE-9	Enforcement of the authorisation
REACH-EN-FORCE-10	Integrated chemical control of products
REACH-EN-FORCE-11	Currently in progress

Source: Forum enforcement projects (ECHA Home page)

With the first Forum project "REF-1" in 2010, 1543 companies from 25 member countries were inspected. In 11% of the companies, SDSs were not or only partially available. Structures or tools (e.g. software) that enable the creation of SDSs in accordance with the REACH Regulation were available in 1008 (65%) companies.

Three years later in "REF-2" improvement in the availability of SDSs in the companies (97% of the companies inspected had SDSs) was observed, but a review showed that up to 52% of the SDSs had deficiencies in content (European Chemicals Agency, 2013). The content of the SDSs was assessed in relation to sections 1, 2, 3, 8 and 15, and deficiencies of varying nature and extent were found (see Table 4). The observed deficiencies in the SDSs were found with similar frequency in all company sizes.

Table 4: Number of identified deficiencies in SDSs under REACH-REF-2

Section	Number of analysed SDSs	Number of SDSs with deficiencies	Defects in %
1: Identification of the substance/mixture and of the company/undertaking	4205	474	11
2: Hazard(s) identification	4313	552	13
3: Composition/information on ingredients	4143	574	14
8: Exposure controls/Personal protection	3760	671	18
15: Regulatory information	4063	483	12

In 2018, the "REF-5" project investigated supply chain communication and implementation of information on the safe handling of chemicals in the supply chain (European Chemicals Agency, 2018). Of the companies inspected, 28% (302) were in the first tier of the supply chain, 25% (270) were suppliers and 47% (519) were categorised as downstream users. The inspected companies were spread across different sectors: manufacturing, wholesale and retail and other sectors. Of the companies inspected, 71% were small and medium-sized enterprises (SMEs), 28% were non-SMEs and 1% were unknown. Overall, 18% of companies were reported for at least one violation, with 42% found in "first tier" companies, 29% in "supplier" companies and also 29% in "downstream user" companies. Wholesale and retail had the highest proportion of reported violations (31%).

The overall results of the REF-5 project show that many obligations are being fulfilled with regard to the compilation, distribution and use of safety information in the form of the CSRs and the eSDSs for substances. However, significant quality deficits have been identified in the CRSs, which are reflected in the eSDSs. The majority of the exposure scenarios submitted (63%) are copies of the exposure scenarios from the CSR, indicating unsatisfactory quality in terms of accuracy, clarity and usefulness. This was also confirmed by inspectors during the inspections. However, the quality of the eSDSs themselves was not analysed further.

The "REF-11" forum project is intended to assess compliance with the revised requirements of Annex II, which came into force in 2023.

3.2 German national research projects on safety data sheets

In addition to EU-wide initiatives, there are also national research projects in Germany that have focussed on the data availability and quality of SDSs.

A recent project by the Federal Institute for Occupational Safety and health (BAuA) analysed the availability of data and the flow of information at the interface between the requirements of the REACH Regulation and occupational health and safety with regard to the registration dossier, the (e)SDS and the risk assessment (BAuA, 2024). The focus was on analysing how incomplete,

contradictory or insufficient information and the quality of the information flow can affect the risk assessment and consequently occupational health and safety.

The evaluation of the CSRs and (e)SDSs as part of this project revealed that many of them had deficiencies in relation to the legal information requirements. Even in cases where the CSR was assessed as compliant, deviations and deficiencies were found in the (e)SDS. However, there were also situations where a CSR assessed as non-compliant had a corresponding (e)SDS of significantly higher quality. In particular, differences in labelling and classification information between the registration dossier and the (e)SDS were identified.

3.3 Observed deficits in safety data sheets outside the EU

Various research projects outside the EU have also identified deficits in SDS, examples are presented in the following.

3.3.1 USA

In a US study by the BlueGreen Alliance and Clearya reviewed more than 650 SDSs and found that a total of 30% of the SDSs analysed contained inaccurate chemical hazard warnings (Brody et al., 2022).

- 15% of the 30 analysed SDSs with carcinogenic substances did not contain any information on carcinogenicity in the hazard identification section.
- 21% of the 372 SDSs with reprotoxic chemicals contained no warnings about this hazard.
- 13% of 278 SDS with chemicals with specific target organ toxicity contained either no or inaccurate warnings about this hazard.

In order to find out whether the observed shortcomings depend on the size of the company, 34 SDSs from three large chemical manufacturers were also analysed as example. Shortcomings in the description of hazards were identified in these larger sized companies to a similar extent.

Another analysis was repeated separately for different regions in order to check whether the grievances found in the SDSs of companies from different regions were similar. Once again, 228 SDSs from the USA, 147 SDSs from Europe and 236 SDSs from the Asia-Pacific region were analysed. The SDSs from Europe performed comparatively better, although here too there was a lack of information on hazards. 12% lacked information on carcinogenicity, 10% had no information on reproductive toxicity and 6% lacked information on specific target organ toxicity.

3.3.2 Indonesia

In a study of 42 SDSs submitted to the Indonesian Industry Information System (SIINAS), weaknesses were found in the completeness and accuracy of the information available in the SDSs (Hidayat et al., 2021). To assess the completeness of information, 75 elements were defined according to the national guidelines in Indonesia. In total, all 42 SDSs were rated as incomplete. For the assessment of accuracy, only sections relating to the hazard classification were considered (in addition to national regulations, the GHS classification of the ECHA info page was also compared). The content of 21 SDSs corresponded to the classification on the ECHA info page. The authors assume that the deficits observed in the SDSs could be due, among other things, to a lack of knowledge on the part of those responsible for creating the SDSs (e.g. lack of training, lack of information on databases).

4 Project approach

To assess the D4 lifecycle, and in connection with this the communication of environmental relevant information for safe use conditions for the environment along the supply chain, a detailed survey with actors along the supply chain of D4 was prepared in the present project. The survey should then also be used to assess, whether problems during the communication along the supply chain led to data gaps or relevant environmental relevant information missing and if these were systematic problems. The project was divided into three different project phases. A breakdown of these phases is shown in Figure 1.

Figure 1: Different project phases

Source: own illustration, Ramboll

4.1 Project Phase 1: Survey preparation

Project phase 1 formed the basis for the project to obtain information on the situation regarding supply chain communication as accurately as possible. In order to ensure on the one hand side an easy handling by respondents and on the other hand the necessary level of details, a special focus was placed on the preparation of the survey.

In consultation with the German Environment Agency (UBA), a detailed distribution list was compiled through intensive research of relevant companies and associations from various industrial sectors. The following list shows industrial sectors identified as relevant for the substance D4 and the possible roles of the respondent in the sectors:

- Chemical manufacturing
- Chemical distribution
- Chemical processing
- Automobile and transport
- Construction
- Electronic and electric devices
- Paints and varnishes
- Cosmetics
- Leather
- Medicine and medical technology
- Paper and cardboard
- Textiles and detergents and cleaning products.

4.1.1 Survey

A comprehensive questionnaire customised to the position of the participating experts was created in order to map supply chain communication and communication problems along the supply chain as accurately and in as much detail as possible. The questionnaire was divided into the following possible positions along the supply chain: manufacturer, importer, only representative (OR), distributor and downstream user. Individual chapters, which are adapted to the positions in the supply chain, were used to find out where certain problems occur and whether these are systematic problems.

The survey was prepared in German and English and programmed online using SurveyXact. In addition to the individual chapters for the various positions along the supply chain, logical links were built into the survey that enabled the experts to automatically skip irrelevant questions in order to keep the very detailed survey as precise as possible and minimise the workload for the experts. Irrelevant questions mean questions that are only relevant for individual actors in the supply chain. Figure 2 shows the start page of the survey for online participation and the entire catalogue of questions can be found in Appendix A.1.

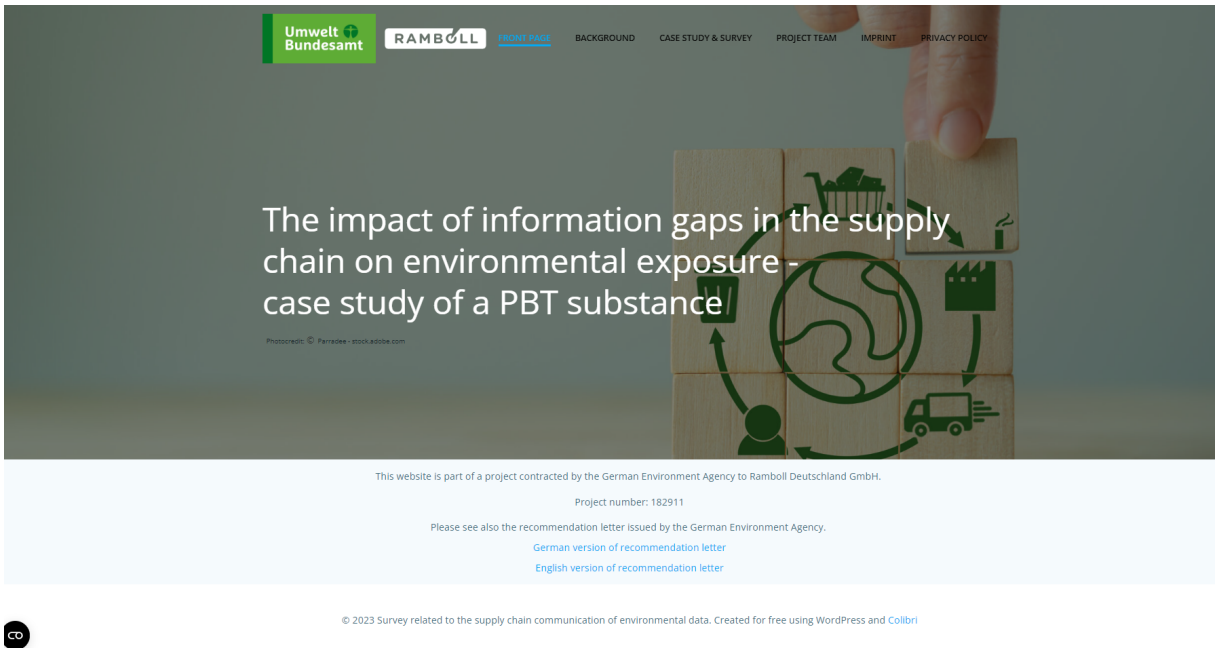
Figure 2: Survey start page

Source: own illustration, Ramboll

4.1.2 Website

To give the contacted experts the opportunity to prepare for the survey and provide additional information on the project, an informative website was programmed. It is accessible via the domain: Survey related to the supply chain communication of environmental data (survey-supply-chain-env-data.com). The website contains subpages on the project background, the case study and the survey, as well as the project team. Data protection aspects were fully taken into account. Figure 3 shows the landing page. The full content is available in Appendix A.2.

Figure 3: Website



Source: own illustration, Ramboll

4.2 Project phase 2: Carrying out the survey

Project phase 2 covered the entire period in which the survey was open for feedback, including all undertakings made to generate additional feedback.

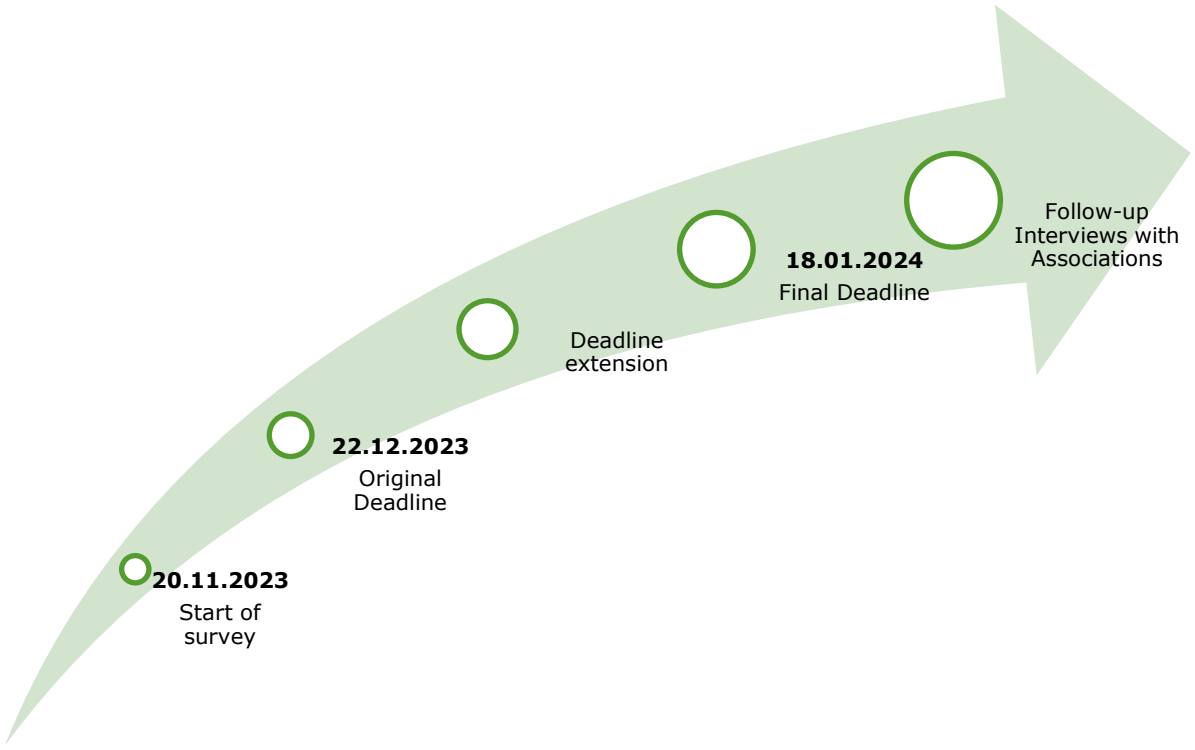
Together with the invitation to participate in the survey a cover letter was written to the experts to provide them with all the necessary information about the project and the survey participation, as well as to prevent misunderstandings between the survey and the current legislative processes going on for the substance D4. The cover letter can be found in Appendix A.3**Error! Reference source not found.**.

The invitation was then sent to relevant associations and to companies along the supply chain that were identified as potentially relevant in work phase 1. In addition, service providers in the area of safety data sheets were also contacted. In total, around 300 stakeholders from all relevant sectors that could use D4 were contacted via an initial mailing list.

The rough timeline for conducting the survey is shown in Figure 4. The first reminder letter was sent out 2 weeks after the start of the survey. During the course of the survey, new contact options were also constantly sought if a potential survey participant could not be reached through the previous contact options (e.g. due to incorrect e-mail, no longer working for the company, etc.).

Only a small number of responses were received by the original deadline. This can be attributed to various reasons, including the time of the year, as many companies and businesses are busy with end of year business and do not have the capacity to complete an extensive survey. This lack of capacity was also communicated by experts contacted as the reason why participation was not possible at the given time. As a result, the deadline was extended to 18 January 2024 and a reminder about the new deadline was also sent to potential participants 10 days after the new deadline was announced.

Figure 4: Rough timeline of the survey



Source: own illustration, Ramboll

Before the start of the project certain risks were identified and appropriate risk management measures were derived. One of these risks was a low response rate to the survey carried out. Unfortunately such a very low response rate did occur. As a possible solution for this problem, the focus on obtaining feedback and responses was shifted to associations and performing interviews instead of having them to fill out the extensive survey. Thus, further contact persons were researched for the identified associations in order to give them the opportunity to provide general information – without filling out the extensive questionnaire – in written or in a personal meeting. A condensed catalogue of questions was also sent to the associations in January 2024:

- For which actors along the supply chain do you see the greatest risk that information necessary for the safe handling of D4 and mixtures with D4 with regard to the environment is not available or is lost and why?
- Where do you see the biggest problems regarding supply chain communication?
- Do you have any general suggestions for improvement/wishes regarding supply chain communication?
- If available: Are you aware of the effects of information deficits on environmental emissions from D4 or what effects are conceivable?
- Are there any information tools (e.g. via an association) that provide information on the safe handling of D4 with regard to the environment?

Two associations (CEFIC and DUCC) were found who were willing to share their views and the experiences of their members in an interview. However, they faced the problem of not being able to get enough information from their respective members focused on the substance D4, so that no common statement could be reached and therefore not information was brought forward to the project team. The associations, however, encouraged the project team to enlarge the scope of the project to a more general discussion on supply chain communication rather than focusing on a specific substance supply chain. This would enable them to contribute more effectively.

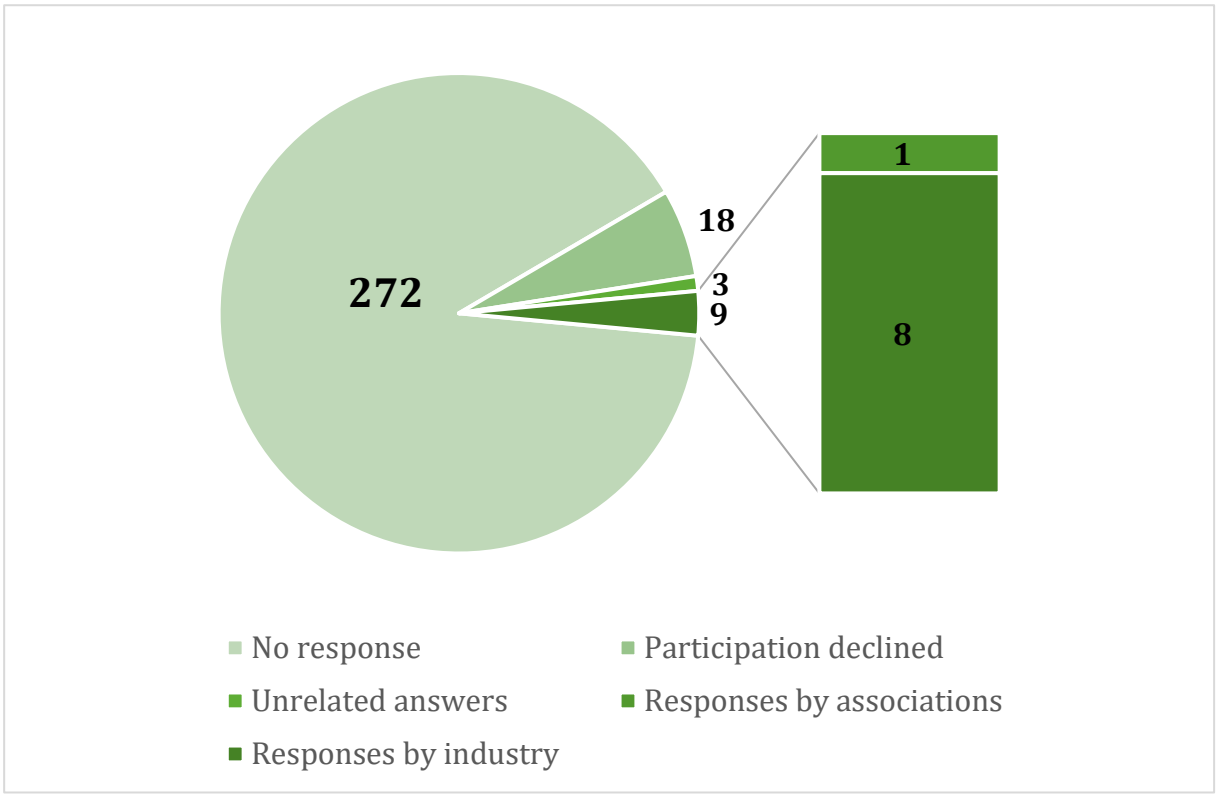
4.3 Project phase 3: Analysing the survey results

Project phase 3 comprised the evaluation of the survey results received and of possible reasons why only a low response rate was received.

4.3.1 General feedback

A total of 302 associations and companies were contacted in various ways as part of the survey. Figure 5 shows that despite all attempts to increase the number of responses, the majority of enquiries remained unanswered. However, there were also a small number of individual respondents that declined participation in the survey either due to time constraints, the responsible person of the company being on leave, or due to not using the substance D4 in their substances, mixtures or articles. A very small amount of answers from some of the respondents showed that the initial inquiry was not understood and generic or for the study unusable answers were obtained. These included either just the statement that SDS were used for supply chain communication or the question which mixtures or articles from the respondent we were using, so they could support us in our inquiry. Further most associations answered that they cannot give feedback for single substances. This was justified because either as an umbrella association they cannot supply answers on single substances or substance groups, or because the use of D4 is already prohibited in the relevant sector, or because the response to the survey among their members was too low, mainly due to D4 not being a priority substance amongst the members, to give a sufficiently based statement. One association however tried to answer questions on a slightly broader scope, which are also incorporated in the project results. During an interview another association further established, that due to only few members using or having to deal with the substance D4, they as association cannot give a well based statement on the supply chain communication for that single substance, however, they would be willing to give more information if the survey was done on supply chain communication of PBT substances in general on a much broader approach.

Figure 5: Illustration of the feedback from the survey



Source: own illustration, Ramboll

A more detailed list on the feedback from the individual actors and positions in the supply chain is shown in Table 5.

Table 5: Detailed list of feedback from survey

Position in the supply chain	Number of actors contacted	Declined participations[10]	Unrelated answers	Answered surveys	No feedback
Associations	26	3 (+1 interview)	1	1	21
Manufacturer	3	-	-	1	2
Distributor	30	1	-	2	27
Importer	8	-	-	-	8
Downstream user	235	13	2	5	227
Total	**302**	**17 (+1 interview)**	**3**	**9**	**272**

Nevertheless, it was possible to obtain at least one response from each of the positions along the supply chain except for importers and Table 6 shows an overview of the survey participants, their relevant sectors and company sizes.

[10] Assumptions on the position of the stakeholders along the supply chain for declined participations are based on general company information.

Table 6: Overview of relevant sectors and position in the supply chain of the survey participants

Position in the supply chain	No.	Relevant sectors	Size of the company
Manufacturer (M)	M1	Chemical production, chemical processing	Large enterprise > 250 employees
Distributor (T)	T1	Chemicals trade	Small enterprise < 50 employees
Distributor (T)	T2	Chemical production, Chemical trade, Chemical processing, Detergents and cleaning agents	Small enterprise < 50 employees
Downstream user (DU)	DU1	Chemical processing, paints and varnishes, detergents and cleaning agents, technical aerosols	Medium enterprise < 250 employees
Downstream user (DU)	DU2	Chemical processing, detergents and cleaning agents[11]	Small enterprise < 50 employees
Downstream user (DU)	DU3	Chemical processing, paints and varnishes, Detergents and cleaning agents	Large enterprise >250 employees
Downstream user (DU)	DU4	Paints and varnishes	Small enterprise < 50 employees
Downstream user (DU)	DU5	Cosmetics	Micro enterprise < 10 employees

As shown in Table 6 the survey was mainly answered by small and medium-sized enterprises (SME) and only two large enterprises. Furthermore, none of the respondents used the upload option for their own SDS in the survey and as such all SDS investigated during this project were sourced through desk research and were publicly available without the purchase of any substances, mixtures or articles.

Despite various attempts to increase the number of survey participants (as described in chapter 4.2.), an increase of participants could not be achieved. The following reasons for the low participation rate were identified:

- Some industry associations stated that they did not generally deal with individual substances and therefore did not pursue the survey any further.
- One paint and coatings industry association stated that, in their experience, D4 is not a priority substance for their members and the response to surveys on the substance is usually correspondingly low.

[11] However, the downstream user states that he does not use D4.

- Some stakeholders stated that they did not use D4 and therefore did not complete the survey. A lack of knowledge about D4 and/or a lack of relevance could also be one of the reasons for the low level of interest on the part of industry in participating in the survey.
- Some stakeholders stated that they generally do not take part in surveys.
- The enquiry was sometimes not understood or answered with generic information on compliance with safety regulations. After further attempts with more detailed explanation, no further response was received.
- In some cases, the correct contact person could not be identified and attempts to contact them via contact forms or general information e-mail addresses were unsuccessful.

Nevertheless, it was possible to obtain a general opinion from individual industry associations, and the information thus obtained were also taken into account in the preparation of the report.

5 Project results

5.1 Industry's knowledge of the hazards of substance D4

As already mentioned in chapter 2.1 D4 is considered a SVHC due to its fulfilment of the criteria for PBT and vPvB. In order to obtain an overview of the knowledge of the hazards of substance D4, particularly with regard to environmental exposure, in the industrial environment, the survey participants were not only asked about their own level of knowledge, but also how they see the situation in relation to the entire industry.

Overall, most respondents stated that, from their point of view, both their level of knowledge and the level of knowledge of the industry regarding the hazards of the substance are sufficiently known. However, one distributor (1 out of 2) and one downstream user (1 out of 5) stated that, from their point of view, the hazards of D4 are only partially known throughout the industry. The distributor nevertheless states that he has sufficient information from the manufacturer to ensure safe handling of the chemical in relation to the environment.

One manufacturer of D4 (M1) claims to have information on the tonnages used in relevant sectors and has restricted its use to industrial purposes since the substance was identified as SVHC.

Downstream users were also asked whether it is immediately recognisable from the containers if they contain a hazardous substance with >= 0.1 w%. All downstream users surveyed stated that hazardous substances are immediately recognisable. In addition, the downstream users stated that instructions and pictograms on the containers are read and understood.

The downstream users were further asked whether they were aware of their company's role in the supply chain and the associated obligations. All downstream users surveyed stated that they were aware of their company's role in the supply chain and the associated obligations.

Although most of the survey participants stated that, from their point of view, the hazardousness of D4 is sufficiently known in industry, the feedback from individual stakeholders who do not see sufficient knowledge of the hazardousness of the substance in industry should be taken very seriously - especially as the total number of survey participants was low. Individual responses suggested that some companies were not aware of the substance D4 in general. This assumption was confirmed by individual associations that do not see a high relevance of D4 among their members. However, it was not possible for the project team to check at this point whether the relevant companies do not use the substance or whether the substance is used without the relevant knowledge and whether this could therefore be a systematic problem.

5.2 Identified supply chain communication processes

5.2.1 Creation and provision of safety data sheets

The obligations on the creation and provision of safety data sheets along the supply chain is regulated according to REACH article 31 as were already mentioned in chapter 2.4. As such a supplier of a substance or a mixture shall provide the recipient of the substance or mixture with a safety data sheet compiled in accordance with Annex II if any of the following criteria are met:

- where a substance or mixture meets the criteria for classification as hazardous in accordance with Regulation (EC) No 1272/2008; or
- where a substance is PBT or vPvB in accordance with the criteria set out in Annex XIII; or

- where a substance is included in the list established in accordance with Article 59(1) for reasons other than those referred to in points (a) and (b).

Further the SDS has to be supplied free of charge on paper or electronically no later than the date on which the substance or mixture is first supplied. In this survey the experts were asked on how they create their own safety data sheets and which information they implement, as well as if and how they receive safety data sheets from the supplier. The following responses were obtained categorized by the position along the supply chain the respondents had.

Manufacturer

One manufacturer (M1) stated that it uses, among other things, test results it has commissioned itself to prepare the SDS. The manufacturer stated that it provides an SDS for all products[12] including non-hazardous substances, in the respective language of the destination country. Each dispatch of goods triggers an automatic SDS (e-mail or paper) to the recipient of the goods from the IT system. This is intended to ensure a seamless flow of information, including the subsequent dispatch of SDSs in the event of significant changes up to 12 months after receipt of the goods. In addition, he gives distributors/users access to safety data sheets via the homepage with highlighting revised sections.

Downstream users

The downstream users surveyed (DU1, DU2, DU4 and DU5) stated that safety data sheets are provided digitally by the supplier without being requested to do so. In addition, DU1, DU2 and DU4 are regularly informed about updates. DU3 stated that safety data sheets are not provided by the supplier without being requested and that no reason for this was given when asked. Updates to safety data sheets are therefore regularly requested by DU3 and DU4. In all cases, the information is presented in an understandable language. All downstream users that responded to the survey provide their safety data sheets in a digital format to downstream users along the supply chain and they proactively inform about updates as well.

Distributor

Both distributors (T1 and T2) stated that safety data sheets are provided digitally by the supplier without being requested. As a distributor, the original SDSs of the suppliers are forwarded to the customers. T1 is regularly informed about updates, while T2 stated that it does not receive or request automatic updates. T1 also stated the SDSs are checked for plausibility and completeness as standard. For both distributors, a safety data sheet is requested from the manufacturer or importer if a mixture with D4 is classified as non-hazardous.

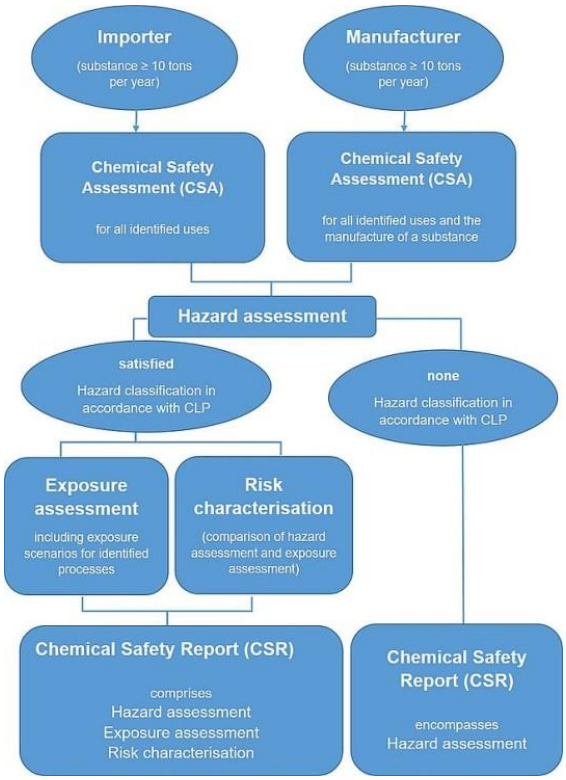
5.2.2 Identified use and exposure scenarios

Should the chemical safety assessment of a substance or a mixture reveal that it fits the criteria to trigger a hazard classification (physical-chemical hazard, health hazard, environmental hazard), or is the substance or mixture of concern a PBT- or vPvB-substance or classified as PBT or vPvB, then in addition to the chemical safety and hazard assessment an environmental assessment and risk characterisation have to be performed. The PBT classification for mixtures is still in a transitional period and depending on different criteria has to be implemented latest by May 2028. This would then trigger a classification for mixtures containing PBT substances in >0.1% and thus make exposure assessments and extended safety data sheets mandatory for

[12] Unfortunately it could not be verified if product means in this regard substances, mixtures or articles.

these mixtures. Figure 7shows a decision tree on which assessments have to be performed depending on different criteria (PBT criteria not yet included).

Figure 6: Decision tree on the assessments that need to be performed



Source: (IFA, 2024)

The additional exposure assessment and risk characterisation must be included in the chemical safety report and relevant exposure scenarios must be added to the safety data sheet in the form of an eSDS. The recipient of an eSDS may only use the substance or mixture under the conditions displayed in the exposure scenario. Should the use of the downstream user not be listed in the exposure scenario, this should be communicated to the supplier to prepare an additional exposure scenario. Should the supplier not prepare an additional exposure scenario, the downstream user must check whether he is obliged to prepare his own chemical safety report covering the relevant exposure scenario for his use. In previous studies (REF-5 project) the majority of companies (77%, n=456) reported to supply the same exposure scenario annex to all their customers without selecting just the relevant exposure scenarios for that specific customer (European Chemicals Agency, 2018). It was also pointed out, that the inclusion of a table of content in that case was the preferred action, to make it easier for the downstream user to find the most appropriate exposure scenario for his case.

In this survey the experts were asked if they receive feedback from actors along the supply chain that uses are not covered in the exposure scenarios or if they receive an eSDS that contains exposure scenarios and whether it also includes their use. The responses are shown below divided into the positions along the supply chain.

<u>Manufacturer:</u>

One manufacturer of D4 (M1) stated that it has considered every identified use for which the product is intended and everything that is required for treatment in the CSR within the meaning of REACH in the safety data sheet. In addition, the manufacturer stated that it has sufficient knowledge of the customers and typical industry uses to ensure the reference to registered uses in the exposure scenarios. The manufacturer states that in very rare individual cases it receives feedback from downstream users whose uses are not covered by the exposure scenarios. If the proposed use is not safe or outside the industrial sector, the SDS tends to advise against specific applications. The company explicitly states in the SDS: "The use of the product should be limited to industrial applications where the product is used as an intermediate or as a laboratory chemical. The use of the product in the commercial sector or by private end users, including in the form of mixtures, is not supported." This is communicated directly to the requested user.

Downstream User:

One question towards downstream users during this survey was, whether safety measures to minimize emissions when used as intended are described in a sufficiently comprehensible manner and two downstream users (DU2 and DU5) stated that this is the case for them. Three other downstream users (DU1, DU3 and DU4) stated, that the safety measures that are described resemble, or are similar to the safety measures written in chapter 6 of the SDS, which contain information on safety measures for accidental release. As no safety data sheets were uploaded during the survey, it was not possible to check to which extend the information from chapter 6 was reused The downstream users were also asked if they would also implement insufficiently described emission reduction measures or emission reduction measures from outside their industry and out of the five respondents, only DU1 would implement emission reduction measures in such a case. The three respondents DU2, DU4 and DU5 would not implement measures in such a case but communicate this situation to the supplier and ask for the emission reduction measures in the safety data sheet to be reviewed/adapted. Only DU3 would neither implement insufficiently described emission reduction measures, nor communicate this to their supplier. Following this question, the downstream users were also asked if they would consider creating a chemical safety assessment for their own use according to Title V, Article 37ff of the REACH regulation in case the emission reduction measures are insufficiently defined. DU1, DU3, DU4 and DU5 would not consider this but communicate this issue to the supplier to derive emission reduction measures. Only DU2 would in such a case also consider creating a chemical safety assessment for their own use according to Title V, Article 37ff of the REACH regulation. However, DU2 is also the only respondent stating, that they do not know the recipients of their products well enough, to ensure the connection to the registered uses in the exposure scenario, whereas all other respondents answered that they have sufficient knowledge of their customers. DU1, DU3, DU4 and DU5 also stated that their own use was covered in the first SDS they obtained from the supplier. DU2 however had to communicate to the manufacturer or supplier, that their own use was not covered in the first SDS they obtained from the supplier. Two respondents, DU2 and DU4, stated that they receive feedback from their recipients, if the recipients corresponding use is not covered in the SDS. DU3 stated, that they do not receive feedback from their recipients, whereas DU1 and DU5 stated this question to be irrelevant for them.

Distributors:

Both distributors (T1 and T2) stated that they do not receive feedback from users in cases where uses are not shown in the safety data sheet. One distributor (T2) also stated that it receives extended safety data sheets containing exposure scenarios. One distributor (T1) though stated that it does not receive exposure scenarios as D4 is only included in concentrations of <10% or <1,5% in most cases. However according to the updated Regulation 1272/2008 from 01.12.2023

(Annex I Paragraph 4.3.3.) as stated above, mixtures containing PBT substances in concentrations higher than 0.1% are also to be classified as PBT (transitional period until May 2028 for mixtures already on the market), in which case an environmental assessment would be mandatory if produced in tonnages of >10 t/a from that point onward. As such from that time onward the supplier would also have to include exposure scenarios with his SDS in form of an eSDS.

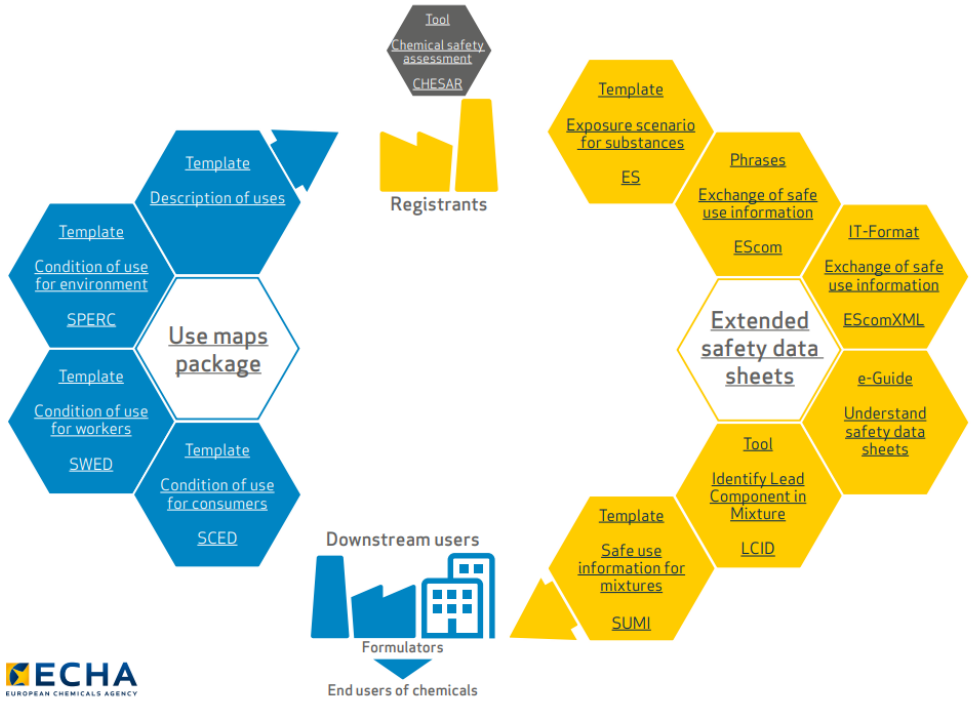
In conclusion, most respondents reported that their use was already covered when they first received the SDS and if not, it was communicated to the supplier/manufacturer. Further only one respondent mentioned they would not implement insufficiently described emission reduction measured nor communicate this to the supplier/manufacturer. Unless this is due to the measures not concerning their own use, this clearly shows a communication problem resulting in the loss of information. Aside from this all respondents reported that communication between manufacturers/suppliers was working and in place in case of discrepancies of SDS contents or identified uses. One Distributor stated that they do not receive eSDS even though D4 is often included in concentrations of <10% or <1.5%. As the new CLP update from December 2023 still states transitional periods for mixtures already on the market until latest May of 2028, exposure scenarios will have to be included by that point in time.

The focus in this project was not the evaluation of individual SDS. Further, no respondent used the option to upload relevant (e)SDS for investigation during this study. As a case study, publicly available SDS of D4 as pure substance (6 SDS) or in mixtures (2 SDS) from the internet were sourced during a short desk research. As the investigated SDS were downloaded from different manufacturers/downstream users and not requested from the supplier, no appendices or eSDS were available for the screening. As such the only information that could be investigated were concerning personal safety measures or equipment, information on storage and handling or in some cases also measures on environmental exposure. It revealed that the information provided in chapter 8 regarding the exposure control, contain roughly the same core information concerning D4 among all the SDS reviewed. However, no detailed technical measures could be found such as minimal purification measures for air or water needed and thus not evaluated during this project.

5.2.3 Guidance offered by ECHA and other tools used to facilitate data generation and for data communication

The ECHA has collaborated with industry stakeholders and Member States to create guidance products supporting the communication of safe use information in the supply chain. These products, collectively known as "Exchange Network on Exposure Scenarios (ENES) tools," include harmonized templates, IT tools, and guidance to ensure consistent and clear presentation of information required by REACH actors (an overview on tools improving communication on the safe use of chemicals is presented in Figure 7) (European Chemicals Agency, 2024b). The tools should help companies to minimize variability in formats, enhance clarity, and facilitate easier retrieval of information. By improving the flow of realistic and meaningful data on use and exposure, these tools aim to enhance communication in the supply chain.

Figure 7: Improving communication on the safe use of chemicals



Source: ECHA website (789d0235-5872-4527-baad-db681edefdb0 (europa.eu)) (accessed 2.5.2024)

In the REACH-REF-5 project the level of awareness of these products amongst the "first level supplier" and "supplier" companies was analysed (European Chemicals Agency, 2018). One finding was that 64 % of the inspected companies (n=464) used specific tools/methods to facilitate the generation of extended SDSs. The following tools were reported most frequently (multiple options were possible):

- Exposure scenario templates (from guidance document or CSA via Chesar) (42%)
- Use Map information from (downstream) sectors/companies (20%)
- For mixtures: Safe Use of Mixtures Information (SUMI) or Lead Component IDentification (LCID) methodology (13%)
- ESCom standard phrases (12%)

Other tools reported were e.g., information/assistance from consortiums, external consultants, own software tools, ChemGes software, Chemeter software.

When it comes to the communication of the extended SDS the following tools were reported in REF-5 most frequently:

- For substances: exposure scenario template given in guidance document (33%)
- For mixtures: Safe Use of Mixtures Information (SUMI) or Lead Component IDentification (LCID) methodology (19%)

Other tools used for communicating were e.g., own software tools, communication by email, external consultants, SAP, use of consortiums.

The findings of REF-5 overall indicate a modest level of awareness and understanding among registrants and downstream users regarding available tools/methods, which was expected at that time due to the development of the ENSES-tools end of 2016 whereas the operational phase of REF-5 started beginning of 2017.

In the survey performed during this project stakeholders were asked for their awareness of the ECHA initiatives (e.g. exposure scenario templates) and/or other tools used.

Awareness and use of ECHA initiatives

The manufacturer surveyed (M1) was aware of the ECHA initiates but does not use them because in the opinion of the stakeholder the material is too generic. Not all DUs responding to the survey were aware of the initiatives taken by ECHA (e.g. exposure scenario templates) to support supply chain communication. Three downstream users were aware of ECHA's initiatives (e.g. exposure scenario templates) to support supply chain communication and one company (DU2) claims to use them, while another (DU5) does not. The other company (DU3), on the other hand, finds them unhelpful because the guidelines are too theoretical. Two other downstream users (DU1 and DU4) were not aware of ECHA's initiatives.

The ECHA guidance on the preparation of safety data sheet was considered to be helpful by the manufacturer and all of the downstream users surveyed.

In contrast, the ECHA guidance on communication on PBT substances in articles was considered to be helpful not by all respondents. The manufacturer and three downstream users (DU1, DU2, DU4) thought that the guidance is helpful, one downstream user was not aware of the guidance (DU5) and another downstream user (DU3) stated that this guidance in not relevant for his company.

Information tools

An association emphasises that the eSDS is the main source of information on the safe handling of hazardous substances. The respondents were asked for additional information tools (e.g. email newsletters, hazardous substance databases, etc.) they use for safe handling of D4 with regard to the environment. The following tools were mentioned:

- A toolbox for emission reduction measures on the trade association's website (stated by a manufacturer).
- Information tools provided by associations (IHO, IKW, VCI, VDMI, VDL) (stated by three downstream users (DU2, DU4, DU5), no further information was given)
- Information tools for accessing safety data sheets or tools with access to further information on the chemical or mixture provided by the manufacturer/distributor (stated by three downstream users (DU2, DU4, DU5))
- Customer portals provided by downstream user to their own end user (stated by a downstream user (DU3))
- Information tools to make updates of safety data sheets available (DU3)

One downstream user (DU1) was not aware of any information tools. In addition, the user states that their manufacturer/distributor does not offer any special tools and that the company itself does not use any tools for data communication to the end user.

Both distributors surveyed also were not aware of any additional information tools. However, one distributor (T1) mentioned that the manufacturer offers an online download of the SDS

which is perceived as helpful. The other distributor (T2) provides their end users with information on its website.

Overall, the received responses indicate large discrepancies between the company's handling of data of D4 with regard to the environment, the use of specific tools and the access to additional information tools. While ECHA guidance documents were in general known by the companies surveyed with only some exemptions, additional ECHA initiatives (e.g. exposure scenario templates) were only know by some downstream users. Interestingly from the downstream users who were aware of these tools, only one downstream user uses these tools, the other two does not and one of them even claimed to find them unhelpful. There seem to be additional information tools by associations available, but not all downstream users surveyed were aware of these tools or had access.

5.3 Protective measures taken by companies for the safe handling of PBT substances

5.3.1 Company representative

While the REACH Regulation does not contain an explicit requirement for the designation of a specific "company representative" for chemical safety and the environment, there are nevertheless specific obligations for companies in connection with the assessment and safe handling of chemicals (see chapter 2.4). This may include the need to appoint specialised staff with knowledge of chemical safety and environmental protection to ensure compliance with REACH requirements. In addition, according to REACH Regulation Annex II Paragraph 1.3, at least the e-mail address of a person responsible for the safety data sheets in the company must be stated on the safety data sheets. This applies to all positions along the supply chain.

With the exception of one downstream user (DU5), all survey participants, regardless of their role in the supply chain, stated that they have a company representative who deals with the topic of chemical safety and the environment. The downstream user without a company representative stated that the small size of the company was the reason for this and that the associated tasks are divided among the staff. Even though the majority of the participants communicated that their company representative receives further training, information on the professional background of the company representative and the type of further training differed widely between the survey participants as can be seen in Table 7.

Table 7: Competent person for SDS and further training of personnel

Survey participant	Company representative available	Receives further training	Comment
Manufacturer (M1)	+	Yes	Specialist education and further education
Distributor (T1)	+	Yes	Knowledge fresh up training and receiving help from external service providers
Distributor (T2)	+	No	-

Survey participant	Company representative available	Receives further training	Comment
Downstream user (DU1)	+	Yes	At KIT and receiving help from external service providers
Downstream user (DU2)	+	Yes	Further training as needed, specialist knowledge and through BG training courses
Downstream user (DU3)	+	Yes	External training courses tailored to requirements
Downstream user (DU4)	+	Yes	Dangerous goods annually, SDS if required and chemicals legislation by associations
Downstream user (DU5)	-	-	Task distributed among several employees

From the feedback received some might conclude that the company representative does not appear to be a person with a standardised qualification who also does not receive standardised training. In most cases, it was also stated that training is only provided as required. Training on demand can create a risk that important changes to regulatory requirements are missed. This risk is particularly high the smaller the company is, as in this case the company officer responsible for chemical safety and the environment also has other roles in the company. This problem is also encountered if there is no company officer due to the small size of the company and the tasks are distributed among several employees. In one case, it was also stated that the company officer does not receive any training, which also represents a major risk that important regulatory changes or innovations, such as the adaptation of regulatory processes, will be missed.

5.3.2 Updating safety data sheets

As already mentioned in chapter 2.4.2.1 an SDS must be updated immediately as soon as one of a couple different situations in accordance with Article 31 Paragraph 9 of the REACH Regulation arise, or different occurrences take place. These incidents can be found on an ECHA website and include the deadline for updating the SDS (European Chemicals Agency, 2024c):

- Any changes in the status of the registrant, such as being a manufacturer, an importer or a producer of articles, or in their identity, such as their name or address. (3 months)
- Any change in the composition of the substance (3 months)
- Changes in the annual or total quantities manufactured or imported by the registrant (3/6 months in case of testing proposals)
- New identified uses and new uses advised against for which the substance is manufactured or imported (3 months)

- New knowledge of the risks of the substance to human health or the environment of which the registrant may reasonably be expected to have become aware which leads to changes in the SDS or the CSR (6 months)
- Any change in the classification and labelling of the substance (6 months for self-classification)
- Any update or amendment of the CSR or the Guidance on safe use (12 months)
- The registrant identifies the need to perform a test listed in Annex IX or Annex X, in which cases a testing proposal must be submitted (6/12 months)
- Any change in the access granted to information in the registration (3 months)

Accordingly, there is no unique fixed time frame for when a safety data sheet must be updated. However, as processes regarding SVHC, CLH or restrictions always contain a public consultation as well, decision dates on changes regarding these topics are predictable. Further, the ECHA Guidance document on SDS should be taken into account, which also gives an overview on the need for updating an SDS (ECHA guidance document chapter 2.8) (European Chemicals Agency, 2024d). As part of the survey, the experts were asked how often safety data sheets are updated in their company. In addition to the event-related reasons, as prescribed by the REACH Regulation, they also stated the periods in which updates take place (annually, every 2 years, etc.). Since the answers in connection with the question leave some room for interpretation, it can be assumed that if there are no event-related reasons for an update within a certain period of time, the data sheet is checked to ensure that it is up to date and this is considered an update. Even if this is not prescribed by the REACH Regulation, such an additional temporal update helps to minimise data gaps if one of the situations requiring an update that has occurred is not communicated along the supply chain. However, it must also be noted that updating a safety data sheet for reasons other than the required situations takes additional time and this means a lot of extra work, especially for companies that process or create many safety data sheets.

Table 8: Information on the number of managed safety data sheets and information on the frequency of updating

No.	Role in the supply chain	Number of SDS	Update details
M1	Manufacturer	> 500	Annually, as required (in the event of significant changes)
DU2	Downstream user	> 500	Occasion-related (as required)
DU3	Downstream user	> 500	Occasion-related, in the event of recipe changes or classification changes, at the latest every 2 years
DU4	Downstream user	>500	Annually & if reclassifications of raw materials are to be taken into account
DU1	Downstream user	100-500	Annually
T1	Retailer	100-500	Occasion-related (for change notifications, checking the SDS at regular intervals)

No.	Role in the supply chain	Number of SDS	Update details
T2	Retailer	100-500	Every two years
DU5	Downstream user	20-50	Occasion-related (in the event of a change in raw material SDS/ laws/ recipe adjustment

5.3.3 Internal company protective measures

If a substance or mixture, which is to be placed on the marked, fulfils the in chapter 5.2.2 mentioned criteria (production over 10 t/a, PBT or vPvB substance/mixture), then according to the REACH regulation, additional exposure assessments and risk characterisations have to be performed in the chemical safety report. This includes the derivation of exposure scenarios, including risk management measures and conditions of use in accordance with Annex II, which have to be included in an annex to the SDS (eSDS).

In a previous project (REF-5), it was already found that of the companies reported, 75 % (n=328) have implemented the operational conditions and risk management measures described in the exposure scenarios without any changes, while the rest reported to have used scaling based on information given by the supplier (European Chemicals Agency, 2018). 46 % (n=362) of the companies reported to apply additional safety measures, most often complementary to the measures for control of workers' exposure given in the exposure scenarios.

In another workshop (REACH2SDS) from the German federal institute for occupational safety and health (BAuA), it was also worked out, that a one-to-one transfer of exposure scenarios to workplaces is usually not possible and that an adaption of the risk management measures to the individual workplace is almost necessary (Schumacher et al., 2022). This however requires the communication of the exposure scenarios along the supply chain.

As such the experts in this survey were asked, if the internal company protective measures are based on the safety data sheets alone, or if additional exposure scenarios were also communicated in the form of extended safety data sheets and if those were used to derive internal safety measures for the use of the substance. Further it was investigated whether and how these safety measures were communicated internally and what was done to make sure they were uphold. The responses from the experts are shown below summarized into the position of the supply chain.

Manufacturer:

Manufacturers have a slightly different situation concerning exposure scenarios, as being the first instance along the supply chain, they have the responsibility to develop and derive exposure scenarios and corresponding uses for the other positions along the supply chain. As such different questions were asked on which information was used to derive their internal safety instructions.

One manufacturer (M1) reported that they derived their internal safety instructions for D4 regarding the environment for the CSR and that they also used information that is not in the SDS. Measured values, information from suppliers and customers, information from trade associations and registration data under REACH were used. The requirements in accordance with authorisation notices were taken into account, as well as internal projects and investments to reduce emissions. Internally, the measures are communicated through company-related training and sensitisation of the relevant committees and employees. Regular training sessions

provide opportunities for questions and discussions. Compliance is ensured through internal documentation. The success of the measures is ensured by monitoring the facilities and measuring emissions.

Associations:

One association emphasises that the eSDS is the main source of information on the safe handling of hazardous substances. As a rule, the downstream user does not have the manpower/knowledge or resources to carry out the research themselves and is dependent on the information from the manufacturer.

Another association states, that the greatest risk to the safe handling of D4 with regard to the environment lies with the downstream users. If the risk of a hazardous substance is not known to downstream users, processes to control the risk at the companies cannot be adapted. Thus, again showing the importance of exposure scenarios to be communicated along the supply chain.

Downstream User:

DU1 has a release routine for each received raw material/mixture in which the risk to humans and the environment is assessed. The downstream user specifies that the data from all sections of the safety data sheet and the relevant environmental information in the exposure scenario are to be taken into account for the risk assessment. The downstream user states that he has not derived any in-house protective measures for D4 for the environment, as the amount of D4 used in the purchased mixture is < 0.01%.

DU2 derives internal protective measures based on the information in the safety data sheet, e.g. by creating operating instructions and work processes. This is done by a working group that assesses substances and derives measures. For the risk assessment, the data from all sections of the safety data sheet are taken into account and the relevant environmental information is considered in the exposure scenario. Internally, the measures are communicated to employees through training and instruction and compliance is ensured by monitoring activities. This downstream however does not use D4 according to his own information.

DU3 states that it does not have any specific measures for D4 but has established general occupational health and safety measures, that affect all chemicals (substances and mixtures), such as occupational hygiene and the appropriate handling of chemicals in general (operating instructions). Information from the safety data sheet and other information was used for this purpose. The downstream user states that for the risk assessment the data from all sections of the safety data sheet and the relevant environmental information in the exposure scenario are taken into account. The downstream user further states that relevant environmental information in the exposure scenario is only used to derive measures if they are very specific measures and, as often no eSDS is available, because mixtures are primarily used. The measures are passed on internally to employees through annual training courses. Compliance is ensured by supervisors who support employees in applying the measures.

DU4 states that no special internal protective measures for D4 for the environment are derived from the safety data sheet, as according to the user the low content does not require any special measures. Furthermore, information from the safety data sheet is used to exclude hazard classes and SVHC, carry out risk assessments and prepare operating instructions. The downstream user states that the data from all sections of the safety data sheet and the relevant environmental information in the exposure scenario should be taken into account for the risk assessment.

DU5 also states that it does not derive any internal safety measures for D4 for the environment from the safety data sheet, as D4 is generally avoided. Information from the safety data sheet

continues to be entered into a database for use within the company. Furthermore, all sections of the safety data sheet are used by the downstream user for the risk assessment. However, no relevant environmental information is taken into account in the exposure scenario to derive measures, as the safety data sheet is used without an exposure scenario.

Distributor:

T2 states that the information from the safety data sheet is generally used to categorise their own products. They further state, that for a safe use of the substance, data from part 6, 8 and 15 as well as 7, 12, 13, 14 and 16 from the SDS are used and that relevant environmental information from the exposure scenarios are used to derive measures. However, contradictory to that the distributor also states that they themselves do not derive internal safety measures regarding the environment due to missing information concerning the safe use of D4.

Considering all the responses, a mixed situation regarding the derivation of internal safety measures in regard to the environment from extended safety data sheets could be obtained. In multiple cases, exposure scenarios from extended safety data sheets were used to derive internal safety measures. However, in some cases the extended safety data sheets or exposure scenarios were not provided by the supplier. This was justified by the nature of the mixture either not triggering a classification according to the CLP regulation or not being used or produced in sufficient amounts (10t/a). Thus, in such cases exposure scenarios or exposure assessments were not available to be used for the derivation of internal safety measures. However, since no SDS were uploaded by any of the respondents, further investigation on the content of the corresponding SDS in regard to the information given during the survey was not possible.

With the update to the CLP regulation also including the PBT classification of mixtures if >0.1% of a PBT substance is included though, some of the arguments stated in this survey (concentration of D4 is too low to trigger a classification) will become invalid after the transitional period for mixtures already on the market on May 1st, 2028. These will then also be required to have exposure assessments and extended safety data sheets until the substance D4 is included in concentrations of <0.1%.

In contrast to this, the respondents all have similar actions in force, to implement and enforce the internal safety measures in their companies.

5.4 Data gaps in the supply chain

Data gaps in supply chains refer to missing or incomplete information within the flow of data that supports and manages the various processes of the supply chain. These gaps can occur at different stages of the supply chain, from sourcing raw materials to delivering the final product to the end customer. High-quality, accurate data is crucial for making informed decisions, optimising processes and ensuring supply chain efficiency.

Several research projects carried out by EU or national initiatives show that, despite considerable efforts to date, communication within the supply chain does not work as intended and that there are data gaps in supply chain communication, e.g. due to missing or incorrect information in the SDS (for more information see chapter 3). This is also experienced by enforcement authorities, who encounter similar issues as companies but from a distinct perspective (Schumacher et al., 2022).

On the other hand, during the project several industry associations emphasised that in their experience communication along the supply chain is reliable and that there are no known problems in relation to D4. This was supported by all downstream user and retailers surveyed

who were not aware of any information gaps along the supply chain that hinder the safe handling of D4 with regard to the environment.

In general, the risk of loss of information during the supply chain communication was seen by all actors of the supply chain. Three downstream users (DU1, DU2 and DU3) see the greatest risk of loss of information among downstream users or end users due to a lack of knowledge or among formulators when combining the different safety data sheets of the raw materials. One downstream user (DU5) sees the greatest risk for the loss of information with importers, only representatives (OR) and distributors. Another downstream user (DU4) sees the greatest risk for the loss of information with importers and only representatives (OR) since the implementation of European regulations in some cases only take place on request.

However, it is assumed that the greatest risk of loss of information lies with downstream users, where there are gaps in knowledge of regulatory requirements or where the hazards of substances are not known (especially in the case of small companies).

5.4.1 Quality of safety data sheets

The Safety Data Sheet (SDS) serves as the conduit for conveying information about the safe utilization of a substance down the supply chain and establishes the link between chemical safety and occupational safety and health. Complete and accurate data is required as the effectiveness and reliability of risk assessments is directly dependent on the accuracy of the information on which they are based.

In the past, several projects and initiatives have assessed the quality of SDSs and identified gaps in completeness and quality (see also chapter 3). In the REF-2 project the content of the SDSs was assessed in relation to sections 1, 2, 3, 8 and 15, and deficiencies of varying nature and extent were found in 52% of all evaluated SDSs (European Chemicals Agency, 2013).

In the survey performed in this project all downstream users (DU1, DU2, DU3, DU4 and DU5) state that the safety data sheet explicitly refers to the PBT status of D4 and the associated requirement to minimise discharges into the environment. The downstream users surveyed further state that they have not yet observed any discrepancies between the main text of the SDS and the exposure scenarios and their identified uses from the eSDS. However, two of these downstream users (DU1, DU3 and DU4) state that they do not have an annex with exposure scenarios, although this was not communicated to the manufacturer/distributor. One of the users (DU4) justified this by not classifying the mixture as (environmentally) hazardous.

T1 states that the SDS explicitly refers to the PBT status of D4 and the associated requirement to minimise discharges into the environment. The distributor states that it does not have an annex with exposure scenarios. The distributor trades in mixtures for which no separate exposure scenarios are available. D4 is contained in concentrations < 10 % (mostly < 1.5 %). Following the amendment to the CLP regulation, which now encompasses the PBT classification of mixtures when a PBT substance exceeds 0.1% concentration, certain assertions made in this survey (such as the D4 concentration being too low for classification) will lose validity post the transitional period for mixtures already available in the market by May 1st, 2028. Subsequently, these mixtures will necessitate exposure assessments and updated safety data sheets until the D4 substance is present in concentrations less than 0.1%.

T2 states that the safety data sheet does not explicitly refer to the PBT status of D4 and the associated requirement to minimise discharges into the environment, although there is an annex with one or more exposure scenarios. If no information on the PBT status of D4 is given in the SDS, the SDS can be considered non-compliant.

Overall, based on the responses in the survey, no direct conclusions can be drawn on the quality of SDS because the survey did not include an evaluation of any SDS. It's important to note that SDS play a critical role in communicating information about the properties and safe handling of chemical substances. A comprehensive assessment of SDS quality involves thorough evaluation, adherence to regulatory standards, and accuracy in conveying essential information to ensure the safe use of chemicals in various applications.

5.4.2 Impact of data gaps on environmental emissions and consequences

SDS, play a crucial role in communicating information about the properties and hazards of chemicals. If SDS are not properly prepared or understood, it can have several consequences for the environment. One essential consideration is that, while the responsibility for preparing an SDS lies with the manufacturer or supplier, different actors in the chemical supply chain are obligated to convey end-use and application details to the suppliers. This is the only way to ensure a thorough incorporation of such specifics in the SDS.

According to (Willey, 2012) SDSs are frequently prepared primarily for compliance rather than fulfilling the essential purpose of informing and safeguarding human health and the environment.

Discrepancies in quality may emerge when an SDS lacks adequate details regarding the severity of the hazardous properties associated with substances or mixtures. Issues may also arise due to insufficient information, the competence of the individual preparing the SDS, and shortcomings in communication within the supply chain (Nayar et al., 2016). The authors assessed 200 SDSs of chemicals used in the aerospace sector and could conclude that the quality of information for non-hazardous chemicals is better than for hazardous chemicals. SDSs for chemicals with the potential to cause severe damage to infrastructure, community, human health, and the environment lack basic information. They specifically highlighted deficiencies concerning information related to safety hazards. This indicates, according to the authors, either a lack of expertise or an assumption by suppliers and manufacturers that all end users handling chemicals during transportation, use, and disposal possess sufficient competence. The inadequate quality of information on safety hazards also implies limited interaction between suppliers/manufacturers and end users of chemicals, as well as a failure to reference best practices in managing safety hazards (Nayar et al., 2016).

Improper or insufficient information on substances of concern can have far-reaching impacts on both the environment and human health. One major consequence is the mismanagement of chemicals, where inadequate SDS contribute to an increased risk of spills, leaks, and improper handling. This can lead to the release of hazardous substances into the environment, causing pollution of air, water, and soil.

The lack of accurate and accessible information poses risks to workers who may be unaware of potential dangers associated with certain chemicals, resulting in accidents and incidents that further contribute to environmental contamination. During emergencies such as spills or leaks, inadequate understanding of SDS hampers effective emergency response, exacerbating environmental damage. Chemicals not properly managed due to incomplete or inaccurate SDS may find their way into ecosystems, causing harm to plants, animals, and microorganisms. This can lead to long-term ecological damage as persistent pollutants accumulate in various environmental compartments. Improper handling and disposal of chemicals without sufficient information can result in soil and water contamination, impacting agricultural productivity, harming aquatic ecosystems, and posing risks to human health through contaminated food and

water sources. Additionally, inappropriate chemical handling can contribute to air pollution, affecting both the environment and human health.

For PBT substances, additional environmental impacts come into play. These substances can persist in the environment for extended periods, leading to chronic exposure for organisms. Their ability to accumulate in the tissues of organisms at higher trophic levels in food chains can result in biomagnification, posing greater risks to predators, including humans. PBT substances also have the potential to disrupt ecosystems by affecting the balance of populations within food webs, leading to population declines and alterations in community structures. Their persistent and volatile nature allows for long-range transport through air and water currents, contributing to widespread contamination in regions far from the original source. Remediating areas contaminated with PBT substances presents challenges due to their persistence, requiring long-term monitoring and management efforts to mitigate their environmental effects. Overall, the proper understanding and communication of information on substances of concern are crucial for mitigating these environmental and human health risks.

Respondents were asked how far they are aware of impacts of information gaps on the environment. Four of the users (DU1, DU2, DU3 and DU4) are not aware of any effects of information deficits on the environmental emission of D4, whereas one user (DU5) indicates the release of D4 into the environment as an effect of information deficits on environmental emissions of D4. Furthermore, no retailer is aware of any effects of information deficits on environmental emissions from D4.

5.5 Recommendations for actions to improve supply chain communication

Although, the study – due to a limited response rate - could not show systematic problems as regards communication along the supply chain, several provided replies suggest that there are difficulties that need to be overcome to ensure a more comprehensive and transparent communication structure between all involved actors. Improving supply chain communication for both industry and authorities involves a collaborative effort to enhance coordination, transparency, and responsiveness. As such recommendations for possible actions are divided into industry and agency groups. With the feedback and responses received from a modest participation in the stakeholder survey, as well as through previous projects on the communication along the supply chain the following recommendations were derived:

For Authorities:

- **Streamlining data formats, standardized digital format for eSDS:** Respondents in this stakeholder survey reported that it would be a great improvement, if the eSDS were available in a standardised digital format so that downstream users in particular could easily read and process information digitally in their systems. This point was emphasised by both the downstream users surveyed and the associations. This could also improve the interpretation, reading and understanding of eSDS and a faster implementation into or derivation of internal safety measures for companies.

- **Soft-skill trainings for company representatives:** As the appointment of a company representative and the regular training of said representative lies within the hands of industry, authorities could also support strengthening the expertise these employees need to reach higher quality SDS or eSDS. Through the provision of trainings tailored to the position of company representative handling SDS, the interpretation of received SDS, creation of new SDS for downstream users as well as the derivation of internal safety measures could be improved, thus leading to less non-compliant SDS. Other supports such as checklists for SDS,

which already exist, could need either more advertisement or more concise tailoring to the needs of the company representative depending on their place along the supply chain.

- **Regular exchange with stakeholders**: Regular exchanges with stakeholder groups, e.g. involving industry representatives, government officials and regulators through regular meetings (e.g. quarterly) could establish a better feedback culture between industry and authorities. This could result in more opportunities to discuss challenges, share insights, and collaboratively address issues affecting the supply chain, so that quicker and more fitting solutions can be found.

- **Investment in infrastructure**: Allocate resources to enhance communication infrastructure, including digital platforms and networks, to ensure smooth information exchange between industry stakeholders and/or regulatory bodies. This may include collaborative investments in technology, data-sharing platforms, and information security. Creating secure and centralised information-sharing platforms can ensure regulatory compliance and conducting thorough risk assessments.

- **Standardised reporting requirements**: Develop a regulatory framework that encourages and enforces standardised reporting requirements and communication practices within the industry. Foster partnerships between authorities and private sector stakeholders to enhance communication infrastructure. This can include guidelines for data sharing, reporting, and collaboration. Most stakeholders surveyed were aware of the ECHA guidance documents on preparation of safety data sheet and PBT substances in articles and considered them as helpful. It might be discussed whether additional guidance on communication requirements and best practices for different actors in the supply chain would be beneficial.

For Industry:

- **Appointment of a company representative:** Even though it may be difficult especially for small companies to implement, appointing one company representative (or more if the number of safety data sheets to handle reaches certain amounts) in charge for the handling of safety data sheets could provide more certainty. This should not keep the representative from fulfilling other duties within the company, however by not splitting up the task of handling SDS between employees, more expertise could be concentrated in one person, which could result in a higher quality of SDS.

- **Continuous education and training:** As already implemented by most respondents from this survey, the provision of continuous education and training of a responsible person for chemical safety and the environment (e.g., a company representative) on a routinely basis could help to stay up to date with current or upcoming legislative changes or obligations. This could reduce the risk of non-compliance in SDS.

- **Tools for guidance**: Use the available information tools, such as ECHA guidance documents and or those generated by the Exchange Network on Exposure Scenarios (ENES) to prepare SDS and establish further risk measurements. This can contribute to improving the quality of the exposure scenarios/extended SDSs. Registrants are encouraged to invest effort in suggesting functional risk management measures within the chemical safety reports and corresponding exposure scenarios in SDSs. Clarity and practicality, using specific and self-explanatory language, are essential in these proposals. The effectiveness of this information is vital to actively assist downstream users in effectively managing risks associated with the supplied substances.

- **Quality assessment and feedback**: All actors in the supply chain (especially downstream users) should check received SDS for their quality and plausibility before proceeding with the risk assessment and communicate any incorrect or inappropriate information in the extended SDS they receive back to the supplier. This will contribute to enhancing the quality of information for everyone within the downstream supply chain. A more transparent exchange with other actors along the supply chain seems beneficial to reach a high level of completeness for SDSs.
- **Industry standards and best practices**: Collaborate with industry associations and other initiatives to establish and adopt standardised communication protocols and best practices. This helps in creating a common language and streamlining information exchange. Regularly assess performance against industry standards and regulatory needs and identify areas for improvement.
- **Interoperable technologies**: Ensure that technologies used across the industry are interoperable. This allows for seamless integration of systems and data exchange between different organizations within the supply chain. Invest in collaborative digital platforms that allow industry partners to share real-time information, updates, and forecasts. This facilitates better coordination and responsiveness across the supply chain. Some stakeholders in the survey already mentioned to use tools with access to SDS or to further information on the chemical or mixture provided by the manufacturer/supplier.
- **Supply Chain Visibility Initiatives**: Support and participate in initiatives that promote end-to-end visibility in the supply chain. Unfortunately, the response rate to the survey in this project was relatively low. For future projects, we would encourage industry to engage in dialogue with associations and authorities to share their difficulties and opportunities for improving supply chain communication.

By implementing these recommendations, both industry and authorities can work together to create a more resilient and responsive supply chain ecosystem. Improved communication fosters better collaboration, risk management, and overall efficiency.

6 List of references

BAuA, 2024. Vom Registrierungsdossier über das Sicherheitsdatenblatt zur Gefährdungsbeurteilung - Datenverfügbarkeit und -qualität zwischen REACH und Arbeitsschutz (REACh2SDS) [ONLINE]. URL https://www.baua.de/DE/Forschung/Forschungsprojekte/f2415.html (accessed 2.5.24).

Brody, Ch., Avila, E., Rosner, A., Holzer, T., 2022. Obstructing The Right To Know - A Bluegreen Alliance/Clearya Analysis Of The Chemical Industry's Health Hazard Warnings On Safety Data Sheets [ONLINE]. URL https://www.bluegreenalliance.org/wp-content/uploads/2022/12/Obstructing-the-RIght-to-Know-Report-vFINAL.pdf (accessed 2.5.24).

European Chemicals Agency, 2024a. Guidance on Information Requirements and Chemical Safety Assessment [ONLINE]. URL https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment (accessed 2.5.24).

European Chemicals Agency, 2024b. Exchange Network on Exposure Scenarios [ONLINE]. URL https://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios (accessed 2.5.24).

European Chemicals Agency, 2024c. Respect the deadlines for updating [ONLINE]. URL https://echa.europa.eu/en/support/registration/respect-the-deadlines-for-updating (accessed 2.5.24).

European Chemicals Agency, 2024d. Guidance on the compilation of safety data sheets [ONLINE]. URL https://echa.europa.eu/documents/10162/2324906/sds_en.pdf/01c29e23-2cbe-49c0-aca7-72f22e101e20 (accessed 2.19.24).

European Chemicals Agency, 2018. REF-5 PROJECT REPORT Extended safety data sheets, exposure scenarios, risk management measures and operational conditions. https://doi.org/10.2823/671313

European Chemicals Agency, 2017. Guidance on requirements for substances in articles, Version 4.0 [ONLINE]. URL https://echa.europa.eu/documents/10162/2324906/articles_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c (accessed 2.5.24).

European Chemicals Agency, 2013. Forum REACH-EN-FORCE 2 Project Report Obligation of downstream users - formulators of mixtures [ONLINE]. URL https://echa.europa.eu/documents/10162/13577/forum_report_ref2_en.pdf/6ae12cf0-a24d-4263-a30f-3dabf9928aed (accessed 2.5.24).

Hidayat, D., Andella, C., Tejamaya, M., 2021. Evaluation of the completeness and accuracy of 42 safety data sheets (SDSs) of chemical substances, 2019. Gaceta Sanitaria 35, S468–S471. https://doi.org/10.1016/j.gaceta.2021.07.026

IFA, 2024. Chemical safety assessment – chemical safety report [ONLINE]. URL https://www.dguv.de/ifa%3B/fachinfos/reach/stoffsicherheitsbericht-stoffsicherheitsbeurteilung/index-2.jsp (accessed 2.5.24).

Nayar, G.A., Wehrmeyer, W., Phillips, C.A., Crankshaw, N., Marsh, N., France, C., 2016. The efficacy of Safety Data Sheets in informing risk based decision making: A review of the aerospace sector. Journal of Chemical Health and Safety 23, 19–29. https://doi.org/10.1016/j.jchas.2015.09.002

Schumacher, C., Eickholt, C., Haverkamp, M., Godas, N., Ashton, P., 2022. REACh2SDS-Workshop Bericht. [ONLINE] URL https://www.baua.de/DE/Angebote/Publikationen/Berichte/REACH2SDS.html

Willey, R., J., 2012. Understanding a Safety Data Sheet (SDS) in Regards to Process Safety. Procedia Engineering, 2012 International Symposium on Safety Science and Technology 45, 857–867. https://doi.org/10.1016/j.proeng.2012.08.250

A Appendix

A.1 Survey

Effects of information gaps in the supply chain on environmental exposure - Case study based on a PBT substance

Data Protection

Background and aim:

Regulation (EC) No 1907/2006, also known as REACH, was developed with the aim of ensuring a high level of protection for humans and the environment, as set out in Article 1 of the REACH Regulation. Establishing safe conditions of use is a complex process as these measures need to be adapted on a case-by-case basis, taking into account factors such as the specific location, installation or application. The safety data sheet (SDS) serves as the primary communication tool for conveying information on safe conditions of use.

The Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, represented by the Federal Environment Agency, has commissioned Ramboll Deutschland GmbH, Werinherstraße 79, Building 32a in 81541 Munich with a project in which all relevant information and data gaps in environmental information in safety data sheets along the supply chain are to be identified. Subsequently, the consequences and the necessary needs of the stakeholders under REACH are to be identified.

The project focuses specifically on the objective of environmental protection, with a particular emphasis on the assessment of environmental exposure. It is to understand whether environmental findings that are not traceable or too high according to the registration are possibly due to information gaps along the supply chain.

This survey is primarily aimed at all stakeholders along possible supply chains of the PBT substance octamethlycyclotetrasiloxane (also known as D4) (CAS No. 556-67-2).

The substance has only been selected as an example. No properties or market data are requested in this regard.

If you are not a manufacturer, importer, only representative or downstream user related to this substance, but still have helpful data on information gaps along the supply chain, you can indicate this in the initial questions. You will then be redirected to a general questionnaire.

Further information on the scope and background of the project can be found at https://survey-supply-chain-env-data.com/ .

Please fill in the questionnaire to the best of your ability. Question, in which multiple answers are possible are identified as such and required fields are marked with an asterisk (*). In case of any further questions please contact us via mail through

survey-supply-chain-env-data@ramboll.com or directly to Dr. Alexandra Polcher (apol@ramboll.com).

Please provide your name.

_____

Please indicate your company/organisation/affiliation.

_____

Please indicate your position within your company/ your organisation.

_____

_____

_____

_____

_____

_____

Are we allowed to contact you for further queries or questions via mail if the need arises?*

- Yes, please provide your e-Mail address. ____
- No

How large is the company/organisation, that you represent?*

- Micro enterprise < 10 employees
- Small enterprise < 50 employees
- Medium enterprise <250 employees
- Large enterprise >250 employees

The REACH regulation defines different stakeholder positions in the supply chain. As the duties in regard to the communication along the supply chain are dependent on this position, it is impertinent for the evaluation of the survey that you define the position of the company or organisation that you represent.

Therefore the definition of the different positions is given below.

Manufacturer - According to REACH manufacturer means any natural or legal person established within the European Union who manufactures a substance within the European Union.

Importer - According to REACH importer means any natural or legal person established within the European Union who is responsible for import. Import is defined in REACH as the physical introduction of substances, mixtures or articles from states outside of the European Union through an economic actor seated within the European Union. Aside from the member states, states from the European economic area, such as Norway, Iceland and Liechtenstein also belong to the European community according to REACH.

Only Representative (OR) - According to REACH only representative means any natural or legal person established within the European Union, who is appointed by a manufacturer of substances, mixtures, or articles established outside of the European Union. The only representative has as such to fulfil the obligations on importers.

Distributor - According to REACH distributor means any natural or legal person established within the European Union, including a retailer, who only stores and places on the market a substance on its own or in a mixture.

Downstream User - According to REACH downstream user means any natural or legal person established within the European Union, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. These downstream users can typically be formulators, who produce mixtures from

different substances or companies, that produce mixtures or articles using substances. A special position is the DU Importer - since as soon as a only registrant for a substance within the European Union is appointed, the actual importers are considered downstream users.

Considering the information provided above, which position along the supply chain would you consider most fitting for the company or organisation that you represent? (If the company or organisation that you represent fills more than one position, please check more than one answer.)*

- Manufacturer of the substance D4.
- Importer of D4 as substance, in mixtures or articles.
- Only representative of D4 as substance, in mixtures or articles.
- Distributor of D4 or mixtures, that contain D4.
- Downstream user in regard of D4 or mixtures, that contain D4.
- I do not represent any of the positions in the supply chain mentioned above, but I still want to provide information regarding information gaps along the supply chain (e.g. relevant for associations, consultants, etc.)

In your opinion, is the danger of the substance D4 (octamethylcyclotetrasiloxane) - especially considering environmental effects - sufficiently known for industrial use?

- Yes
- Only partially
- No
- other ____

Which sector does the company or organisation you represent belong to? (More than one answer is possible)*

- Chemical manufacturing
- Chemical distribution
- Chemical processing
- Automobile and transport
- Construction
- Electronic and electric appliances
- Paints and varnishes
- Cosmetics
- Leather
- Medicine and medical technology
- Paper and board

- Textile
- Detergents and cleaning products
- others, please specify ____

How many safety data sheets is the company or organisation you represent responsible?*

- <20
- 20-50
- 50-100
- 100-500
- >500

How often are the safety data sheets updated?*

- Quarterly
- Half-year
- Annually
- Biennial
- Occasion related (please specify) ____
- specific time span (please specify) ____

Do you receive support in creating / updating the safety data sheets? (e.g. from service providers)*

- Yes
- No

Do you employ a company representative specifically for chemical safety and environment?*

- Yes
- No (What is the reason for this?) ____

Does this employee receive specific training?

- Yes (Which kind of training and how often?) ____
- No

In the following, individual questionnaires are asked for the various actors along the supply chain.

If you have selected several positions in the supply chain, the questions will be asked for each position in turn.

In this case, some questions may be repeated.

Please answer them if the answers differ from the point of view of the various actors, otherwise please simply skip them.

A.1.1 Manufacturer

The following questions on the flow of information along the supply chain are intended to provide an insight into where communication gaps may occur. We therefore ask you to fill in the questions with text fields in as much detail as possible.

How do you ensure that the company or organization you represent provides an unsolicited safety data sheet for D4?

_____

_____

_____

_____

_____

_____

How many uses are taken into account in the extended safety data sheet?

_____

_____

_____

_____

_____

_____

Which data source(s) are relevant for you when creating the SDS (multiple answers)?

- Self-commissioned test results
- Data available for purchase (please specify) ____
- Other data sources (please specify) ____

Are you sufficiently familiar with your customers and typical industry conditions of use to ensure the reference to registered uses in the exposure scenarios?

- Yes
- No

To your knowledge, is the substance also used in sectors other than the following?

a) Automobile and transport

b) Construction

c) Electric and electronic appliances

d) Paints and varnishes

e) Cosmetics

f) Leather

g) Medicine and medicinal technology

h) Paper and carton

i) Textile

j) Detergents and cleaning products

- Yes (Which ones?) ____
- No
- I have no knowledge of this.

Are you aware of the tonnages used that are directly processed in the relevant sectors or contained in mixtures/articles?

- Yes
- No

Do you receive feedback from actors along the supply chain that uses are not covered in the exposure scenarios? (Both yes answers can be selected at the same time)*

- Yes, by downstream users. (How often?) ____
- Yes, by other stakeholders. (How often?) ____
- No

In such cases, is the list of supported uses typically supplemented after prior checking?*

- Yes
- No, the SDS rather advises against specific applications (What are the reasons for this?) ____
- No, other (please specify) ____

Is this communicated directly to the requesting user?*

- Yes ____
- No (What is the reason?) ____

How do you provide your customers with safety data sheets? (Several answers are possible)

- Digital (PDF, Word, etc.)
- Analogue (Print etc.)
- Other (Please specify) ____

Do you proactively inform actors along the supply chain about updates of the safety data sheet (e.g. in the event of changes in the data and information situation)?

- Yes

- No (Is it possible for stakeholders along the supply chain to ask for updates and if yes how often does this happen?) ____

Have there been changes in the use behaviour of the substance since SVHC identification / inclusion on the ECHA candidate list, or with regard to a possible POP nomination?

- Yes (please specify) ____
- No
- I have no knowledge about this.

For which actors along the supply chain do you see the greatest risk that information necessary for the safe handling of D4 and mixtures with D4 with regard to the environment is not available or is lost and why? (Up to 3 answers are possible)

- Manufacturer ____
- Importer ____
- Only representative ____
- Distributor ____
- Downstream User (please specify) ____

Are you aware of the effects of information deficits on environmental emissions from D4 or what effects are conceivable?

- Yes (Which ones?) ____
- No

Are you aware of information gaps along the supply chain that hinder the safe handling of D4 with regard to the environment?

- Yes, please describe them. ____
- No

Have internal safety instructions for D4 for the environment been derived from your chemical safety assessment?

- Yes, all the necessary data is also available in the SDS
- Yes, but additional information was used that as well is not in the SDS
- No, because safety measures are not needed during production. (What is the reason for this?) ____
- No, because important relevant information is missing. (Which information is missing and how do you guarantee alternatively a safe handling with D4?) ____
- Other ____

You stated, that based on your safety data sheet internal safety measures for D4 regarding the environment were derived.

Please describe them.

_____

_____

_____

_____

_____

_____

How were these measures communicated internally?*

_____

_____

_____

_____

_____

_____

How do you make sure that the safety measures are comprehensible for the employees?*

_____

_____

_____

_____

_____

_____

How do you make sure, that the safety measures are known by the employees and followed by them?*

_____

_____

_____

_____

_____

_____

How do you make sure, that the safety measures have the desired effect (meaning safety for the environment)?*

_____

_____

_____

_____

_____

_____

Are you missing additional information that could be helpful for the internal safety measures?*

_____

_____

_____

_____

_____

_____

Which additional information do you use?*

_____

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_____

_____

_____

For a better assessment of supply chain communication, it is important that we also collect information on specific tools (e.g. email newsletters, hazardous substance databases, etc.) that you use to share safety-related information regarding D4 and its environmental exposure. You can also specify more than one tool below.

- Do you offer distributors/downstream users special tools, as specified above, and are they used regularly?
- Tools with which they have access to the safety data sheets? ____
- Tools with which they have access to updates of the safety data sheets? ____
- Tools with which they have access to further information in regard to the chemical or the mixture? ____
- Tools with which data on safe handling of D4 are or can generally be exchanged? ____
- No special tools are offered.

Are there other information tools (e.g. via an association) that provide information on the safe handling of D4 with regard to the environment? Please describe them briefly.

- Yes, there are and we use the information. ____
- Yes, there are but we do not need additional information. ____
- Yes, there are but not all stakeholders have access. ____
- Yes, there are but the access is not free of charge. ____
- I do not know of any other tools.

Are you aware of ECHA's initiatives (e.g. exposure scenario templates) to support supply chain communication?

- Yes (Do you think they are helpful and are you using them?) ____
- No

Do you consider the ECHA guidelines for the preparation of safety data sheets as sufficiently helpful?

- Yes
- No (Why not?) ____
- I do not know of the guidelines.

Do you consider the ECHA guidelines regarding the communication of PBT substances in articles to be sufficiently helpful?

- Yes
- No (Why not?) ____
- I do not know of the guidelines.

A.1.2 Importer

The following questions on the flow of information along the supply chain are intended to provide an insight into where there may be gaps in communication. We therefore ask you to complete the questions with text fields in as much detail as possible.

How do you ensure that your company provides an unsolicited safety data sheet for D4 as a substance, in mixtures or in articles?

_____

_____

_____

_____

_____

_____

How many uses are taken into account in the extended safety data sheet?

_____

_____

_____

_____

_____

_____

Are you sufficiently familiar with your customers and typical industry conditions of use to ensure the reference to registered uses in the exposure scenarios?

- Yes
- No

Do you receive feedback from actors along the supply chain that uses are not covered in the exposure scenarios? (Both "Yes" answers can be checked at the same time.)

- Yes, by downstream users. (How often?) ____
- Yes, by other stakeholders. (How often?) ____
- No

In such cases, is the list of supported uses typically supplemented after prior checking?*

- Yes
- No (What are the reasons for this?) ____

Is this communicated directly to the requesting user?

- Yes
- No (please specify the reasons) ____

How do you provide your customers with safety data sheets? (Several answers are possible)

- Digital (PDF, Word, etc.)
- Analogue (Print etc.)
- others (please specify) ____

Do you proactively inform actors along the supply chain about updates of the safety data sheet (e.g. changed data and information situation)?

- Yes
- No (Is it possible for stakeholders along the supply chain to ask for updates and if yes how often does this happen?) ____

Are the safety data sheets provided to you during import available in a language you can understand?

- Yes
- No (Why not?) ____

Are you provided with safety data sheets for the imported substances in a format that enables the creation of a safety data sheet required for the European area? (Is all the required information available?)

- Yes
- No (What is the reason and how do you deal with data gaps?) ____

What data are made available to you in the case of articles to be notified?

_____

_____

_____

_____

_____

_____

Do you have sufficient information from the manufacturer to ensure safe handling of the chemical with regard to the environment?

- Yes
- No (Which information is missing?) ____

Do you have clear and sufficient information from the imports regarding the substance? (substance as substance, in mixtures, in articles)

- Yes
- No (Which information is missing?) ____

Do you initiate investigations in regard to D4 in the imported substances/mixture/article?

- Yes, routinely
- Yes, in case of suspicion
- No

Are there any obstacles at the import/remarketing interface with regard to data forwarding?

- No
- Yes, please explain ____

For which actors along the supply chain do you see the greatest risk that information necessary for the safe handling of D4 and mixtures with D4 with regard to the environment is not available or is lost and why? (Up to 3 answers are possible)

- Manufacturer ____
- Importer ____
- Only representative ____
- Distributor ____
- Downstream User (Please specify) ____

Are you aware of the effects of information deficits on environmental emissions from D4 or what effects are conceivable?

- Yes (Which ones?) ____

- No

Are you aware of ECHA's initiatives (e.g. exposure scenario templates) to support supply chain communication?

- Yes (Do you think they are helpful and are you using them?) ____
- No

Do you consider the ECHA guidance on the preparation of safety data sheets as sufficiently helpful?

- Yes
- No (Why not?) ____
- I do not know of the guidelines.

Do you consider the ECHA guidance on the communication of PBT substances in articles as sufficiently helpful?

- Yes
- No (Why not?) ____
- I do not know of the guidelines.

For a better assessment of supply chain communication, it is important that we also collect information on specific tools (e.g. email newsletters, hazardous substance databases, etc.) that you use to share safety-related information in relation to D4 and its environmental exposure. You can also specify more than one tool below.

Do you offer distributors/downstream users special tools, as specified above, and are they used regularly?

- Tools with which they have access to the safety data sheets? ____
- Tools with which they have access to updates of the safety data sheets? ____
- Tools with which they have access to further information in regard to the chemical or the mixture? ____
- Tools with which data on safe handling of D4 are or can generally be exchanged? ____
- No special tools are offered.

Are there other information tools (e.g. via an association) that provide information on the safe handling of D4 with regard to the environment? Please describe these briefly.

- Yes, there are and we use the information. ____
- Yes, there are but we do not need additional information. ____
- Yes, there are but not all stakeholders have access. ____
- Yes, there are but the access is not free of charge. ____
- I do not know of any other tools.

Do you know of any other sectors the substance is used in than the following?

a) Automobile and transport

b) Construction

c) Electric and electronic appliances

d) Paints and varnishes

e) Cosmetics

f) Leather

g) Medicine and medicinal technology

h) Paper and carton

i) Textile

j) Detergents and cleaning products

- Yes (Which ones?) ____
- No

Have internal protective measures for D4 for the environment also been derived from your safety data sheet?

- Yes
- Yes, but additional information was used as well.
- No, because safety measures are not needed during production. (What is the reason for this?) ____
- No, because important relevant information is missing. (Which information is missing and how do you guarantee alternatively a safe handling with D4?) ____

Considering the safe use of the chemical in regard to the environment, does the company or organisation you represent take data from the sections 6, 8, and 15 of the safety data sheet into account?

- Yes
- No we use general safety measures.
- No, no internal safety measures were derived
- Other ____

Are data from further sections of the safety data sheet taken into account as well (e.g. 7, 12, 13, 14, 16)?

- Yes
- No (What is the reason?) ____
- Other ____

You stated, that based on your safety data sheet internal safety measures for D4 regarding the environment were derived.

Please describe them.

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How were these measures communicated internally?*

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How do you make sure that the safety measures are comprehensible for the employees?*

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How do you make sure, that the safety measures are known by the employees and followed by them?*

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How do you make sure, that the safety measures have the desired effect (meaning safety for the environment)?*

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Are you missing additional information that could be helpful for the internal safety measures?*

_____

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_____

Which additional information are you using?*

_____

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_____

Are you aware of information gaps along the supply chain that hinder the safe handling of D4 with regard to the environment?

- Yes, please describe them. ____
- No

A.1.3 Only representative

The following questions on the flow of information along the supply chain are intended to provide an insight into where there may be gaps in communication. We therefore ask you to complete the questions with text fields in as much detail as possible.

How do you ensure that your company provides an unsolicited safety data sheet for D4 as a substance or in mixtures or relevant articles?

_____

_____

_____

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_____

How many uses are taken into account in the extended safety data sheet?

_____

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How do you ensure that your company has sufficient knowledge of the practical handling of substances and information about them?

_____

_____

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_____

Are you sufficiently familiar with your customers and typical industry conditions of use to ensure the reference to registered uses in the exposure scenarios?

- Yes
- No

How do you provide your customers with safety data sheets? (Several answers are possible)

- Digital (PDF, Word, etc.)
- Analogue (Print etc.)
- Other (Please elaborate) ____

Do you proactively inform stakeholders along the supply chain about updates of the safety data sheet (e.g. when a substance receives a new classification)?

- Yes
- No (Is it possible for stakeholders along the supply chain to ask for updates and if yes how often does this happen?) ____

Do you get feedback from actors along the supply chain about uses, which are not considered in the exposure scenarios? (Both "Yes" answers can be checked at the same time.)

- Yes, by downstream users. (How often?) ____
- Yes, by other stakeholders. (How often?) ____
- No

In such cases, is the list of supported uses typically supplemented after prior checking?*

- Yes
- No (What is the reason for this?) ____

Is this communicated directly to the requesting user?*

- Yes
- No, please specify reason ____

For which actors along the supply chain do you see the greatest risk that information necessary for the safe handling of D4 and mixtures with D4 with regard to the environment is not available or is lost and why? (Up to 3 answers are possible)

- Manufacturer ____
- Importer ____
- Only representative ____
- Distributor ____
- Downstream User (please specify) ____

Do you know of any other sectors the substance is used in than the following?

- Automobile and transport
- Construction
- Electric and electronic appliances
- Paints and varnishes
- Cosmetics
- Leather
- Medicine and medicinal technology
- Paper and carton
- Textile
- Detergents and cleaning products
- Yes (Which ones?) ____
- No

Are you aware of the effects of information deficits on environmental emissions from D4 or what effects are conceivable?

- Yes (Which ones?) ____
- No

Do you have sufficient information from the manufacturer to ensure safe handling of the chemical with regard to the environment?

- Yes
- No (Which information is missing?) ____

For a better assessment of supply chain communication, it is important that we also collect information about specific tools (email newsletters, hazardous substance databases, etc.) that you use to share safety-related information regarding D4 and its environmental exposure. You can also specify more than one tool below.

Do you offer distributors/downstream users special tools, as specified above, and are they used regularly?

- Tools with which they have access to the safety data sheets? ____
- Tools with which they have access to updates of the safety data sheets? ____
- Tools with which they have access to further information in regard to the chemical or the mixture? ____
- Tools with which data on safe handling of D4 are or can generally be exchanged? ____
- No special tools are offered.

Are there other information tools (e.g. via an association) that provide information on the safe handling of D4 with regard to the environment? Please describe these briefly.

- Yes, there are and we use the information. ____
- Yes, there are but we do not need additional information. ____
- Yes, there are but not all stakeholders have access. ____
- Yes, there are but the access is not free of charge. ____
- I do not know of any other tools.

Are you aware of ECHA's initiatives (e.g. exposure scenario templates) to support supply chain communication?

- Yes (Do you think they are helpful and are you using them?) ____
- No

Do you consider the ECHA guidance on the preparation of safety data sheets as sufficiently helpful?

- Yes
- No (Why not?) ____
- I do not know of the guidelines.

Do you consider the ECHA guidance on the communication of PBT substances in articles as sufficiently helpful?

- Yes
- No (Why not?) ____
- I do not know of the guidelines.

Are you aware of information gaps along the supply chain that hinder the safe handling of D4 with regard to the environment?

- ► Yes, please describe them in detail. ____
- ► No

A.1.4 Distributer

The following questions on the flow of information along the supply chain are intended to provide an insight into where there may be gaps in communication. We therefore ask you to complete the questions with text fields in as much detail as possible.

Does the manufacturer provide a safety data sheet for D4 as a pure substance or for mixtures containing D4 with a concentration >=0.1% by weight without being asked?

_____

_____

_____

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_____

_____

Does the safety data sheet explicitly refer to the PBT status of D4 and the associated requirement to minimize discharges into the environment? (see Annex I, paragraph 6.5 of the REACH Regulation)

- ► Yes
- ► No

Does the safety data sheet contain an annex with one or more exposure scenarios? (If not, was this communicated to the manufacturer?)

_____

_____

_____

_____

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_____

In what form are the safety data sheets made available to you? (More than one answer is possible)

- ► Digital (PDF, Word, etc.)
- ► Analogue (Print etc.)
- ► Other (Please describe) ____

Are you automatically informed about updates to the safety data sheet or do you regularly request updates?

- We are automatically informed of updates.
- We regularly ask for updates. (How often?)
- Updates are neither communicated automatically nor asked for. (Why not?) ____

Do you have a standardized process for requesting safety data sheets?

- Yes (Please describe) ____
- No

Do you ask for a safety data sheet from the manufacturer or importer, if D4 is contained in a mixture, which is not classified as hazardous?

- Yes
- No (Why not?) ____

Do you receive feedback from users in cases where uses are not considered in the safety data sheet?

- Yes
- No

You have indicated that you receive feedback from users in cases where uses are not shown in the safety data sheet.

Was this communicated to the manufacturer? (If not why?)

____

Did the manufacturer or importer include additional information in the safety data sheet or did they take any other measures? (If not, what is the reason for this?)

____

Do you have sufficient information from the manufacturer to ensure safe handling of the chemical with regard to the environment?

- Yes
- No (Which information is missing?) ____

For which actors along the supply chain do you see the greatest risk that information necessary for the safe handling of D4 and mixtures with D4 with regard to the environment is not available or is lost and why? (Up to 3 answers are possible.)

- Manufacturer ____
- Importer ____
- Only representative ____
- Distributor ____

- Downstream User (Please specify) ____

Are you aware of the effects of information deficits on environmental emissions from D4 or what effects are conceivable?

- Yes (Which ones?) ____
- No

Do you know of any other sectors the substance is used in than the following?

a) Automobile and transport
b) Construction
c) Electric and electronic appliances
d) Paints and varnishes
e) Cosmetics
f) Leather
g) Medicine and medicinal technology
h) Paper and carton
i) Textile
j) Detergents and cleaning products

- Yes (Which ones?) ____
- No

For a better assessment of supply chain communication, it is important that we also collect information on specific tools (e-mail newsletters, hazardous substance databases) that you use to share safety-related information regarding D4 and its environmental exposure. You can also specify more than one tool below.

Do you offer downstream users special tools, as specified above, and are they used regularly?*

- Tools with which they have access to the safety data sheets? ____
- Tools with which they have access to updates of the safety data sheets? ____
- Tools with which they have access to further information in regard to the chemical or the mixture? ____
- Tools with which data on safe handling of D4 are or can generally be exchanged? ____
- No special tools are offered.

Are there other information tools (e.g. via an association) that provide information on the safe handling of D4 with regard to the environment? Please describe these briefly.

- Yes, there are and we use the information. ____
- Yes, there are but we do not need additional information. ____
- Yes, there are but not all stakeholders have access. ____

- Yes, there are but the access is not free of charge. ____
- I do not know of any other tools.

Does the manufacturer offer special tools and do you use these actively/regularly? (Please describe the tools in detail)

- Tools with which they have access to the safety data sheets? ____
- Tools with which they have access to updates of the safety data sheets? ____
- Tools with which they have access to further information in regard to the chemical or the mixture? ____
- Tools with which data on safe handling of D4 are or can generally be exchanged? ____
- No special tools are offered.

Are these tools helpful in regard to a safe handling of the chemical?

- Yes
- No (Why not?)

Please describe how the information from the safety data sheet are generally used in the company or organisation that you represent?

____

Considering the safe use of the chemical in regard to the environment, does the company or organisation you represent take data from the sections 6, 8, and 15 of the safety data sheet into account?

- Yes
- No, we use general safety measures.
- No, no internal safety measures were derived.
- Other ____

Are data from further sections of the safety data sheet taken into account as well (e.g. 7, 12, 13, 14, 16)?

- Yes
- No (What is the reason for that?) ____
- Other ____

Is the relevant environmental information in the exposure scenario taken into account when deriving measures?

- Yes
- No (What is the reason for this and which data is used alternatively?) ____

Are you aware of information gaps along the supply chain that hinder the safe handling of D4 with regard to the environment?

- Yes, please describe them. ____
- No

Has your company also derived internal protective measures for D4 for the environment on the basis of the safety data sheet?

- Yes
- Yes, but additional information was used as well.
- No, because safety measures are not needed during production. (What is the reason for this?) ____
- No, because important relevant information is missing. (Which information is missing and how do you guarantee alternatively a safe handling with D4?) ____

You stated, that based on your safety data sheet internal safety measures for D4 regarding the environment were derived.

Please describe them.

_____

_____

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How were these measures communicated internally?*

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How do you make sure that the safety measures are comprehensible for the employees?*

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How do you make sure, that the safety measures are known by the employees and followed by them?*

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How do you make sure, that the safety measures have the desired effect (meaning safety for the environment)?*

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Are you missing additional information that could be helpful for the internal safety measures?*

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Did you share these safety measures with other stakeholders?*

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A.1.5 Downstream user

The following questions on the flow of information along the supply chain are intended to provide an insight into where there may be gaps in communication. We therefore ask you to complete the questions with text fields in as much detail as possible.

Please describe how you use D4. (multiple answers are possible)

- To manufacture articles

- To manufacture mixtures (e.g. paints etc.)
- To provide services, please also specify which service. ____
- For synthesizing other substances
- Re-filler of substances or mixtures containing D4.
- Acting as DU Importer.
- Acting as industrial or commercial end user
- other, please specify ____

Is it always easy for your company to understand what role you play in the supply chain and what obligations this entails?

- Yes
- No, please explain ____

Does your supplier provide a safety data sheet for D4 as a substance or in mixtures without being asked?

- Yes
- No, please state why. ____
- Not relevant, please state why. ____

Does the safety data sheet contain an annex with one or more exposure scenarios? (If not, was this communicated to the manufacturer/distributor?)

_____

_____

_____

_____

_____

_____

Does the safety data sheet explicitly refer to the PBT status of D4 and the associated requirement to minimize discharges into the environment? (see Annex I, paragraph 6.5 of the REACH Regulation).

- Yes
- No

Are appropriate measures defined in your supplier's safety data sheet as to how this minimization of emissions can be achieved in the case of intended use (i.e. not "unintentional release" or incidents) and are these measures described in a comprehensible manner?

Safety measures are defined newly and described sufficiently. (Are those safety measures similar to the ones typically used in your sector? Can a connection be found to the relevant BAT information sheets and the technical and organizational measures described within?) ____

- Safety measures are defined newly but not described sufficiently.
- Measures correspond to the specifications described in chapter 6.
- Safety measures are not defined.

If the safety data sheet describes measures to reduce emissions of D4 that are not related to you industry sector or insufficiently described, would you also implement them on site?

- Yes
- No, but I would communicate this towards our distributor and ask for checking/adaption of safety measures in the safety data sheet. (Paragraph 34 (b) REACH)
- No

As a downstream user, would you consider preparing a chemical safety assessment for your own application in case of insufficiently defined measures to reduce emissions in your supplier's D4 data sheet, as described in Title V, Article 37 et seq. of the REACH Regulation?

- Yes
- No, we would change the distributor
- No, we would feed this back to the supplier so that measures can be derived.
- No (Please elaborate why not) ____

In what format do you receive safety data sheets? (More than one answer is possible)

Digital (PDF, Word, etc.)

- Analogue (Print etc.)
- Other (Please specify) ____

Are you automatically informed on updates of the safety data sheet or how often do you ask for updates?

- We get automatically informed of updates.
- We regularly ask for updates. (How often?)
- Updates are neither communicated automatically nor asked for. (Why not?) ____

Is it immediately recognizable, that hazardous substances (D4) are included in >= 0.1 weight percent in the container?

- Yes
- No
- Not relevant

Have you read and understood the pictograms and instructions on the container?

- Yes (Read and understood)
- Yes (Read but not understood. What is the reason for this?) ____

- No, please specify reason ____
- Not relevant

Has the information on the container or safety data sheet been presented in a language you can understand?

- Yes
- No ____

Was your type of use included in the first safety data sheet you received?

- Yes
- No, but it was communicated to the manufacturer/distributor.
- No and it was not communicated to the manufacturer/distributor.

Have there been any changes in the processing of the substance since SVHC identification / inclusion on the ECHA candidate list, or with regard to a possible POP nomination?

- Yes (Please specify) ____
- No

A.1.6 Imports – downstream user

What do you import?

- Articles that contain D4 and are therefore subject to notification
- Mixtures containing D4
- Intermediates
- others, please specify ____

Is an SDS always available for import?

- Yes, an EU-compliant safety data sheet is available
- Yes, but the safety data sheet is not EU-compliant
- No, other formats are used to pass on information (please specify) ____
- others, please specify ____

Do you have clear and sufficient information from the imports regarding the substance? (substance as substance, in mixtures, in articles)

- Yes
- No (Which information are missing?) ____
- Not relevant

Do you initiate investigations regarding D4 in the imported substances/mixtures/articles?

- Yes, routinely
- Yes, in case of suspicion
- No

Are the safety data sheets/information provided to you during DU import available in a language you can understand?

- Yes
- No (why not?) ____

Is the existence of an SDS a prerequisite for import?

- Yes
- No
- others, please specify ____

Are you provided with all necessary data that enables the creation of a safety data sheet required for the European area?

- Yes
- No (What is the reason for this and how do you deal with data gaps?) ____

A.1.7 Formulators – downstream user

Do you provide unsolicited safety data sheets for mixtures containing D4 in a concentration >=0.1% weight by weight and does the safety data sheet contain an annex with one or more exposure scenarios?

- Yes, we do supply safety data sheets unprompted and they contain an annex with exposition scenarios.
- Yes, we do supply safety data sheets unprompted but it does not contain an annex with exposition scenarios. (Why not?) ____
- No we do not supply a safety data sheet unprompted. (Why not?) ____
- We are not formulators.

Would you say that you are provided with sufficient information by manufacturers to be able to prepare safety data sheets for the mixtures you produce?

- Yes
- Yes, but it is not easy to identify relevant information.
- No (Which information are missing?) ____
- Not relevant

Do you have sufficient knowledge of your customers to ensure the connection to the registered uses in the exposure scenario?

- Yes
- No
- Not relevant

In what form do you supply your customers with safety data sheets? (More than one answer is possible)

- Digital (PDF, Word, etc.)
- Analogue (Print etc.)
- Other (Please specify) ____
- Not relevant we do not provide safety data sheets.

Do you proactively/automatically inform actors along the supply chain about updates of the safety data sheet?

- Yes
- No (Is it possible for stakeholders along the supply chain to ask for updates and if yes how often does this happen?) ____
- Not relevant

Do you receive feedback from users in cases where uses are not shown in the safety data sheet?

- Yes
- No
- Not relevant

Do you communicate proactively relevant uses, which are not included in the safety data sheet to the manufacturer?

- Yes
- No (What is the reason for this?) ____

DOWNSTREAM USER

You stated that downstream users inform you about uses, which are not included in the safety data sheet.

Was this communicated to the manufacturer? (If not why?)

____

Did the manufacturer/distributor include additional information in the safety data sheet or were other measures taken? (If not, what is the reason for this?)

____

You stated that you proactively communicate relevant uses which are not implemented in the safety data sheets to the manufacturer.

How often does this happen?

____

Did the manufacturer/distributor include additional information into the safety data sheet?

____

Were other measures taken by the manufacturer/distributor?

____

Have there been difficulties in communication?

____

Did you know the contact person or who to contact?

____

Do you know of any other sectors the substance is used in than the following?

a) Automobile and transport

b) Construction

c) Electric and electronic appliances

d) Paints and varnishes

e) Cosmetics

f) Leather

g) Medicine and medicinal technology

h) Paper and carton

i) Textile

j) Detergents and cleaning products

- Yes (Which ones?) ____
- No
- I have no knowledge about this.

For which actors along the supply chain do you see the greatest risk that information necessary for the safe handling of D4 and mixtures with D4 with regard to the environment is not available or is lost and why? (Up to 3 answers are possible.)

- Manufacturer ____
- Importer ____
- Only representative ____
- Distributor ____
- Downstream User (please specify) ____

Are you aware of the effects of information deficits on environmental emissions from D4 or what effects are conceivable?

- Yes (Which ones?) ____

- No

For a better evaluation of supply chain communication, it is important that we also collect information about specific tools (email newsletters, hazardous substance databases) that you use to share safety-related information regarding D4 and its environmental exposure. You can also specify more than one tool below.

Do you offer downstream users special tools, as specified above, and are they used regularly?

- Tools with which they have access to the safety data sheets? ____
- Tools with which they have access to updates of the safety data sheets? ____
- Tools with which they have access to further information in regard to the chemical or the mixture? ____
- Tools with which data on safe handling of D4 are or can generally be exchanged? ____
- No special tools are offered.
- Not relevant.

Are there other information tools (e.g. via an association) that provide information on the safe handling of D4 with regard to the environment? Please describe these briefly.

- Yes, there are and we use the information. ____
- Yes, there are but we do not need additional information. ____
- Yes, there are but not all stakeholders have access. ____
- Yes, there are but the access is not free of charge. ____
- I do not know of any other tools.

Does the manufacturer/distributor offer special tools, as specified above, and do you use them regularly? (Please describe them in short.)

- Tools with which they have access to the safety data sheets?
- Tools with which they have access to updates of the safety data sheets?
- Tools with which they have access to further information in regard to the chemical or the mixture?
- Tools with which data on safe handling of D4 are or can generally be exchanged?
- No special tools are offered.

Are you aware of ECHA's initiatives (e.g. exposure scenario templates) to support supply chain communication?

- Yes (Do you think they are helpful and are you using them?) ____
- No

Do you consider the ECHA guidance on the preparation of safety data sheets as sufficiently helpful?

- Yes
- No (Why not?) ____
- I do not know of the guidelines.
- Not relevant

Do you consider the ECHA guidance on the communication of PBT substances in articles as sufficiently helpful?

- Yes
- No (Why not?) ____
- I do not know of the guidelines.
- Not relevant

Has your company also derived internal protective measures for D4 for the environment on the basis of the safety data sheet?

- Yes
- Yes, but additional information was used as well.
- No, because safety measures are not needed during production. (What is the reason for this?) ____
- No, because important relevant information is missing. (Which information is missing and how do you guarantee alternatively a safe handling with D4?) ____

Please describe how information from the safety data sheet is generally used in your company or organisation.

____

Have you ever had to carry out scaling or have you been advised of scaling options?

- Yes
- No

Have you ever noticed discrepancies between the main SDS and the extended eSDS - i.e. between the exposure scenarios and the conditions of use prescribed therein and the information in the main SD?

- Yes
- No

Considering the safe use of the chemical in regard to the environment, does the company or organisation you represent take data from the sections 6, 8, and 15 of the safety data sheet into account?

- Yes
- No, we use general safety measures.

- No, no internal safety measures were derived.
- Other ____

Are data from further sections of the safety data sheet taken into account as well (e.g. 7, 12, 13, 14, 16)?

- Yes
- No (Why not?) ____
- Other ____

Is relevant environmental information from the exposure scenario taken into account when deriving safety measures?

- Yes
- No (What is the reason for this and which other relevant data was used instead?) ____

Are you aware of information gaps along the supply chain that hinder the safe handling of D4 with regard to the environment?

- Yes, please describe them. ____
- No

You stated, that based on your safety data sheet internal safety measures for D4 regarding the environment were derived.

Please describe them.

_____

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How were these measures communicated internally?

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How do you make sure that the safety measures are comprehensible for the employees?

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How do you make sure, that the safety measures are known by the employees and followed by them?

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How do you make sure, that the safety measures have the desired effect (meaning safety for the environment)?

_____

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Are you missing additional information that could be helpful for the internal safety measures?

_____

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_____

Is relevant environmental information from the exposure scenario taken into account when deriving safety measures? (If not, what is the reason for this and which other data is used alternatively?)

_____

_____

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_____

_____

Did you share these measures with other downstream users?

_____

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_____

You stated that your type of use was not included in the safety data sheet that was supplied to you, but you communicated this to the manufacturer/distributor.

Did the manufacturer/distributor include additional information in the safety data sheet or were other measures taken? (If not, what is the reason for this?)*

____

You stated that your type of use was not included in the safety data sheet that was supplied to you, but you did not communicate this to the manufacturer/distributor.

What was the reason for this?*

____

A.1.8 Other actors

Are you aware of the effects of information deficits on environmental emissions from D4 or what effects are conceivable?

- ► Yes (Which ones?) ____
- ► No

Do you know of any other sectors the substance is used in than the following?

a) Automobile and transport
b) Construction
c) Electric and electronic appliances
d) Paints and varnishes
e) Cosmetics
f) Leather
g) Medicine and medicinal technology
h) Paper and carton
i) Textile
j) Detergents and cleaning products

- ► Yes (Which ones?) ____
- ► No

Are there information tools (e.g. via an association) with which information for the safe handling of D4 in regard to the environment is distributed? Please describe them in short.

- Yes, there are. ____
- I do not know of any tools.

For which actors along the supply chain do you see the greatest risk that information necessary for the safe handling of D4 and mixtures with D4 with regard to the environment is not available or is lost and why? (Up to 3 answers are possible.)

- Manufacturer ____
- Importer ____
- Only Respondent ____
- Distributor ____
- Downstream User (please specify) ____

Where do you see the biggest challenge regarding the communication along the supply chain?

_____

_____

_____

_____

_____

_____

Do you have general suggestions for improvement/wishes regarding the communication along the supply chain?

_____

_____

_____

_____

_____

_____

A.1.9 All actors

For a more specific evaluation of the survey in regard to the communication along the supply chain, you can, on a free basis, upload a relevant safety data sheet. This can either be best practise or show bad examples. You are also welcome to black out information you do not want to share.

We would also gladly accept any further information that you want to provide us with.

(The upload is possible in the following data formats: PDF, Image (JPEG, PNG), Document (DOCX) or Spreadsheet (XLSX))

Thank you very much for your support! Now click on the "Finish" button to submit your information.

A.2 Website content

A.2.1 Frontpage

This website is part of a project contracted by the German Environment Agency to Ramboll Deutschland GmbH. Project number: 182911 Please see also the recommendation letter issued by the German Environment Agency. German version of recommendation letter English version of recommendation letter

A.2.2 Background

Regulation (EC 1907/2006), also known as REACH, was developed with the objective of ensuring a high level of protection for man and the environment, as stated in REACH Article 1. This goal is pursued through the principle known as “no data, no market,” outlined in REACH Article 5. According to this principle, a chemical can only be manufactured or introduced into the market if a risk assessment, which demonstrates its safety (i.e., a Risk Characterization Ratio (RCR) less than 1), is completed as part of its registration process. The fundamental guidelines for conducting the Chemical Safety Assessment (CSA) are detailed in Annex I of REACH, while the specific information requirements for registration can be found in Annexes VII to X of REACH.

The determination of safe conditions of use for both human beings (including workers and the general public) and the environment is derived from the evaluations made during the chemical safety assessment. Safety measures for workers are generally standardized, whereas the usage by the general public assumes the absence of substance-related risks, as continuous monitoring is often not feasible in such cases. It is essential to ensure that the intended use of the chemical is inherently safe, a principle that extends to safeguarding the environment as well. The establishment of safe conditions of use is a complex process, as these measures must be customized on a case-by-case basis, considering factors such as the specific location, facility, or application, among other variables. The Survey related to the supply chain communication of environmental data safety data sheet (SDS) serves as the primary communication tool for conveying information about safe conditions of use. In some research projects (e.g., BAuA’s REACH2SDS, REF-5 Forum project) it has become evident that shortcomings exist along the supply chain as regards data availability. As a result, users of chemicals often find themselves lacking essential data, encountering inaccuracies, or receiving inadequate or absent guidance on safety measures. The REACH single substance assessment framework, in some instances, remains unclear or is regarded as advisory, contributing to data gaps in the supply chain as well. This project specifically focuses on the objective of environmental protection, with a particular emphasis on evaluating environmental exposure. It is essential to understand environmental findings (which are not comprehensible or too high according to the registration) and to identify needs in order to make supply chain communication on environmental aspects easier to understand and as targeted and efficient as possible, especially under REACH.

A.2.3 Case study & Survey

Why a case study?

The project aims to answer the following key questions:

- How does supply chain communication work?
- What "tools" are there for communicating data upstream/downstream?
- For whom are these "tools" suitable? Does every user of chemicals have access (or, for example, only association members)?
- How do information and data gaps arise?
- What impact do these information or data gaps have on environmental emissions?
- What are the consequences?
- Can recommendations for action be derived from this?

We believe that focusing on feedback of actors along the supply chains of one specific substance helps to ensure a sufficient level of detail.

Which substance has been selected for the case study?

For the present project, Octamethlycyclotetrasiloxane (CAS no. 556-67-2) also known as D4 has been selected. The information obligations resulting from the PBT status of D4 are relevant for answering the survey. Specific properties of D4 are not in focus. For information purpose: D4 has the following properties of concern (more details can be found when following the links to the ECHA website)

- Suspected to be Toxic to Reproduction (Harmonised C&L)
- Officially recognised in the EU as Persistent, Bioaccumulative and Toxic (candidate list of SVHCs).
- Under assessment as Persistent Organic Pollutant (substances proposed as POPs).

Further information related to the substance is available on:

- the substance information form of ECHA
- the website of the German Environment Agency.

How will the information be collected?

Ramboll has prepared an online survey which is open until 22 December 2023. Invitation emails have been sent to actors along the supply chains of D4 as well as industry associations. As it is possible that not all relevant actors have been contacted directly, the survey is open for additional experts as well. Please feel free to enter the survey via the following link:

Online survey in English

Online survey in German

Overall results will be published in form of a report at a later stage of the project.

A.3 Cover letter

Dear Ladies and Gentlemen,

The German Federal Environment Agency has commissioned Ramboll to carry out a case study to analyse supply chain communication regarding a PBT substance. The project is specifically focused on the objective of environmental protection, with particular emphasis on the assessment of environmental exposure.

REACH Regulation (EC) No 1907/2006 sets out a number of information requirements, but determining safe conditions of use is a complex process. Measures need to be adapted on a case-by-case basis. Factors such as the specific site, installation or application need to be taken into account.

The case study aims to show whether environmental findings that appear to be untraceable or too high according to the registration may also be due to information gaps along the supply chain. The results will be used to make recommendations on how to support supply chain communication.

This survey is primarily addressed to all stakeholders along possible supply chains of the PBT substance octamethlycyclotetrasiloxane (also known as D4) (CAS No. 556-67-2). The information obligations arising from the PBT status of D4 are relevant for the response to the survey. Specific properties of D4 are not in the focus.

We would be very grateful if you would take part in our survey and help us to identify opportunities to support supply chain communication.

The survey is available in English and German and will remain open until 22 December 2023.

German: https://surveys.ramboll.com/LinkCollector?key=PH49KR14J13N

English: https://surveys.ramboll.com/LinkCollector?key=5U526M14UJ32

Please feel free to share these links.

Please note that the survey is anonymous, i.e. you will not be able to return to your current status when you close the browser window. If you would like to pause and resume at a later time, we will be happy to send you a personalised link. Please contact survey-supply-chain-env-data@ramboll.com .

You will also be able to upload documents at the end of the survey. Furthermore, you are welcome to send us additional information by email.

If you are not a manufacturer, importer, only representative or downstream user related to this substance, but you have useful data on information gaps along the supply chain, you can indicate this in the initial questions. You will then be directed to a general questionnaire.

Further information on the scope and background of the project can be found at https://survey-supply-chain-env-data.com .