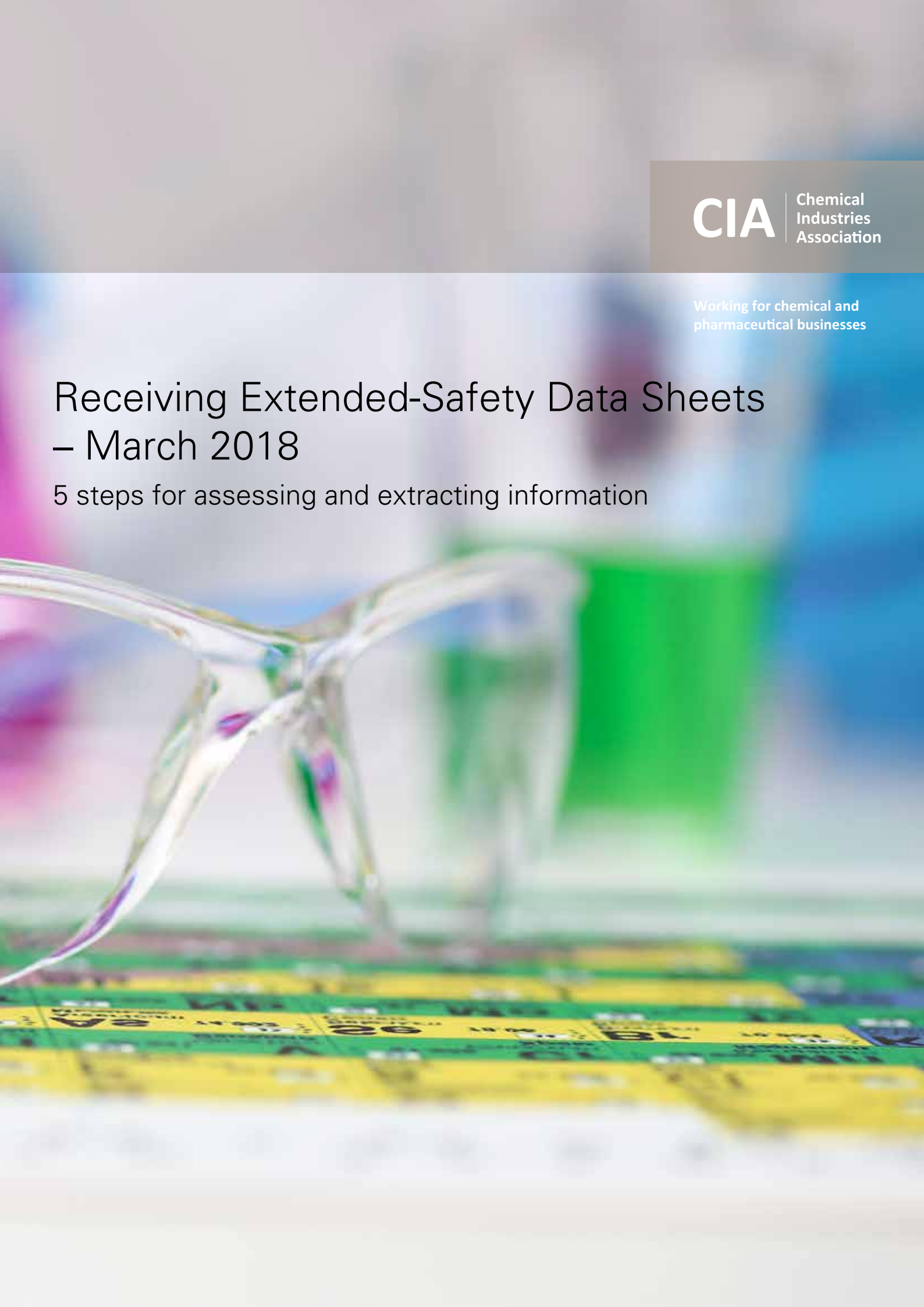
CIA Chemical Industries Association

Working for chemical and pharmaceutical businesses

Receiving Extended-Safety Data Sheets – March 2018

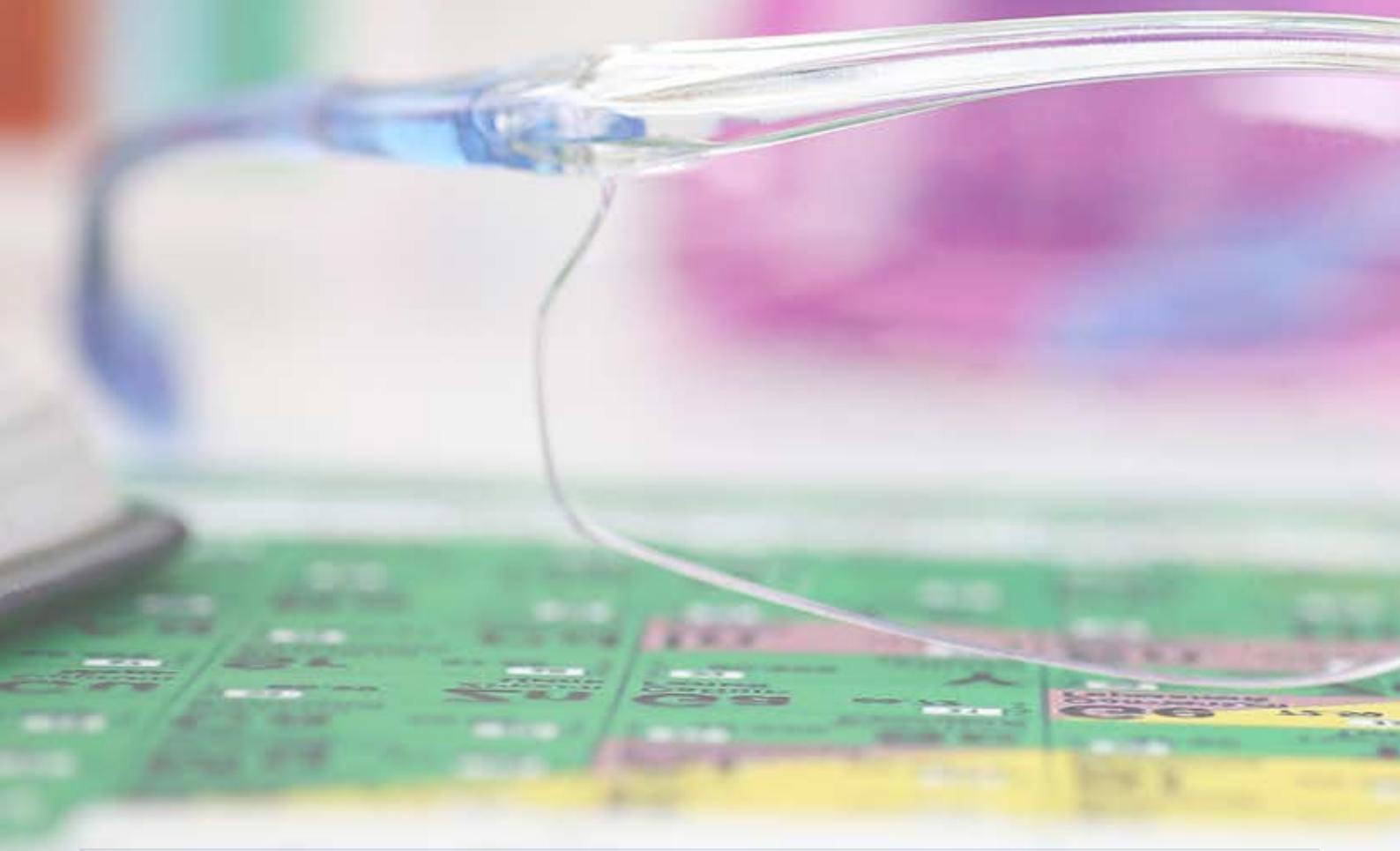
5 steps for assessing and extracting information



Receiving Extended-Safety Data Sheets

5 steps for assessing and extracting information

Focussing on site operations, this document outlines an easy-to-use step-by-step process for assessing and extracting information upon receiving a Safety Data Sheet (SDS) or extended-Safety Data Sheet (ext-SDS). It is based on the experience of a number of companies' experts. Communicating the changes identified to the relevant people is essential to ensure sound on-site chemical management.



This document is part of a series of guidance documents on Extended-Safety Data Sheets produced by the CIA.
Titles in this series include:

Compiling Extended-Safety Data Sheets: Tips and recommendations for substances

Compiling Extended-Safety Data Sheets: Tips and recommendations for mixtures

Receiving Extended-Safety Data Sheets: 5 steps for assessing and extracting information

Background – legal requirements

Every time information is received in the form of an SDS/ext-SDS the recipient is obliged to determine if their use and/or conditions of use are supported by this information. An exposure scenario is defined as *the set of conditions, including operational conditions and risk management measures that describe how the substance is manufactured or used during its life-cycle*, Article 3 (37) REACH. The following steps should be carried out and relevant actions undertaken once the SDS/ext-SDS has been received for all chemical substances and for all suppliers. This means that if you receive the same substance from two different suppliers then two assessments would have to be carried out to ensure that the information in each of the supplier exposure scenarios covers your uses. This is important as information may vary from supplier to supplier and must be taken into consideration. The flow chart below shows a straight forward method for assessing and extracting information upon receiving an SDS/ext-SDS.

Process flow

Step 1: Actions on receipt on an SDS/ext-SDS

a. Keep a record
b. Is this a new version, if so what has been updated
c. Is the substance REACH registered?
d. Hazard classification check
e. Legal time line

↓

Step 2: Identified uses check

a. Identified uses and the Use descriptors system
b. Uses advised against

↓

Step 3: Conditions of use check

a. Operational conditions
b. Risk management measures
c. Discrepancy between suppliers

↓

Step 4: Outcome of assessment

a. Uses are covered
b. Uses are covered but alternative risk management measures
   i. Scaling
   ii. Downstream user chemical safety assessement
c. Uses are not covered

↓

Step 5: Document the assessment

a. Keep the record of the assessment up to date
b. Withdraw all out of date copies of the SDS/ext-SDS

Step 1: Actions on receipt of SDS/ext-SDS

a. Keep a record

Any individual receiving an SDS or ext-SDS should ensure that the person whom is responsible for the sites health, safety and environment receives it for evaluation. The person who reviews the SDS/ext-SDS needs to prepare an updated assessment form to capture all the essential information from both the main body of the SDS and the annexed exposure scenarios. The assessment form will be able to verify the best practices that are in place to protect the workforce and the environment. It will also provide a record of the date of receipt which triggers additional obligations.

b. Is this a new version?

Check the SDS/ext-SDS received from the supplier for a change in date or revision number compared to the SDS/ext-SDS that is currently used. Any changes should be listed within section 16 but it is extremely important to check other key sections where changes are likely to occur i.e. section 8 (exposure controls), 9 (Physical and chemical properties), 11 (toxicological information) and 12 (environmental information). It is also important to ensure that no relevant information is available internally that contradicts changes made in the SDS/ext-SDS, particularly regarding the classification of the substance or the derived no effect level (DNELs)/ predicted no effect concentration (PNECS). Record any changes in the assessment form.

c. Is the substance REACH registered?

If the substance has been registered under REACH then the registration number should be included in section 1 of the SDS. If there is no registration number then the substance is not registered. However, there several valid reasons for the absence of a REACH registration number, for example a supplier of small quantities of a substance may not have undergone REACH registration yet. If in doubt you should contact your supplier for confirmation.

IMPORTANT! The receipt of a registration number on the SDS, not the receipt of an exposure scenario, triggers the 12 month timeline for downstream users to fulfil their duties under Article 37 REACH. However, downstream users can not complete their obligations without an exposure scenario; if you think you should have received an exposure scenario contact your supplier immediately.

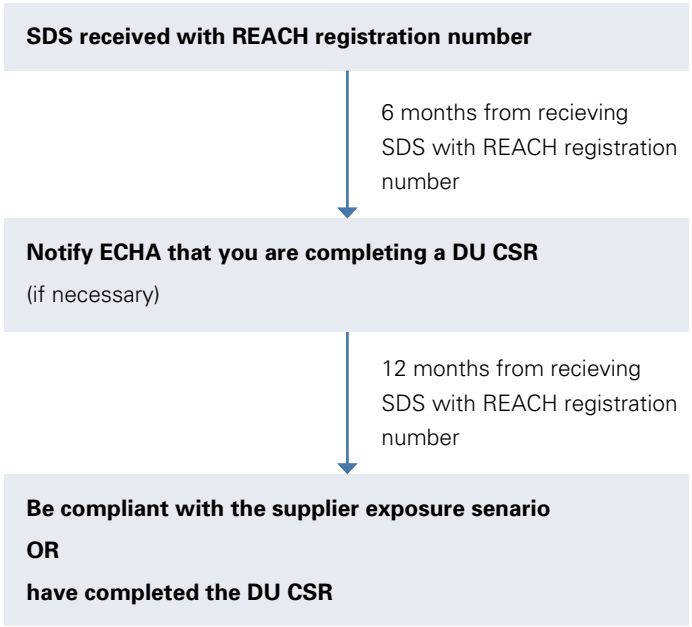
d. Hazard classification check

Review the chemical classification in section 2 of the SDS/ext-SDS and record in the assessment form. It is important to review if the classification has changed from the previous SDS/ext-SDS as certain classifications trigger additional oligations such a specific handling and storage requirements. If there is a change and you agree with the reasoning behind the change, ensure that all relevant people (compliance manager, operations manager, waste management managers etc.) on site are informed. If the substance has a REACH registration number and has been classified for human health and/or environment then it is likely that exposure scenairos will be provided in the annex. There are however, valid reasons for a supplier not to include an exposure scenario for classified substances these include; supply below 10 tonnes/year, the substance is an intermediate, substance is classified for only aspiration or skin dryness hazards.

e. Legal time line

The recipient of the extSDS has several legal time lines in which to adhere to when assessing the received exposure scenarios. Figure 1 shows the lgeal time line for downstream users receiving exposure scenarios .

Figure 1: Legal time line for downstream users receiving exposure scenairos



Step 2: Identified uses check

a. Identified uses and the Use descriptor system

If an exposure scenario has been provied you need to ensure that how you are currently using that substance has been covered within the exposure scenario assessment. You can carry out a first screening based on the short titles of the exposure scenarios and use descriptions. The way in which the supplier describes the use of a substance will normally be done using the standardised use descriptor system.

The use descriptor system is composed of five sets of descriptors (Sectors of use [SU], Product category [PC], Process category [PROC], Environmental release category [ERC], Article category [AC]), which can be used to briefly describe identified and are designed to harmonise and facilitate how uses are described in the supply chain. Therefore, it is important to ensure that you become familiar with these descriptors and understand how they are used.

It is advised that you translate how you currently use the substance into your own set of use descriptors. You can then compare your uses to the uses that have been covered within the exposure scenario, completing this check will enable you to determine if your use is covered by the exposure scenario or not. If there are any uses that are not covered by the exposure scenario you should record these within your assessment, please see **Step 4c** for further guidance.

b. Uses advised against

Also at this stage, it is worth checking that your use is not included in section 1.2 of the SDS under the 'uses advised against' heading, uses advised against will not have been included within the exposure scenario assessment for reasons such protection of human health or the environment. The uses advised against may also be described using the use descriptor system.

Step 3: Conditions of use check

a. Operational Conditions

Compare the information on operational conditions provided within the exposure to your own operational conditions for each of your identified uses. If you have already carried out a risk assessment under the Chemical Agents Directive or have information from applications for environmental permits you may be able to use this information for this task. From this comparison you should be able to determine if the operational conditions you are currently using are adequate or better than recommended and if any improvements are required. Document all findings within the assessment.

b. Risk management measures

Compare the information on the risk management measures (RMM) provided including their effectiveness to your own RMMs for each of your identified uses. The effectiveness of the RMMs is key information as it indicates the degree of exposure or emission reduction is achieved by the application of that RMM. Therefore, you can be sure that your RMM are covered if their effectiveness is equal to or higher than what is specified within the exposure scenario. The hierarchy of RMM that is defined in worker legislation must also be considered when assessing the effectiveness of a RMM.

[Engineering controls > Administrative controls > Personal protective equipment]

c. Discrepancy between suppliers

If you purchase a substance from more than one supplier then you may receive exposure scenarios that are not comparable. For example they could differ in scope or in conditions of use or there could be a difference in substance properties. You should check your conditions of use are covered by the most stringent of the exposure scenarios received, if so your use will also be covered by the other exposure scenario. When exposure scenarios from different suppliers diverge it is recommended that you contact your suppliers and inform them of the difference with a view to aligning their exposure scenarios. You could also ask for confirmation that the selected measures ensure safe use event though they are less stringent than measures recommended by other suppliers.

Step 4: Outcome of assessment

a. Uses are covered

If all of your identified uses are included within the exposure assessment and the operational conditions and RMMS are covered, then retain the current RMMs and record your decision within the assessment. No further action is required under REACH.

b. Uses are covered but alternative risk management measures

If your identified uses are covered but the supplier recommends alternative operational conditions and RMMs then there are several options that can be looked into. First check if that your own operating conditions and RMMs are more stringent than those required in the suppliers exposure scenario. If this is the case then record the assessment and no further action is required. If this is not the case, then one of the following options as outlined in Artcile 37 (4) of REACH will need to be implemented.

- Implement the conditions of use as described in the exposure scenario you have received if easy to do so for example chaning an engineering control/PPE or make changes to prevent release to the environment

  OR

- Discuss and make your use known to your supplier to determine if it is appropriate that the RMMs in their exposure scenario can be adjusted or scaled see **Section 4bi.**
- Carry out a downstream user chemical safety assessment see **Section 4bii.**

i. Scaling

Scaling is a mathematical approach whereby the conditions of use that are described within the exposure scenario may be modified to determine if the conditions implemented by a downstream user are covered by the exposure scenario. If scaling applies you may be able to implement conditions of use that are different to what the supplier recommends in the exposure scenario without any further action. Scaling options should be communicated within section 4 of the exposure scenario; however, if no scaling rules are provided then scaling is not applicable for that substance. Please note that the application of the scaling techniques requires technical knowledge of both the hazards of the substance and the efficiency of the control methods. This should be carried out by an appropriate individual with the support of the supplier.

ii. Downstream user chemical safety assessment

A downstream user chemical safety assessment establishes that the conditions of use not covered by the exposure scenario are adequately controlling the risk to human health and the environment. If, however, the assessment shows that the risks are not adequately controlled then changes to you conditions of use must be implemented and the assessment must be repeated. This assessment doesn't need to be carried out if one of the following exemptions applies. Total use of substance is less than 1 tonne per year, the substance is used in product and process orientated research and development (PPORD), the substance is present in a mixture in a concentration lower than any of the concentration set out in Article 14 (2). Please note that the chemical safety assessment must be completed within the 12 months of the receipt of the registration number on the SDS/ext-SDS and ECHA must be notified if an exemption applies within the first 6 months.

c. Uses are not covered

If your identified uses are not covered then the following actions must be taken. First retain all current RMMs that are in place but take into consideration any alterations due to updates in the SDS. Next notify your supplier with your use along with sufficient information with the intention to ask if they will cover your use by updating their chemical safety assessment. Please note that a downstream user has 12 months from the receipt of the registration number on the SDS/ext-SDS to contact the supplier to request that they consider your use. If your supplier will not cover you use or if you use is confidential then you will have to carry out a downstream user chemical safety assessment (Section 4bii). Moreover, you could look for an alternative supplier who covers you use or look for an alternative substance!

Step 5: Document the assessment

a. Keep the record of the assessment up to date

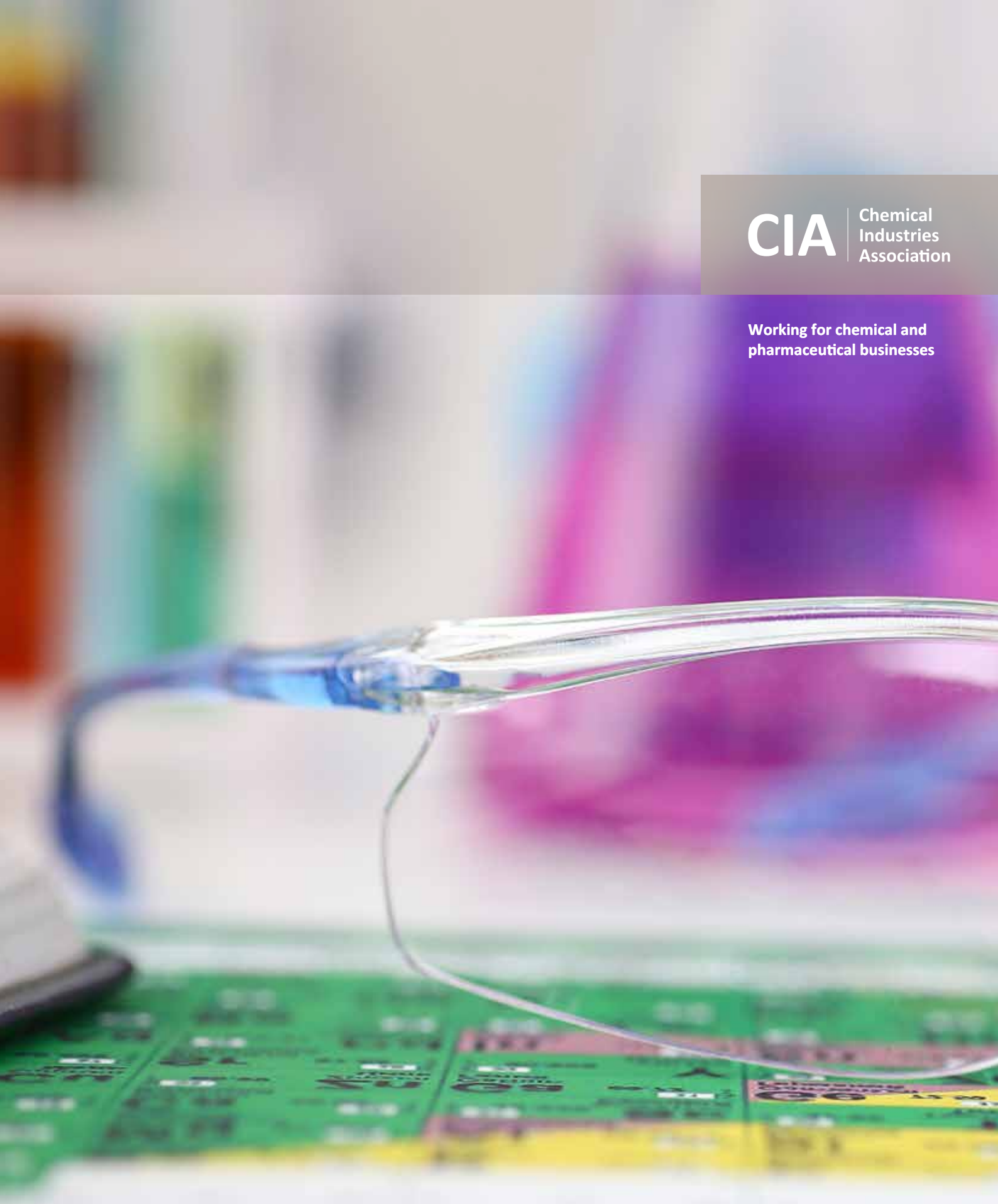
All of the documentation associated with the substance must be reviewed, updated and circulated to the relevant people on site. These actions include health and safety summaries for manufacturing, information for laboratories, environment permitting etc. The new SDS/ext-SDS should also be sent to the relevant colleagues or stored in a centralised system.

b. Withdraw all out of date copies of the SDS/ext-SDS

Ensure that all out of date copies of the SDS/ext-SDS are withdrawn from use and retain at least one copy for historical and legal purposes but make use it is clearly marked as obsolete. Please note that REACH Article 36 states that records should be kept for at least 10 years after the last manufacture, import, supply or use of the substance or mixture. They should be made available without delay to ECHA and the REACH competent authority should they require it.

Further Guidance

For a full list of guidance documents on this topic produced by ECHA and Cefic please see the Directory of Guidance on Exposure Scenarios document.



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Kings Buildings, Smith Square, London, SW1P 3JJ
Telephone: 020 7834 3399

www.cia.org.uk

Disclaimer: This guidance document is intended as a starting point only and should not be used in isolation. It is not designed to inform the reader of what is an extended-safety data sheet, exposure scenario etc. A selection of additional sources of information is provided in a separate document to help the reader further.