THE REACH REGULATION

THE CHEMICAL ASSESSMENT & REPORTING PROCESS IN THE MINISTRY OF DEFENCE

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Produced on behalf of DE&S by:

BMT Cordah Limited,
Chemical Regulatory Services,
Scotstown Road,
Bridge of Don, Aberdeen,
AB23 8HG, UK.

Tel: +44 (0)1224 414200
Fax: +44 (0)1224 414250
Email: enquiries@bmtcordah.com
Website: www.bmtcordah.com
CRS: www.bmtcrs.com
REACH: www.bmtreach.com

BMT Isis Limited
Maritime House
210 Lower Bristol Road
Bath
BA2 3DQ, UK

Tel: +44 (0) 1225 473 727
Fax: +44 (0) 1225 448 714
Email: info@bmt-isis.com
Website: www.bmt-isis.com

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1 INTRODUCTION

The Registration, Evaluation, Authorisation and restriction of Chemicals (REACH) Regulation (EC 1907/2006) provides for an exemption from its requirements where it can be shown to be 'in the interests of defence'. Authority has been vested in the Secretary of State for Defence (SofS) by Part 3 of The REACH Enforcement Regulations 2008 (Statutory Instrument No. 2852/2008) for this exemption.

The defence exemption is supported by a robust process detailed in MOD REACH Guidance and Process for Implementation in MOD document. Applications for exemption must be supported by sufficient evidence or it can accepted if it can be shown another participating Member State has granted exemption for the same substance and use. Exemption will only be granted in specific cases for substances which the SofS deems necessary in the interest of defence. Should an exemption application be unsucessful it will be necessary to register the substance under REACH.

The UK Ministry of Defence (MoD) policy dictates that, where exemptions, disapplications or derogations from legislation have been granted, internal standards and management systems at least as good as that required by the legislation should be introduced where this is reasonably practicable. In accordance with this policy, an internal 'registration' system mirroring the requirements of REACH has been implemented by the MoD.

This document describes the requirement for, and guidance on, the chemical assessment process only to be applied to a substance evaluation (MoD equivalent REACH Technical Dossier (TD) and/or compliant Safety Data Sheet (SDS)) in support of an MOD exemption. This document is not intended to meet the requirement for Chemical Safety Assessment (CSA) nor for substances covered by the Regulation for which an defence exemption does not apply.

This document should be read by all MoD Project Teams (PT) and Defence Industry Partners (DIP) who have applied for and obtained a REACH defence exemption in accordance with the Regulation. Specifically, it provides a stepwise guide to gathering all the relevant information needed on a chemical substance to compile a MoD equivalent REACH Technical Dossier (TD) and/or compliant Safety Data Sheet (SDS). The assessment may identify the need to conduct a Chemical Safety Assessment (CSA) and document the results in the form of a Chemical Safety Report (CSR). Conducting and reporting a CSA is outside the scope of this document and any enquiries of this nature should be referred to the MoD REACH Helpdesk (see below).

Due to the scientific and technical nature of this process all assessments should be undertaken and recorded by suitably qualified and experienced personnel. Once an assessment is complete, it should be reviewed and submitted to the MoD REACH Helpdesk by the individual responsible for the exemption application.

This document should be read in conjunction with the MoD REACH Guidance and Processes document (Report No.: A.139.001) which describes the framework under which this assessment process is being carried out. The report also provides basic information on REACH and the exemption process currently implemented in the MoD. Any questions or concerns regarding the completion of chemical assessments and reports detailed in this document should be directed to the MoD REACH Helpdesk (email to: DESSESEP-REACH@mod.uk).

2 PREPARATION OF MOD CHEMICAL DOSSIERS

The internal MoD REACH registration process involves the production of 'MoD Chemical Dossiers' for each exempted chemical substance, providing detailed information on its safe storage, use and disposal. PTs must ensure that an individual dossier is produced and submitted for each of their exempted substances in accordance with the instructions contained herein. The registration process is deemed complete once a finalised dossier has been submitted to the MoD Restricted Materials Steering Group and has been accepted as meeting the requirements. However, these dossiers are 'living' documents and should be subject to regular review to ensure currency. An associated management system has been devised in order that assurance may be provided against this activity.

The process begins with a competent member of the relevant PT, DIP or their contracted specialist undertaking an initial appraisal of the substance as detailed in Section 2.1. This will determine the level of chemical assessment required by comparing the substance and annual quantities with set criteria. Once the correct approach has been identified, a chemical assessment must be conducted and a TD and CSR compiled as necessary.

2.1 MoD Criteria for Chemical Assessment

The MoD will use a risk-based approach to chemical assessment. The risk rating is determined using available information on the annual quantity of manufacture or import and the classification of the substance. Table 1 indicates the levels of assessment required.

Table 1 – MoD criteria for level of chemical assessment

Risk Level and Requirements	Criteria
Enhanced Technical Dossier Chemical Safety Report Safety Data Sheet	Authorised or Restricted Chemicals * CMR >1 tonne per annum R50/53 >100 tonnes per annum >1000 tonnes per annum 100-1000 tonnes per annum 10-100 tonnes per annum
Standard Technical Dossier Safety Data Sheet	1-10 tonnes per annum
Low Safety Data Sheet	<1 tonne per annum

* - "Restricted" and "Authorised" are designations detailed in the REACH Regulation, see Section 2.1.1.

Substances classified as “low” risk to human or environmental health will only require a SDS. The SDS should clearly outline the risks associated with the product and contain appropriate guidance on safe use. Guidance on the production of a SDS is given in Section 8.

Substances classified as “standard” risk require an assessment consisting of data gathering and evaluation and compilation of a TD. The MoD has introduced an internal TD template based on actual REACH requirements but streamlined in accordance with the objectives laid down by the SofS.

The purpose of the TD is described in Section 2.2 below and guidance on completion is presented throughout this document.

Substances posing an “enhanced” risk to human health or the environment require a detailed assessment and this is the most comprehensive of the three assessment categories. These potentially high risk substances require both a TD and CSR. The CSR relays the information gathered from a CSA.

While further information on CSA/CSR is presented in Section 2.3, this document does not contain specific guidance on the CSA/CSR process. In these instances, advice should be sought from the MoD REACH helpdesk.

With respect to the classification criteria for an “enhanced” assessment in Table 1, guidance on how to ascertain if a chemical is considered Carcinogenic, Mutagenic or Reprotoxic (CMR) category 1 and 2, and R50/53 is presented in Section 2.4.

2.1.1 Authorised and Restricted Chemicals

Chemicals subject to authorisation are listed under Annex XIV of the REACH Regulation. As this list is updated periodically, it is recommended that it is checked regularly on the European Chemicals Agency (ECHA) website (http://echa.europa.eu/). It is worth noting that “candidate lists” contain chemicals being considered for inclusion in Annex XIV, but are not currently subject to authorisation.

Restricted chemicals are listed under Annex XVII of the REACH Regulation. This annex may also be updated periodically so regular review of the ECHA website is again recommended.

All authorised and restricted chemicals exempt from the REACH requirements by the SofS are considered to pose an “enhanced” risk to human and environmental health, and must undergo the appropriate level of assessment in Table 1, regardless of tonnage.

2.2 Technical Dossier

A TD provides all the necessary information on the intrinsic properties of a substance (e.g. physico-chemical data, toxicity data, classification and labelling). Submission of a TD to the MoD Restricted Material Steering Group (RMSG) is required for all substances that meet the criteria for standard or enhanced levels of risk.

The TD will comprise of the following eight categories:

1. Substance identity and MoD contact information;
2. Manufacture, use and exposure;
3. Physical and chemical properties;
4. Environmental fate and pathways;
5. Ecotoxicological information;
6. Toxicological information;
7. Classification and labelling;
8. Guidance on safe use.

Guidance on how to complete each TD category is presented in Sections 3 to 7.

2.3 Chemical Safety Assessment and Chemical Safety Report

The CSA is required in addition to the TD for all substances that meet the criteria for enhanced risk, with the results reported in the form of a CSR. The CSA uses data from the TD and consists of a series of hazard, exposure and risk assessments for the identified uses of a chemical.

The first step of the CSA is to conduct a hazard assessment for human health, the physico-chemical properties of the substance, and the environment. The substance will then be screened for persistent, bioaccumulative and toxic properties (PBT) and very persistent, very bioaccumulative properties (vPvB).

As a result of the hazard assessments, should any substances be classified as dangerous in accordance with EC Directive 67/548/EEC or are found to be PBT or vPvB, the CSA must also include exposure assessment and risk characterisation steps.

This document does not contain guidance on the CSA/CSR process; the MoD REACH Helpdesk will assist with any CSA/CSR requirements as needed.

2.4 Screening for CMR and R50/53

To determine whether a substance is classified as CMR category 1 and 2 and/or R50/53, the first step is to input a substance identifier into the European chemical Substances Information System (ESIS) located at http://ecb.jrc.ec.europa.eu/esis/. The identifier may be the substance name, Chemical Abstracts Service (CAS) number, or European Commission (EC) number. Once the correct chemical substance-specific information page is located, there will be a section on the page called “Classification and Labelling Information”. Sometimes this information may be a simple paragraph, stating that *“This substance is not classified in the Annex I of Directive 67/548/EEC as*

such, but it may be included in one of the group entries". If this is present then it can be reasonably assumed that there are no serious classification issues for this particular substance.

Using benzene as an example, the classification on ESIS is stated as

"*F; R11 -* ***Carc. Cat. 1****; R45 -* ***Muta. Cat. 2****; R46 - T; R48/23/24/25 - Xn; R65 - Xi; R36/38"*

The above line indicates that benzene is classified as a carcinogen (category 1) and a mutagen (category 2). Therefore, under the criteria for the MoD REACH approach, a CSA/CSR would be required. Please note, reprotoxic (or toxic to reproduction) is written as Repr. Cat #.

Another example would be naphthalene, for which the classification on ESIS is stated as:

*"****Carc. Cat.*** *3; R40 - Xn; R22 - N;* ***R50/53****"*

As naphthalene is a category 3 carcinogen it does not meet the criteria for CMR under REACH. However, it is also categorised as R50/53 as demonstrated above, therefore would still require a CSA/CSR under the MoD criteria.

A CSA/CSR is required if just one of the CMR classifications is present as a category 1 or 2, or if the substance is classified as R50/53.

3 CHEMICAL MANUFACTURE, USE AND EXPOSURE CATEGORISATION

This section provides guidance on completing Section 3 of the TD template and covers manufacture, use and exposure categorisation of chemical substances. This section is required for all chemicals that meet the criteria of “standard” or “enhanced” risk.

3.1 Manufacture (Technical Process)

If the chemical substance is manufactured by the MoD, a technical description of the manufacturing process must be given in the “manufacture (technical process)” field. This documentation will provide essential data for any future occupational exposure and risk assessments that may be required if the chemical meets the criteria for “enhanced” risk.

If the chemical substance is imported from outside the EU indicate “imported”. Where the substance is procured from an EU-based upstream supplier, indicate “supplied from within the EU” in this field. The identity and contact details of each supplier should be included.

3.2 Estimated Quantities

In the relevant field, provide the estimated quantities of manufacture, import or procurement of the chemical, in tonnes, for the current calendar year. This documentation will confirm that the appropriate set of data has been included in the TD as required by the REACH Regulation. In some instances it may not have been possible to locate accurate data on tonnage prior to the submission of an exemption application. For the submission of the MoD TD this is a compulsory field, and failure to complete may result in the TD being rejected.

Any accurate forecasts of tonnage for subsequent years that can be added to this field should also be included. This helps to plan for any future increase in regulatory requirements, should the MoD move into a higher REACH tonnage band.

3.3 Sites

All known production and/or use sites for the chemical must be input into the relevant fields of this table. An indication of the type of site should also be added using the pull down menus provided. It should be noted that a production site refers to the manufacture of chemical substances and a use site refers to the formulation (mixing or blending) of chemical substances - this does not refer to the end use of a chemical substance or product.

Additionally, documentation of use sites does not apply in a theatre situation.

3.4 Forms in the Supply Chain

This field documents the form in which the chemical substance is available to the MoD. This is important when categorising routes of exposure for humans and the environment. This

documentation will also provide essential data for any future exposure and risk assessment that may need to be conducted if the chemical meets the criteria for a CSA/CSR.

Fill in as many sections of this table as necessary to document all available forms of the chemical as used by each MoD PT or DIP. Should multiple PTs and/or DIPS be working together to assess the same chemical, each will be responsible for documenting their own form(s) of the chemical substance in the supply chain to be recorded in the TD.

The first row of each record contains a field with a pull down menu for documenting whether the chemical substance is available as a substance on its own, as part of a mixture, or as part of an article. The next row of each record is a free text field for documenting the % composition of the chemical substance as part of a mixture or article and only needs to be completed if the chemical substance is contained in a mixture or article. The final row of this field is only for substances that are components of an article, and requests a brief description of the article (what it is, what it is used for, etc.).

3.5 Identified Uses and Exposure Scenarios

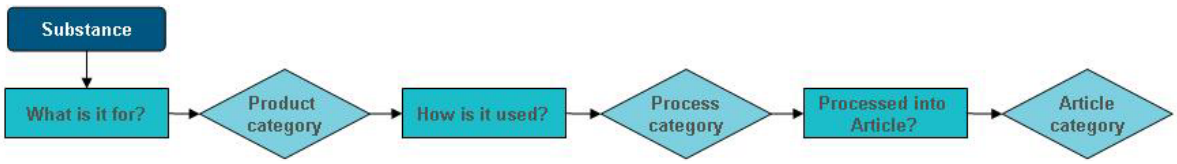
This section provides guidance on completing an important aspect of the REACH process; identifying and categorising the uses of chemicals throughout their life cycle. All intended uses of a chemical (including manufacture if relevant) should be reported in the "identified uses and exposure scenarios" field in this section of the TD. Documentation of each use will provide essential data for any future exposure and risk assessment that may need to be conducted if the chemical meets the criteria for "enhanced" risk.

Before any detail on the use is addressed, there are 5 fields in each record for uses and exposure that must be completed. These fields are the main use category, the specification for industrial and professional use, human and environmental routes of exposure (if applicable) and the pattern of exposure. Multiple selections can be made for these fields, which should be filled out using expert judgement based on the knowledge of each use of the chemical substance.

3.5.1 Description of Use

To complete this field, the REACH "use descriptor system" is used. The use descriptor system is designed to place a substance into simple categories of use, with potentially up to 3 codes as follows; product category, process category and article category. Figure 1 demonstrates the stepwise process to take when choosing appropriate use descriptors.

Figure 1 – Use Descriptor decision diagram



A list of all relevant product, process and article categories can be found in Appendix 1. The product and process categories must always be completed. The article category only applies if the substance is incorporated into an article and is considered dangerous (see Section 6 on classification and labelling) or is intended to be released from the article during the intended use(s) of the article.

Once the use descriptor system for each identified use of the chemical substance has been finalised, enter a brief description of the use in the “description of use” field and include a reference to the relevant product, process and article (if relevant) categories.

3.5.2 Exposure Scenario

This section should only be filled out for chemical substances that meet the criteria for “enhanced” risk. Where human or environmental exposures are identified, if the chemical is considered dangerous, PBT or vPvB (see Section 6 on classification and labelling) then an exposure and risk assessment must be conducted as part of the CSA (see Section 2.1 and 2.3).

Once conducted, the exposure scenarios generated using modelling software and documented in the CSR will be referenced in the field of the use and exposure table.

3.6 Uses Advised Against

Any uses of the chemical substance that are already advised against (e.g. under manufacturers or suppliers instructions, in existing SDS), or uses that pose unacceptable levels of risk identified during this assessment process should be documented in this table. A brief description of the use should be added to the free text field.

4 DATA GATHERING AND EVALUATION

4.1 Introduction

The confidence in the conclusions of any chemical assessment is reliant on the availability and quality (fit for purpose) of data (also called “endpoints”) used by the assessor. In the ideal situation, the assessor has access to a complete set of studies appropriate for the tonnage band, conducted in accordance with the principles of Good Laboratory Practice (GLP) and according to current standard EU methods. In practice, however, the assessor may have a mix of GLP and non-GLP studies, published papers and database entries, which together can often provide equivalent information to assess the properties of the substance appropriately. As this mix of variable quality data is common, a critical first step in any chemical assessment is to assemble all available information on a substance. The assessor must then judge the quality of the data for use in the substance assessment and discard data that are unreliable.

This section aims to give an overview of public domain data acquisition methods. Furthermore, guidance is provided on how these data may be basically evaluated and scored in terms of their reliability and applicability to the substance assessment. The basic principles contained herein follow those proposed in the ECHA guidance (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r3_en.pdf?vers=20_08_08), with the exception that it has been adapted to meet the specific assessment requirements of the MoD.

A list of all the data endpoints required for each tonnage band under REACH, and information on conditions where studies may be derogated, is presented in Supplementary Document 1.

4.2 Data Acquisition

The MoD is unlikely to be in possession of any propriety GLP reports, and such reports are rarely available in the public domain (being the intellectual property of commercial organisations); so unless willing to purchase the right to access or own GLP reports, assessors will need to rely on alternative sources of data. These alternative sources may include one or more of the following main categories:

- Government databases and existing chemical inventories (e.g. EINECS, HPVC, ESIS);
- Internet (much information, such as review papers and academic reports or sources of papers are available online);
- Commercial databases (e.g. Chemical Abstracts Registry, File BIOSIS, CAB Abstracts).

The following sections deal with each of these data sources separately, and provide a list of examples.

4.2.1 Government Databases

Many regulatory authorities enact their freedom of information legislation by publishing summary reports, scientific opinions or dossier format files (such as IUCLID) on the internet, access to which is freely available.

An assessor wanting to search these files generally has two options:

1. Visit all the sites separately (a list is provided in Appendix 2) and search each one individually (which is currently the most comprehensive method);

2. Use the OECD ChemPortal (Global Portal to Information on Chemical Substances). The OECD has developed a web site giving free public access to information on existing chemicals. The Portal gives access to many assessment reports and datasets (see http://webnet3.oecd.org/eChemPortal/) and can, at this stage, be queried by CAS number and chemical names. This is a developing project and, as such, should not be used as a definitive source. If no results are found, it is suggested that other government sources are systematically searched.

4.2.2 Internet Searches

Standard internet search engines can provide a good source of indirect data (e.g. SDSs) and direct data, such as academic papers and review articles, as well as providing access to paid biographic data bases (e.g. Science Direct / Elsevier).

Sources vary in many aspects including quality, reliability and accuracy, indexing policy, extent of peer review, the time-spans covered, number of chemicals addressed and the extent of detail.

There are various chemical specific search engines which specialise in providing access to data (indirect and direct) on various topics such as mammalian toxicity, ecotoxicity and environmental fate (e.g., PubChem and Toxnet).

It is suggested that before internet searching is undertaken that a list of search terms for the different codes and commonly used synonyms for the identity of the substance are compiled.

An example is provided in Table 2 (overleaf) for the organic solvent acetone.

The search terms should then be entered, one at a time, into the search engine in parenthesis (e.g. ”2-propanone”), followed by an secondary term to help provide the most relevant results (e.g. ”2-propanone” and “acute toxicity”).

Table 3 (overleaf) provides a list of suggested terms – “general”, for returning review type, and “focused”, intended to provide endpoint specific data.

Table 2 – List of common synonyms and reference codes for acetone

Name	Synonyms /Codes
Acetone	CAS No.: 67-64-1
	EC No.: 200-662-2
	2-Propanone
	Dimethylketone
	Dimethylformaldehyde

Table 3 – Examples of general and focused secondary search terms

General Secondary Search Term	
“Risk Assessment”	“Inherent properties”
“Hazard Assessment”	“Classification”
“Occupational Risk”	“ECB”
”Environmental Risk”	“RAR”
“MSDS”	“TGD”
“TSDS”	“OECD”
“SDS”	“Inchem”
“physicochemical properties”	
Focused Secondary Search Term	
“Toxicity”; “Acute Toxicity”; “Chronic Toxicity”	“Ecological”
“LD50”	“Aquatic toxicity”; “Ecotoxicity”
“LC50”	“Irritation”; “Sensitisation”
“NOEL”	“PBT”
“NOAEL”	“Oral”; “Inhalation”; “Dermal”
“EC50”	“Repeat Dose”; “Two-Generation”; “Prenatal”
“NOEC”	“Rat”; “Mouse”; “Dog”; “Rabbit”
“PNEC”	“Fish”; “Daphnia”; “Invertebrate”; ”Algae”
“DNEL”	“Mutagencity”; “Cytotoxicity”; “Carcinogenicity”
“Solubility	“DT50” (50 % degradation time)
“Degradation”	“OEL” (operator exposure limit)
“Biodegradable”	“Reprotoxicity”
“Environmental fate”	

4.2.3 Commercial Databases

Commercial databases are convenient centralised repositories for large amounts of chemical data, often not available through other public sources. However, the costs can be high and do not always allow access to the full document until additional fees are paid. Examples include:

- Chemical Abstracts Registry “SciFinder”;
- BIOSIS “biological abstracts”;
- CAB Abstracts.

4.2.4 Alternatives to Substance Specific Data

The REACH process aims to assess thousands of substances in a relatively short time period, at minimal cost and with minimal animal testing. This, combined with the fact that most of these substances will have minimal or no safety data, means that the objectives of REACH cannot be met solely through classic testing methods to provide information for classification; alternative methods must be used.

Alternative methods are expert systems, requiring expertise in chemistry, toxicology, and often modelling. It is suggested that these techniques be employed by the MoD, using an expert practitioner, when all other data acquisition methods fail to provide sufficient information of desired quality. In summary the methods are as follows:

Read-across and Grouping. Where information exists on a structurally similar compound or group of compounds (category), the properties of the substance under assessment can, on a case-by-case basis, be predicted from data on the structurally-similar chemicals. Usually, physicochemical, toxicological and ecotoxicological properties will be similar or follow a regular pattern. The structural similarities may be based on:

- A common functional group (e.g. aldehyde, epoxide, specific metal ion);
- Common precursors or common breakdown products (e.g. the metabolic pathway approach of examining related chemicals such as acid/ester/salt);
- A constant pattern of potency changes across the category (e.g. categories of substances with an incremental and constant change in chain length exhibit a change in properties as a result);
- Common constituents or chemical classes or similar carbon range numbers.

Calculation Methods and Estimation by (Q)SARs. Some properties of chemical substances can be estimated by Structure-Activity Relationships (SARs) or Quantitative Structure-Activity Relationships (QSARs), collectively referred as (Q)SARs. These are theoretical models that can be used to predict in a qualitative or quantitative manner the physicochemical, biological (e.g. toxicological) and environmental properties of substances from a knowledge of their chemical

structure. Information generated by (Q)SARs may, in principle, be used instead of test data, provided that the method is validated by an expert, and meets certain pre-conditions.

4.2.5 Recording the Search Strategy

The exact search strategy employed will be highly chemical substance dependent. A proprietary molecule is unlikely to have any information in the public domain whereas information may be found in comprehensive reviews obtainable from international organisations for some high production volume (HPV) substances. Whatever strategy is employed, it is important to record what approach has been taken and when. This serves two purposes: as a check on the detail and thoroughness of the search and also, if a search needs expanding or further attention, the records will document the time and extent of the previous search. The major elements to capture in this record include:

- Date of search;
- Chemicals names and synonyms used for the search;
- Secondary search terms used;
- Search engines used;
- Search terms used.

4.3 Reliability and Relevance Assessment

The quality of existing studies can vary greatly and their adequacy can be defined by two basic elements:

- **Reliability**: the inherent quality of a study relating to the test method, performance of the study and the reporting. There is a scoring system to record the assessment of reliability, the so-called Klimisch score (see Table 4 overleaf);
- **Relevance**: the extent to which a test is appropriate for a particular hazard or risk assessment.

In general, publications in peer-reviewed journals are preferable to those which are not. High quality reviews, summaries or abstract publications may be used as supporting information. If there is no statement on GLP in the studies published on the web, then they should be regarded as non-GLP studies.

Handbooks are considered reliable only if they are based on a critical evaluation of peer-reviewed data. If the analysis of bibliographic references is limited to secondary data sources it is essential to create a weight of evidence approach.

Table 4 – Klimisch Ratings and Examples

Klimisch Rating	Example
1. Reliable without restrictions	GLP Study report, reported study conducted to relevant international guideline with substance equivalent to that under assessment
2. Reliable with restrictions	Peer reviewed publication, non-GLP Test done with non-guideline species, test conditions Formal regulatory review: EU RAR (Risk assessment report) HPV assessment (EPA or OECD) ISIS IUCLID file
3. Not reliable	Data is fundamentally incomplete, insufficiently detailed, conducted on inappropriate species, or route of exposure.
4. Not assignable	Endpoint listed in handbook, text summary, abstract only, e.g. MSDS

4.4 Data Gaps

Once all available data have been gathered and evaluated, the data applicable for each endpoint must be compared to the data required for the relevant REACH tonnage band (Supplementary Document 1). This process is known as data gap analysis.

Should any data gaps be identified, there are a number of options on the best way to proceed and advice on a suitable strategy should be sought from the MoD REACH Helpdesk.

5 DATA REPORTING

Once the data package for a chemical substance has been compiled, it will need to be reported in the form of study summaries using the MoD TD template, which can be obtained from the MoD REACH Helpdesk.

Form tables for entering study summary information are located in the following sections of the TD template:

Section 4. Physical and chemical properties;

Section 5. Environmental fate and pathways;

Section 6. Ecotoxicological information;

Section 7. Toxicological information.

This section provides guidance on completing endpoint study summaries for the data package compiled on each chemical.

5.1 Good Laboratory Practice

Every study summary template contains a section on the GLP compliance for the data endpoint, in the form of a pull down menu (indicating “yes” or “no”). For each endpoint, identify if the data were generated in accordance with the principles of GLP. If there is no information relating to the GLP status of the study, assume that the study was not GLP compliant.

5.2 Data Source

Every study summary template also contains a section titled “data source”. This section must be completed for all entries and should contain enough information for the reviewer of the dossier to identify the source of the data that has been included in the TD. Use all necessary information from the records of your data search (see Section 4.2.5).

5.3 Physical and Chemical Properties

Section 4 of the TD template presents a tabular form for entering physical and chemical data on the chemical. The form contains 17 physico-chemical endpoints that should be filled in based on the requirements set out in Supplementary Document 1 for the relevant REACH tonnage band.

The first fields requiring input of information are in the “result” column. This is where the actual result of the test or observation will be inserted. In this column, five of the endpoints have pull down menus that should be viewed and the correct result selected. The other twelve endpoints have a field for inserting a specific value. Standard units have been indicated, but if the units are different in the data source being used, make a note in the “data source” column.

The next fields requiring input are the “GLP” and “Data source” columns. Fill in each row of the GLP column in accordance with Section 5.1 and each row of the Data source column in accordance with Section 5.2.

Should there be any additional information deemed necessary to support any of the data included in this section, this can be added in the remarks field at the bottom of the table.

5.4 Environmental Fate and Pathways, Ecotoxicological and Toxicological Information

Sections 5, 6 and 7 of the TD template present individual study summary form tables for each standard study that may be required for a chemical in all of the REACH tonnage bands. To help the user, each study summary table indicates which tonnage band the study is required for under normal circumstances.

The following instructions provide guidance on completing each section of the study summary table.

Endpoint

The endpoint title should match that of the data source that was selected to fill this endpoint study summary.

Method

The second part of the study summary, the “method” section, documents the specific methodology employed to generate the data selected for each endpoint. Each study summary contains fields to include information specific to the endpoint and should be completed, as far as possible, with the information available from the data source. If no information is available for certain methodology fields, please indicate “no data” in the input field.

There are also generic methodology fields present in some or all of the study summary form tables. These fields should ideally be filled in for all endpoints if the information is available. If no information is available for any of these fields, please indicate “no data” in the input field. Table 5 provides information on the generic methodology fields and a summary of information that should be input into these fields.

Table 5 – Generic methodology fields

Methodology Field	Information Requirements
"Test chemical identity"	This section should define the identity of the chemical substance used for the test, including all available identifiers (e.g. name, CAS number, EINECS number, IUPAC name).
"Guideline"	A reference to the specific international guideline that was followed when conducting this study (e.g. EC Guidelines, OECD Guidelines, EPA Guidelines).
"Method" or "test type"	Where guidelines offer multiple options for a test methodology, sometimes the specific method needs to be indicated.
"Duration"	The length of time the "live" or "experimental" phase of the study lasted for. For example, many acute fish tests run for 96 hours.
"Duration of exposure"	Different from "duration", and refers to the time that the test subjects were exposed to the test chemical.
"Test organisms (species)" "Strain" "Sex"	Tests that are conducted on animals will need to have the species that was used in the test documented. Other tests, such as studies on rats or mice often require the strain and sex of animals used and their numbers.
"Route of administration" "Route of exposure" "Type of coverage"	This refers mainly to animal tests and is an indicator of how the test chemical was delivered to the test subject (e.g. oral, intravenous, topical application).
"Vehicle"	The vehicle is any medium or carrier material used when delivering the test substance to an animal (e.g. with food, water, saline, etc) or to aid dissolution in an aquatic study (e.g. a solvent).
"Analytical monitoring" "Analytical verification of doses"	This refers to whether the test involved chemical analysis of the doses (animal study) or water concentrations (aquatic study) to confirm the actual concentrations of the test chemical present. Please also indicate in the results or remarks section whether the results are based on measured concentrations or nominal concentrations (nominal concentrations are when the concentration is assumed based on test chemical preparation and dilution).

Result

The third part of the study summary, the "result" section, documents the key results generated during the test.

Each study summary has its own set of input fields for data specific to the endpoint. These should be completed, as far as possible, with the information available from the data source. If no information is available for certain result fields, please indicate "no data" in the input field.

Table 6 provides information on many of the standard result fields that are included in the study summaries of the TD template, indicating the type of information that is needed.

Table 6 – Result fields

Result Field	Information Requirements
"Endpoint"	The specific value that was derived from the test using the data or statistical transformation of the data (e.g. LC_{50}, EC_{50}, IC_{50}, EC_{10}, NOEC, NOAEL).
"Duration" "Time-point"	The specific time during the live phase of the test for which the endpoint was calculated (e.g. 24 hours, 14 days, 96 days, etc).
"Effect concentration" "Effect level"	The test concentration or dose level specific to the endpoint and duration (e.g. the LC_{50} at 24 hours was 24 $mg.L^{-1}$).
"Basis for effect"	The parameter that was used to define the endpoint (e.g. mortality, growth inhibition, reproduction inhibition).
"Details on observations"	Other more detailed studies (e.g. repeated dose toxicity, developmental toxicity) often have data in the form of observation documentation (such as malformations, pathological observations) that are a key element of the study. This information should be added to the study summary when available.
"Interpretation of results"	Certain studies have a section for "interpretation", which is a way of classifying the results of the study. For example, the results of an acute toxicity study may generate enough information to determine that the substance should be classified as "toxic" under EU classification and labelling legislation. This information is also used for classification and labelling section of the TD (see Section 6).
"Criteria for interpretation"	This indicates under which legislation the above interpretation falls under. This may not be EU-related if the study was conducted in the USA, or Canada for example. Note: If a situation arises where the criteria for classification is non-EU, the results of the study can be used to determine EU classification and labelling requirements by following the instructions in Section 6. Such conversion of criteria should be noted in the TD.

If there are result fields not included in Table 6 for which further clarification is required, information on each type of test is generally available on the OECD website in the "OECD Guidelines for the Testing of Chemicals" section. These guidelines can be used as a general guide to each study included in the TD, or to obtain further information on specific aspects of studies.

The OECD guidelines can be found at:

http://titania.sourceoecd.org/vl=78513/cl=40/nw=1/rpsv/periodical/p15_about.htm?jnlissn=1607310x

GLP and Data Source

The next fields requiring input are the “GLP” and “Data source” columns. Fill in each row of the GLP column in accordance with Section 5.1 and each row of the Data source column in accordance with Section 5.2.

Remarks

Should there be any additional information deemed necessary to support any of the data included in this section, this can be added in the remarks field at the bottom of the table.

6 CLASSIFICATION AND LABELLING

This section provides guidance on completing Section 8 of the TD template for documenting classification and labelling schemes for a chemical substance.

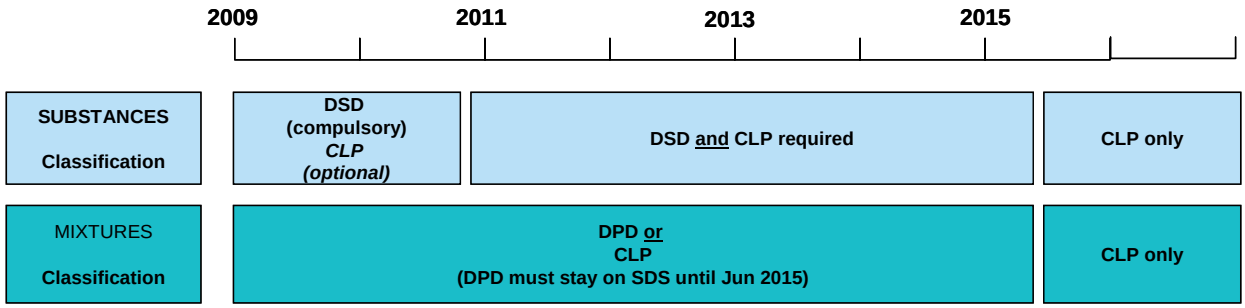
Classification and labelling of a chemical substance should be derived using information from the data gathering, evaluation and reporting stage of this assessment. There are currently two systems that may be used in REACH: the Dangerous Substance Directive (67/548/EEC) (DSD) and the EC Regulation on Classification, labelling and packaging of substances and mixtures (Regulation EC 1272/2008) (CLP) which is the European implementation of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS).

Both approaches have the same underlying aims and principles; using applicable warning symbols and phrases that will demonstrate risks posed by the chemical to the user. Once the classification has been decided, it will be communicated to the user of the substance via the SDS.

At present, REACH only requires submission of classification and labelling schemes using the DSD system, but the CLP scheme will become mandatory in the EU. This transition will coincide with the first REACH registration deadline and therefore, from the 1 December 2010, the CLP scheme for classification and labelling must be implemented for all chemical substances. The deadline for classifying mixtures in accordance with CLP is 31 May 2015.

Companies registering chemicals under REACH directly with ECHA will be required to agree on a harmonised classification and labelling scheme consistent with CLP by 1 December 2010. Therefore, any MoD chemical assessment resulting from a REACH exemption conducted before 1 December 2010 should only implement the DSD reporting system as indicated in this section. The timeline for the transition is demonstrated in Figure 2.

Figure 2 – Timeline showing the transition to the CLP Regulation.



After the 2010 REACH registration deadline, the agreed scheme for classification and labelling of substances under the CLP Regulation will be publicly available from ECHA (http://echa.europa.eu). **After 1st December 2010, Section 8.2 of the TD for a chemical should be updated with the CLP scheme. This scheme of labelling should also be implemented throughout the MoD where necessary.**

6.1 Dangerous Substances Directive

The DSD currently provides EU-wide provisions on the classification, packaging and labelling of dangerous substances. The following guidance on the DSD provides a fundamental overview of applying a classification and labelling scheme.

This document should not be used on its own to apply a classification and labelling scheme in accordance with DSD, as inclusion of all the necessary information and references is outside of its scope. The document should be used in conjunction with Annex VI of DSD which can be downloaded from:

http://ec.europa.eu/environment/chemicals/dansub/consolidated_en.htm.

The end result of the classification and labelling is to assign a substance with categories of danger, risk phrases and safety phrases based on the intrinsic properties of the substance. The categories of danger are as follows and are indicated in listed Section 8.1 of the TD template:

- Explosiveness (E);
- Oxidizing substances and preparations (O);
- Extremely flammable substances and preparations (F+);
- Highly flammable substances and preparations: (F);
- Flammable substances and preparations: (R10);
- Very toxic substances and preparations (T+);
- Toxic substances and preparations (T);
- Harmful substances and preparations (Xn);
- Corrosive substances and preparations (C);
- Irritant substances and preparations (Xi);
- Sensitizing substances and preparations (R42 and/or R43);
- Carcinogenic substances and preparations (Carc);
- Mutagenic substances and preparations (Muta);
- Substances and preparations which are toxic for reproduction (Repr);
- Substances and preparations which are dangerous for the environment (N and/or R52, R53, R59).

The abbreviations associated which the categories are shown in brackets. For further description of the danger categories please refer to Annex VI of DSD.

Any substance with one or more of the above classifications will be considered dangerous as defined by the DSD and thus may require further assessment if the substance meets the criteria of "enhanced" risk (see Section.2.1).

To complete Section 8.1 of the TD template, the simplest approach is to visit the ESIS website: http://ecb.jrc.ec.europa.eu/esis/.

Using this website you can search for a substance using the criteria listed in the pull down menu on the search bar near the top of the page. The results of the search will give an indication of the classification and labeling scheme that should be used for a chemical substance. An example of the results derived from this approach is presented in Figure 2 for the chemical benzene.

Should the ESIS search produce a record indicating that the substance is not classified under Annex I of DSD, or that the substance is not listed on ESIS, a self classification must be carried out in accordance with DSD. This result does not necessarily mean that the substance has no classification, but it is not currently listed on this database. Guidance on a full self-assessment process is outside the scope of this document, and reference should be made to the DSD for conducting this process.

Figure 3 – ESIS search results for benzene

A positive ESIS search result provides all the information needed to complete the classification and labeling scheme for DSD in Section 8.1 of the TD template.

The next step is to input the relevant information from the ESIS search into the table form. The classification phrases from the ESIS search relate directly to the list of classifications in the TD template, and the associated risk, or “R” phrase(s) from the ESIS search should be selected from the pull down menus next to the classification phrase in the TD template. If multiple “R” phrases are required, please use more than one of the pull down menus available. If there is any uncertainty when transferring information from ESIS to the TD template, Annex VI of the DSD provides detailed information on the classification phrases and “R” phrases which will assist with completion of this task.

The DSD labelling section of the TD template should then be completed using the information provided from the results of the ESIS search. Using the pull down menus on the TD template, the fields for “indication of danger” should be completed using the “symbol(s) and indication(s) of danger” information from the ESIS results (which also presents the warning labels that should be present on the substance’s packaging). There are multiple pull down menus in the TD template for this section; use as many as necessary.

All of the “R” phrases identified during this process should then be individually listed in the “risk phrases” section of the TD template, followed by transcription of all the safety phrases, or “S” phrases, including their meanings, from the ESIS results.

The final field of this table is for documentation of specific concentration limits, which are related to the classification of the chemical substance when used in a preparation. These limits are set by Annex III of the Dangerous Preparations Directive (99/45/EC) (DPD). If the defined concentration limits are presented in the ESIS results, then they should be transposed to the “specific concentration limits” field in the TD template. Should the ESIS search produce a record indicating that the substance is not classified under Annex I of DPD, no further action needs to be taken, and “N/A” should be entered in this field.

7 GUIDANCE ON SAFE USE

This section provides guidance on the completion of Section 9 of the TD template. This information should be consistent with that in the SDS as indicated below:

First-Aid Measures

Consistent with SDS Section 4

Fire-Fighting Measures

Consistent with SDS Section 5

Accidental Release Measures

Consistent with SDS Section 6

Handling and Storage

Consistent with SDS Section 7

Transport Information

Consistent with SDS Section 14

If a CSR is not required for a substance, the following information must also be provided in the TD template:

Exposure Controls and Personal Protection

Consistent with SDS Section 8

Stability and Recovery

Consistent with SDS Section 13

Disposal Considerations

Consistent with SDS Section 13

Information on recycling and methods of disposal for both industry and the public (if relevant) should also be provided in this section of the TD.

8 PREPARATION OF REACH COMPLIANT SAFETY DATA SHEETS

The SDS will be the main source of information for the end-user of the product, and is generally a summary of the need-to-know guidance on what the product is, the risks associated with using it, the conditions it should be used in and what to do in case of an accident. Provision of a SDS is the minimum requirement for all exempted chemical substances.

This section provides guidance on what information needs to be included in a REACH compliant SDS.

Section 1 – Identification of the substance/preparation and the Supplier

This should include the product name and its foreseen use, although use is limited to a simple phrase such as “flame retardant”. This section will also contain basic contact information, including an email address and emergency telephone number of the MoD PT or DIP.

Section 2 – Hazard Identification

The demonstration of hazards should be completed using the classification information. An example would be statements such as the GHS hazard statements, indicating clearly the hazards posed by the substance/ preparation during its life cycle. As an example, in this section you may write “Toxic if swallowed, harmful to aquatic life”.

As well as the hazards that require classification, it is recommended that other hazards are also included, even if they do not result in classification but contribute to the overall hazardous impact of the product.

It should also include a description of the most important adverse effects, such as physicochemical, human health or environmental impacts that may arise from the use (or possible misuses) of the substance or preparation.

Section 3 – Composition/ information on ingredients

This section requires a general description of the components of the product, including approximate concentrations.

Section 4 – First aid measures

This will be a general description of the first aid measures that were decided during classification and labelling. If it is recommended that medical attention is sought immediately, then this should be the first statement.

> Following that, symptoms and effects should be summarised with the correct course of action. If applicable, subdivide the information according to the different routes of exposure, i.e. ingestion, inhalation, skin or eye contact.

Section 5 – Fire-fighting measures

This section should include information that is required to safely tackle a fire either caused by the product or occurring near the product and should specify:

- Suitable extinguishing media, as well as specifying any extinguishing media that should not be used for safety reasons;
- Any special protective equipment for fire-fighters;
- Any special exposure hazards arising from the product, e.g. combustion products, toxic fumes.

Section 6 – Accidental release measures

This section should specify the appropriate actions to be taken in the event of a spillage, subdivided into:

- Personal precautions (e.g. prevention of eye and skin contact, removal of ignition sources, control of dust);
- Environmental precautions (e.g. keep away from drains, surface and ground- water);
- Clean-up methods (e.g. use of absorbent material, dilution).

Section 7 – Handling and storage

The SDS should specify precautions for safe handling such as:

- Containment;
- Measures to prevent aerosol and dust generation and fire;
- Local and general ventilation;
- Measures required to protect the environment;
- Any other specific requirements or rules relating to the substance or preparation.

The SDS should also specify precautions for safe storage such as:

- Specific design for storage room or vessels;
- Incompatible materials;
- Conditions of storage (temperature, humidity, light range, etc.);
- Special electrical equipment;

- Prevention of static electricity.

In a final paragraph, detailed operational data should be provided if there are any recommendations for the handling or storage related to specific uses.

Section 8 – Exposure controls/ personal protection

This section is of particular importance as it will specify the measures the user must have in place to safely use the substance. It can be broken down into several sections, with relevance depending on substance. One sub-section is the reporting of exposure limit values, which are the limits on the concentration a worker may be exposed to during a set time period. Values for various substances can be found on the HSE website, by running a search for Indicative Occupational Exposure Limit Values, or IOELV. If the substance is not on the list, it may be necessary to refer to other sources. Contact the MoD REACH helpdesk for further assistance.

The second sub-section focuses on exposure controls, and should outline a full list of Risk Management Measures (RMMs) to be taken to minimise worker and environmental exposure. These RMMs will include:

- Operational exposure controls (work processes and engineering controls);
- Environmental exposure controls (any measures that have been put in place for environmental protection from the substance by UK authorities);
- Organisational measures (training etc);
- Personal Protective Equipment (respiratory, hand, eye and skin protection. An exact specification for each piece of equipment, such as glove material, respiratory filters, or coverage for face masks should also be included as necessary).

Section 9 – Physical and chemical properties

This section should be a summary of the physicochemical information gathered for the TD, under the following headings:

- Appearance;
- Odour (if applicable);
- pH (as supplied in aqueous solution, giving concentrations);
- Boiling point;
- Flash point;
- Flammability (as solid or gas);
- Explosive properties;

- Oxidising properties;
- Vapour pressure;
- Relative density;
- Water solubility;
- Partition coefficient (n-octanol/water);
- Viscosity;
- Vapour density;
- Evaporation rate.

Other information should also be included if relevant to the safe use of the substance. This can include conductivity, melting point and auto-ignition temperature.

Section 10 – Stability and reactivity

Information should be included in the SDS that demonstrates any issues related to stability. Sub-headings may include:

- Conditions to avoid (temperature, pressure etc. which may cause a dangerous reaction);
- Materials to avoid (any substances which may cause a dangerous reaction);
- Hazardous decomposition products (also specify any stabilisers required, the possibility of hazardous exothermic reaction, any changes in physical appearance that may be relevant to safety and the likelihood that these hazardous substances are produced).

Section 11 – Toxicological information

This section deals with the need for a concise but complete description of the various health effects which can arise if the user comes into contact with the substance or preparation. The information should be available from the data gathering performed during the compilation of the TD. The categories of health effects are:

- Toxicokinetics, metabolism and distribution (systemic effects);
- Acute effects (toxicity, irritation and corrosivity);
- Sensitisation;
- Repeated dose toxicity;

- CMR effects.

Section 12 – Ecological information

This section should demonstrate any possible effects, behaviour or fate of the substance or preparation in the environment, taking into consideration air, water and/ or soil if applicable. The information should be categorised as:

- Ecotoxicity (i.e. any acute toxicity data on all aquatic organisms);
- Mobility of the substance (i.e. likelihood to be transported away from the site of release). Refer to:
    - Known or predicted distribution to environmental compartments;
    - Adsorption/ desorption information. If sorbs strongly onto soil (may have a log Kow > 3) the substance is more likely to transfer to the soil compartment.
- Persistence and degradability (degradation through oxidation or hydrolysis. This section should also specify whether the product will degrade in a sewage treatment plant);
- Bioaccumulation potential (means the potential for substance to increase in concentration in organisms by consumption up the food chain. Can be represented by a log Kow > 3 or a Bioconcentration Factor (BCF) value > 2000);
- Results of PBT assessment (the results of the assessment carried out as part of the CSA, Enhanced Dossier only);
- Other adverse effects (e.g. ozone depletion, endocrine disrupting and/or global warming potential).

Section 13 – Disposal considerations

The purpose of this section is to outline the correct disposal procedures for substances or preparations that may require special attention. This could mean that the waste has to be managed as hazardous waste under EU Regulations. The options are:

- Landfill: For information on substances that may be sent to landfill refer to Directive 99/31/EC Article 5;
- Recycling: plastics, glass, paper etc. This will also apply to the packaging of the product;
- Incineration: May apply to a large variety of substances, as legislation only covers the emissions rather than the products incinerated. This should be considered as a back-up for any substances that cannot be recycled or sent to landfill.

For further detailed information on disposal consideration refer specifically to advice in local or regional waste regulations.

Section 14 – Transport information

This shall include any special precautions that a user may need to be aware of regarding transport of the product on the premises or elsewhere. This may include:

- UN Number;
- Class;
- Proper shipping name;
- Packing group;
- Marine pollutant;
- Other applicable information.

Section 15 – Regulatory information

This section will include health, safety and environmental information from the DSD and GHS labelling exercise (R-phrases, hazard statements etc.). Additionally, if the substance is subject to Authorisation or is Restricted under REACH, this will need to be communicated to the user in this section.

Section 16 – Other information

This section should include any information that is considered to be of importance but does not fall specifically under the previous categories. Examples may include:

- Training advice;
- Sources of key data used to compile the SDS;
- Non-statutory recommended restrictions on use;
- Technical contact point.

APPENDIX 1. PRODUCT, PROCESS AND ARTICLE CODES FROM THE REACH USE DESCRIPTOR SYSTEM

A1.1 Descriptor for Types of Preparations [PC = Chemical Product Category]

Product Categories	
PC0	Other products (use ConsExpo subcategories or UCN codes: see last row)
PC1	Adhesives, Sealants
PC2	Adsorbens
PC3	Air Care Products
PC4	Anti-Freeze and De-icing products
PC5	Artists Supply and Hobby Preparations
PC6	Automotive Care Products
PC7	Base metals and alloys
PC8	Biocidal Products (e.g. disinfectants, pest control)
PC9	Coatings and Paints, Fillers, Putties, Thinners
PC10	Building and construction preparations not covered elsewhere
PC11	Explosives
PC12	Fertilisers
PC13	Fuels
PC14	Metal surface treatment products, including galvanic and electroplating products
PC15	Non-metal-surface treatment products
PC16	Heat Transfer Fluids
PC17	Hydraulic Fluids
PC18	Ink and Toners
PC19	Intermediate
PC20	Products such as ph-regulators, flocculants, precipitants, neutralization agents, other unspecific
PC21	Laboratory Chemicals
PC22	Lawn and Garden Preparations, including fertilisers
PC23	Leather tanning, dye, finishing, impregnation and care products
PC24	Lubricants, Greases and Release Products
PC25	Metal Working Fluids
PC26	Paper and board dye, finishing and impregnation product
PC27	Plant Protection Products
PC28	Perfumes, Fragrances
PC29	Pharmaceuticals
PC30	Photochemicals
PC31	Polishes and Wax Blends
PC32	Polymer Preparations and Compounds
PC33	Semiconductor
PC34	Textile dyes, finishing and impregnation products
PC35	Washing and Cleaning Products (including solvent-based products)
PC36	Water softeners
PC37	Water treatment chemicals
PC38	Welding and soldering products, flux products
PC39	Cosmetics, personal care products
PC40	Extraction agents

A1.2 Descriptor for Process Categories [PROC]

Process Categories		
	Process categories based on TRA categories for workers	**Examples and Explanations**
PROC0	Other process or activity	
PROC1	Use in closed process, no likelihood of exposure (Industrial setting).	Use of the substances in high integrity contained system where little potential exists for exposures, e.g. any sampling via closed loop systems.
PROC2	Use in closed, continuous process with occasional controlled exposure, e.g. sampling (Industrial setting).	Continuous process but where the design philosophy is not specifically aimed at minimizing emissions. It is not high integrity and occasional expose will arise e.g. through maintenance, sampling and equipment braking.
PROC3	Use in closed batch process (synthesis or formulation) (Industrial setting).	Batch manufacture of a chemical or formulation where the predominant handling is in a contained manner, e.g. through enclosed transfers, but where some opportunity for contact with chemicals occurs, e.g. through sampling.
PROC4	Use in batch and other process (synthesis) where opportunity for exposure arises (Industrial setting).	Use in batch manufacture of a chemical where significant opportunity for exposure arises, e.g. during the charging, the sampling or discharge of material, and when the nature of the design is likely to result in exposure.
PROC5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) (Industrial setting).	Manufacture or formulation of chemical products or articles using technologies related to mixing and blending of solid or liquid materials, and where the process is in stages and provides the opportunity for significant contact at any stage.
PROC6	Calendering operations (Industrial setting).	Processing of product matrix. Calendering at elevated temperature a large exposed surface.
PROC7	Spraying in industrial settings and applications (Industrial setting).	Air dispersive techniques. Spraying for surface coating, adhesives, polishes/cleaners, air care products, sandblasting; substances can be inhaled as aerosols. The energy of the aerosol particles may require advanced exposure controls; in case of coating, overspray may lead waste water and waste.
PROC8	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non dedicated facilities (Industrial setting).	Sampling, loading, filling, transfer, dumping, bagging in non dedicated facilities. Exposure related to dust, vapour, aerosols or spillage, and cleaning of equipment to be expected.
PROC9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing) (Industrial setting).	Filling lines specifically designed to for both, capturing vapour and aerosol emissions and minimise spillage.

PROC10	Roller application or brushing of adhesive and other coating (Industrial setting).	Low energy spreading, including cleaning of surfaces. Substance can be inhaled as vapours, skin contact through droplets, splashes, working with wipes and handling of treated surfaces.
PROC11	Spraying outside industrial settings or applications (Industrial setting).	Air dispersive techniques (OU9). Spraying for surface coating, adhesives, polishes/cleaners, air care products, sandblasting; (also includes manufacture of foam, including blowing operations). Substances can be inhaled as aerosols. The energy of the aerosol particles may require advanced exposure controls; in case of coating, overspray may lead waste water and waste.
PROC12	Use of blow agents in manufacture of foam (Industrial setting).	
PROC13	Treatment of articles by dipping and pouring (Industrial or non industrial setting).	Immersion operations (OU5). Treatment of articles by dipping, pouring, immersing, soaking, washing out or washing in substances; including cold formation or resin type matrix. Includes handling of treated objects (e.g. after dying, plating). Substance is applied to a surface by low energy techniques as dipping the article into a bath or pouring a preparation onto a surface.
PROC14	Production of preparations or articles by tabletting, compression, extrusion, pelettisation (Industrial setting).	
PROC15	Use a laboratory reagent (Non-industrial setting).	Use of substances at small scale laboratory (< 1 l or 1 kg). Larger laboratories and research and development installations should be treated as industrial processes.
PROC16	Using material as fuel sources, limited exposure to unburned product to be expected (Industrial or non-industrial setting).	Covers the use of material as fuel sources (including additives) where limited exposure to the product is its unburned form is expected. Does not cover exposure as a consequence of spillage or combustion.
PROC17	Lubrication at high energy conditions and in partly open process (Industrial or non-industrial setting).	Lubrication at high energy conditions (temperature, friction) between moving parts and substance; significant part of process is open to workers or to the environment.
PROC18	Greasing at high energy conditions (Industrial or non-industrial setting).	Use as lubricant where significant energy or temperature is applied between the substance and the moving parts.
PROC19	Hand-mixing with intimate contact and only PPE available (Non-industrial setting).	Addresses occupations where intimate and intentional contact with substances occurs without any specific exposure controls than PPE.

PROC20	Heat and pressure transfer fluids in dispersive use but closed systems.	Motor and engine oils, brake fluids. Also in these applications, the lubricant may be exposed to high energy conditions and chemical reactions may take place during use. Exhausted fluids need to be disposed of as waste. Repair and maintenance may lead to skin contact. Leakage during use may lead to environmental exposure.
PROC21	Low energy manipulation of substances bound in materials and/or articles.	Manual cutting, rolling or assembly of material/article, possibly resulting in the release of fibres or rubber fumes.
PROC22	Potentially closed processing operations (with minerals) at elevated temperature	Activities at smelters, furnaces, refineries, coke Exposure related to dust and fumes to be expected. Emission from direct cooling may be relevant.
PROC23	Open processing and transfer operations (with minerals) at elevated temperature	Sand and die casting, tapping and casting melted solids, raking melted solids paving. Exposure related to dust and fumes to be expected. Emission from direct cooling may be relevant.
PROC24	High (mechanical) energy work-up of substances bound in materials and/or articles.	Substantial thermal or kinetic energy applied to substance by grinding, mechanical cutting, drilling or sanding. Release of solids (dust) or fumes to be expected.
PROC25	Hot work operations with metals.	Welding, soldering, gouging, brazing, flame cutting. Exposure due to the release of fumes to be expected.

A1.3 Descriptors for Substances in Articles with no Intended Release

Article category*	
AC 0	Other Articles.
AC 1-1	Passenger cars and motor cycles.
AC 1-2	Other vehicles: Railway, aircraft, vessels, boats, trucks, and associated transport equipment.
AC 2	Machinery and mechanical appliances thereof.
AC 3-1	Electrical and electronic products, e.g. computers, office equipment, video and audio recording, communication equipment.
AC 3-2	Electrical batteries and accumulators.
AC 3-3	Electrical and electronic products: Household appliances (white ware).

* - This list is not exhaustive but contains articles that will be relevant to MoD operations. An exhaustive list of article codes is available in ECHA Guidance on information requirements and chemical safety assessment: Chapter R.12: Use descriptor system.

APPENDIX 2. LIST OF WEBSITES TO USE FOR DATA ACQUISITION

This section provides the most useful resources on the internet (government and commercial) for gathering data and information on chemical substances.

OECD ChemPortal: http://webnet3.oecd.org/eChemPortal/

The Portal gives access to many existing assessment reports and datasets and can at this stage be queried by CAS No and chemical names. This is a developing project and as such should not be used as a definitive source, if no results are found, it is suggested that other government sources are systematically searched.

ESIS: http://ecb.jrc.ec.europa.eu/esis/

A useful site for general chemical information, classification and labelling information, and for regulatory data that may be available in the "IUCLID & OECD Chemical Data Sheets and Export Files Information" section. If an UCLID chemical data sheet exists, this may contain many of the endpoints being searched for.

ChemSpider: http://www.chemspider.com/Search.aspx

A useful source of intrinsic properties, articles, supplementary information, names and synonyms, and predicted properties. Note that predicted properties should not be used unless you can validate the model(s) used to generate these properties.

Sigma-Aldrich: http://www.sigmaaldrich.com/united-kingdom.html

Sigma – Aldrich is a chemical supplier, but their website has a simple search function and is a good source of basic information on chemical substances, including a database of SDSs.

PubChem Compound: http://www.ncbi.nlm.nih.gov/sites/entrez?db=pccompound

The PubChem Compounds Database contains validated chemical depiction information provided to describe substances in "PubChem Substance" (see below). Structures stored within PubChem Compounds are pre-clustered and cross-referenced by identity and similarity groups. Additionally, calculated properties and descriptors are available for searching and filtering of chemical structures.

PubChem Substance: http://www.ncbi.nlm.nih.gov/sites/entrez?db=pcsubstance

The PubChem Substances Database contains descriptions of chemical samples, from a variety of sources, and links to PubMed cited data.

PubMed: http://www.ncbi.nlm.nih.gov/sites/entrez

PubMed is a service of the U.S. National Library of Medicine that includes over 19 million citations from MEDLINE and other life science journals for biomedical articles back to 1948. PubMed includes links to full text articles and other related resources.

US National Toxicology Programme: http://ntp-apps.niehs.nih.gov/ntp_tox/index.cfm

This US government site provides a number of search functions in order to search for testing information, study results and research projects and information on chemicals and public health.

ToxSeek: http://toxseek.nlm.nih.gov/toxseek/ui8/searchfr.jsp?selectedcategory=Allcat

ToxSeek is a chemical data portal hosted by the Unites States National Library of Medicine. This site provides a search facility spanning a number of databases and repositories that can be selected and deselected as necessary.

ToxNet: http://ntp-apps.niehs.nih.gov/ntp_tox/index.cfm

Toxnet is also part of the United States National Library of Medicine. This search facility provides access to databases specifically on toxicology, hazardous chemicals, environmental health and toxic releases.

CDC: http://www.cdc.gov/niosh/srchpage.html

CDC is hosted by the National Institute of Occupational Safety and Health. It has a simple search function that can be used to obtain data and information relating to occupational safety and health. A useful site when searching for toxicology data, operational exposure limits, etc.

ChemSub Online: http://chemsub.online.fr/

ChemSub online provides access to basic chemical information as well as links to international regulatory agency databases that hold data on the substance.

US PA ECOTOX Database: http://cfpub.epa.gov/ecotox/

US government database that provides single chemical toxicity information for aquatic and terrestrial organisms. This site has a useful user guide worth reading.

Scirus: http://www.scirus.com/srsapp/

Scirus Advanced: http://www.scirus.com/srsapp/advanced/index.jsp

Scirus is a chemical search engine that provides access to over 350 million data sources, including all of the major international scientific journals, MSDS information and health and safety information.