

Unclassified

ENV/JM/MONO(2003)16



Organisation de Coopération et de Développement Economiques  
Organisation for Economic Co-operation and Development

18-Dec-2003

English - Or. English

**ENVIRONMENT DIRECTORATE  
JOINT MEETING OF THE CHEMICALS COMMITTEE AND  
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY**

ENV/JM/MONO(2003)16  
Unclassified

**GUIDANCE DOCUMENT ON REPORTING SUMMARY INFORMATION ON ENVIRONMENTAL,  
OCCUPATIONAL AND CONSUMER EXPOSURE**

JT00156125

Document complet disponible sur OLIS dans son format d'origine  
Complete document available on OLIS in its original format

English - Or. English



OECD Environment, Health and Safety Publications  
Series on Testing and Assessment  
No. 42

**Guidance Document on Reporting Summary  
Information on Environmental, Occupational and  
Consumer Exposure**

## Acknowledgements

This Guidance Document was developed by the Ad-hoc Expert Group on Reporting Summary Exposure Information, consisting of the following experts nominated by member countries and other organizations:

- Chris LEE-STEERE, Environment Australia
- Edward DOYLE, Health Canada
- Jonathan TIGNER, Environment Canada
- Aurélie CHÉZEAU, Institut national de l'environnement industriel et des risques, France
- Heinz GORALCZYK, Federal Environmental Agency, Germany
- Gerhard HEINEMEYER, Federal Institute for Health Protection of Consumers and Veterinary Medicine, Germany
- Leonello ATTIAS, Istituto Superiore di Sanità, Italy
- Renato CABELLA, Istituto Superiore per la Prevenzione e la Sicurezza del Lavoro (ISPESL), Italy
- Fukuya IINO, National Institute of Advanced Industrial Science and Tech (AIST), Japan
- Gregory MOORE, National Chemicals Inspectorate (KEMI), Sweden
- Diane LLEWELLYN, Health and Safety Executive (HSE), UK
- Cathy FEHRENBACHER, US EPA (Chair)
- Scott PROTHERO, US EPA
- Bo WAHLSTRÖM, UNEP Chemicals
- Jennifer ABRIL, American Chemistry Council
- James COOPER, Association Management Center
- Alvaro DECARVALHO, The Soap and Detergent Association
- William GREGGS, Procter & Gamble
- Volker KOCH, Clariant GmbH
- Chris MONEY, Exxon Mobil Petroleum and Chemical
- Jean-Paul ROBIN, MD Noranda Inc.

In addition, the following experts participated in the trial of the draft version of reporting formats.

- Andrea Boehncke, Fraunhofer Institute of Toxicology and Aerosol Research, Germany
- Haruyuki Higashino, National Institute of Advanced Industrial Science and Technology, Japan
- Kyoko Ono, National Institute of Advanced Industrial Science and Technology, Japan
- Hongbin Cao, National Institute of Advanced Industrial Science and Technology, Japan
- Ron Lee, Versar Inc., USA
- Tim Brenza, Eastern Research Group Inc., USA
- Anonymous, Environment Agency, UK
- Dave Brooke, Building Research Establishment, UK
- Jason McEwan and Jonathan Tigner, Environment Canada
- Ellen Stephens, First Chemical Corporation, USA

**Also published in the Series on Testing and Assessment:**

No. 1, *Guidance Document for the Development of OECD Guidelines for Testing of Chemicals (1993; reformatted 1995)*

No. 2, *Detailed Review Paper on Biodegradability Testing (1995)*

No. 3, *Guidance Document for Aquatic Effects Assessment (1995)*

No. 4, *Report of the OECD Workshop on Environmental Hazard/Risk Assessment (1995)*

No. 5, *Report of the SETAC/OECD Workshop on Avian Toxicity Testing (1996)*

No. 6, *Report of the Final Ring-test of the Daphnia magna Reproduction Test (1997)*

No. 7, *Guidance Document on Direct Phototransformation of Chemicals in Water (1997)*

No. 8, *Report of the OECD Workshop on Sharing Information about New Industrial Chemicals Assessment (1997)*

No. 9, *Guidance Document for the Conduct of Studies of Occupational Exposure to Pesticides during Agricultural Application (1997)*

No. 10, *Report of the OECD Workshop on Statistical Analysis of Aquatic Toxicity Data (1998)*

No. 11, *Detailed Review Paper on Aquatic Testing Methods for Pesticides and industrial Chemicals (1998)*

No. 12, *Detailed Review Document on Classification Systems for Germ Cell Mutagenicity in OECD Member Countries (1998)*

No. 13, *Detailed Review Document on Classification Systems for Sensitising Substances in OECD Member Countries (1998)*

No. 14, *Detailed Review Document on Classification Systems for Eye Irritation/Corrosion in OECD Member Countries (1998)*

No. 15, *Detailed Review Document on Classification Systems for Reproductive Toxicity in OECD Member Countries (1998)*

No. 16, *Detailed Review Document on Classification Systems for Skin Irritation/Corrosion in OECD Member Countries (1998)*

No. 17, *Environmental Exposure Assessment Strategies for Existing Industrial Chemicals in OECD Member Countries (1999)*

- No. 18, *Report of the OECD Workshop on Improving the Use of Monitoring Data in the Exposure Assessment of Industrial Chemicals (2000)*
- No. 19, *Guidance Document on the Recognition, Assessment and Use of Clinical Signs as Humane Endpoints for Experimental Animals used in Safety Evaluation (1999)*
- No. 20, *Revised Draft Guidance Document for Neurotoxicity Testing (in preparation)*
- No. 21, *Detailed Review Paper: Appraisal of Test Methods for Sex Hormone Disrupting Chemicals (2000)*
- No. 22, *Guidance Document for the Performance of Out-door Monolith Lysimeter Studies (2000)*
- No. 23, *Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures (2000)*
- No. 24, *Guidance Document on Acute Oral Toxicity Testing (2001)*
- No. 25, *Detailed Review Document on Hazard Classification Systems for Specifics Target Organ Systemic Toxicity Repeated Exposure in OECD Member Countries (2001)*
- No. 26, *Revised Analysis of Responses Received from Member Countries to the Questionnaire on Regulatory Acute Toxicity Data Needs (2001)*
- No. 27, *Guidance Document on the Use of the Harmonised System for the Classification of Chemicals Which are Hazardous for the Aquatic Environment (2001)*
- No. 28, *Guidance Document for the Conduct of Skin Absorption Studies (2004)*
- No. 29, *Guidance Document on Transformation/Dissolution of Metals and Metal Compounds in Aqueous Media (2001)*
- No. 30, *Detailed Review Document on Hazard Classification Systems for Mixtures (2001)*
- No. 31, *Detailed Review Paper on Non-Genotoxic Carcinogens Detection: The Performance of In-Vitro Cell Transformation Assays(draft)*

No. 32, *Guidance Notes for Analysis and Evaluation of Repeat-Dose Toxicity Studies (2000)*

No. 33, *Harmonised Integrated Classification System for Human Health and Environmental Hazards of Chemical Substances and Mixtures(2001)*

No. 34, *Guidance Document on the Development, Validation and Regulatory Acceptance of New and Updated Internationally Acceptable Test Methods in Hazard Assessment (in preparation)*

No. 35, *Guidance notes for analysis and evaluation of chronic toxicity and carcinogenicity studies (2002)*

No. 36, *Report of the OECD/UNEP Workshop on the use of Multimedia Models for estimating overall Environmental Persistence and long range Transport in the context of PBTS/POPS Assessment (2002)*

No. 37, *Detailed Review Document on Classification Systems for Substances Which Pose an Aspiration Hazard (2002)*

No. 38, *Detailed Background Review of the Uterotrophic Assay Summary of the Available Literature in Support of the Project of the OECD Task Force on Endocrine Disrupters Testing and Assessment (EDTA) to Standardise and Validate the Uterotrophic Assay (2003)*

No. 39, *Guidance Document on Acute Inhalation Toxicity Testing (in preparation)*

No. 40, *Detailed Review Document on Classification in OECD Member Countries of Substances and Mixtures Which Cause Respiratory Tract Irritation and Corrosion (2003)*

No. 41, *Detailed Review Document on Classification in OECD Member Countries of Substances and Mixtures which in Contact with Water Release Toxic Gases (2003)*

No. 42, *Guidance Document on Reporting Summary Information on Environmental, Occupational and Consumer Exposure (2003)*

No. 43, *Draft Guidance Document on Reproductive Toxicity Testing and Assessment (in preparation)*

No. 44, *Description of Selected Key Generic Terms Used in Chemical Hazard/Risk Assessment (2003)*

© **OECD 2003**

Applications for permission to reproduce or translate all or part of this material should be made to: Head of Publications Service, OECD, 2 rue André-Pascal, 75775 Paris Cedex 16, France



## About the OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 30 industrialised countries in North America, Europe and the Pacific, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised Committees and subsidiary groups composed of Member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's Workshops and other meetings. Committees and subsidiary groups are served by the OECD Secretariat, located in Paris, France, which is organised into Directorates and Divisions.

The work of the OECD related to chemical safety is carried out in the Environment, Health and Safety Programme. As part of its work on chemical testing, the OECD has issued several Council Decisions and Recommendations (the former legally binding on member countries), as well as numerous Guidance Documents and technical reports. The best known of these publications, the OECD Test Guidelines, is a collection of methods used to assess the hazards of chemicals and of chemical preparations. These methods cover tests for physical and chemical properties, effects on human health and wildlife, and accumulation and degradation in the environment. The OECD Test Guidelines are recognised world-wide as the standard reference tool for chemical testing.

More information about the Environment, Health and Safety Programme and its publications (including the Test Guidelines) is available on the OECD's World Wide Web site <http://www.oecd.org/ehs/>.

The Environment, Health and Safety Programme co-operates closely with other international organisations. This document was produced within the framework of the Inter-Organisation Programme for the Sound Management of Chemicals (IOMC).

**The Inter-Organization Programme for the Sound Management of Chemicals (IOMC) was established in 1995 by UNEP, ILO, FAO, WHO, UNIDO and the OECD (the Participating Organisations), following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. UNITAR joined the IOMC in 1997 to become the seventh Participating Organisation. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.**

**This publication is available electronically, at no charge.**

**For the complete text of this and many other Environment,  
Health and Safety publications, consult the OECD's  
World Wide Web site  
(<http://www.oecd.org/ehs/>)**

**or contact:**

**OECD Environment Directorate,  
Environment, Health and Safety Division**

**2 rue André-Pascal  
75775 Paris Cedex 16  
France**

**Fax: (33-1) 45 24 16 75**

**E-mail: [ehscont@oecd.org](mailto:ehscont@oecd.org)**

## Table of contents

CHAPTER 1. INTRODUCTION .....	10
Purpose of the Exposure Reporting Formats.....	10
Overview of the Guidance.....	10
Overview of the Formats.....	10
How to Use the Formats and Guidance.....	11
Other Considerations in the Context of Exposure Reporting.....	12
CHAPTER 2. FORMATS .....	13
Format A: General Information and Overview of Exposure .....	14
Format B: Monitoring Evaluations .....	18
Format C: Modeling Evaluations. ....	20
CHAPTER 3. FORMAT-SPECIFIC GUIDANCE .....	21
Format A: General Information - Instructions for Completing the Format. ....	22
I. Identification Information.....	22
II. Chemical Information.....	22
III. Purpose and Coverage.....	23
IV. Summary .....	24
V. Production, Import/Export and Use Total Volumes.....	24
VI. Life Cycle Steps Covered in this Report .....	25
VII. Unassociated Format B and/ or Format C .....	29
VIII. References .....	30
Format B: Monitoring Evaluation - Instructions for Completing the Format. ....	31
I. Identification Information.....	31
II. Monitoring Study Design and Description of Scenario Monitored.....	31
III. Sampling and Analytical Methods .....	32
IV. Results and Reliability Description.....	33
V. References .....	34
Format C: Modelling Evaluation – Instructions for Completing the Format .....	35
I. Identification Information.....	35
II. Modeling Objective and Description of Modeled Scenario .....	35
III. Description of Model and Model Validation .....	36
IV. Inputs, Outputs, and Reliability Description.....	37
V. References .....	39
ANNEX 1 INFORMATION ON PHYSICAL AND CHEMICAL PROPERTIES, EXPOSURE LIMITS	40
ANNEX 2 GLOSSARY OF TERMINOLOGY .....	41
ANNEX 3 RESOURCES .....	42
ANNEX 4 LISTING OF INDUSTRIAL CATEGORIES AND USE CATEGORIES. ....	45

## CHAPTER 1. INTRODUCTION

### Purpose of the Exposure Reporting Formats

1. This document contains guidance for using the summary exposure information reporting formats, which were developed by the OECD Ad Hoc Group on Reporting Summary Exposure Information.
2. The objective of the work of this Ad Hoc Group is to develop flexible formats and guidance for the reporting of summary exposure information (quantitative and qualitative), which can be used in various chemical assessment programs.
3. The purpose for developing such formats and guidance is:
  - to enhance consistency in reporting summary exposure information;
  - to support reporting of different levels of information (e.g. Qualitative, Screening Level, Comprehensive) as appropriate to the purpose of the report and the data available to the submitter;
  - to harmonize definitions;
  - to promote transparency of reported exposure information;
  - to provide clarity on the purpose and coverage (or scope) of information reported; and,
  - to provide a consistent approach for describing the reliability of the information.

### Overview of the Guidance

4. The abbreviated guidance provides suggestions on the type of information that may be included in each section of the draft format. Because each exposure assessment will be different (e.g., tailored to the specifics of the chemical and relevant exposure scenarios for that chemical), the guidance is very general. The level of detail that is appropriate for a particular submission, and for different sections within a submission, is based on its purpose and the availability of information. The guidance also provides suggestions for presenting the summary exposure information in a manner that is transparent and enables the reader to understand how the analysis was conducted, and the extent to which potential exposures have been characterized. It also gives an approach for providing the reader with an understanding of the reliability of the monitoring data, modeled estimates and the overall exposure assessment.

### Overview of the Formats

5. The pathways that lead to human and environmental exposure to chemicals may vary greatly by use pattern and receptor population (Figure 1-1). The summary exposure reporting formats described in

these pages are intended to be a flexible framework for reporting summary exposure information that are adaptable to this wide range of exposure scenarios as well as to different levels of exposure information. Therefore, these formats are not intended to be prescriptive. Rather, they provide a suggested flow of information. Three basic formats are provided to facilitate reporting of summary exposure information of interest to industry, governmental organizations, other stakeholders, and the public. *Format A: General Information and Overview of Exposure* summarizes information such as the organization and technical contact for the information provided in the formats, the identity and form of the chemical, its overall volumes, uses in commerce, and background to help in framing information and data provided in associated Formats B and C. *Format B: Monitoring Evaluations* summarizes data and information on direct measurements of chemical exposure for specific use or release scenarios; and *Format C: Modeling Evaluations* summarizes data and information generated by using mathematical models that predict exposure to a chemical for specific use or release scenarios. Chapter 2 of this document presents the three formats and Chapter 3 gives more in-depth guidance on how to complete the formats. Each format contains a suggested set of exposure-related sections covering different types of information that could be reported. Since uses and exposures vary by chemical and since a submitter's purpose and available information may vary, the content of each relevant section of the exposure reporting formats for a given chemical will also vary. However the goal is that a completed summary report will be sufficiently complete and transparent to enable readers to understand the summarized exposures without providing an excess of information that is not needed.

6. A critical aspect in reporting exposure information is to provide an evaluation of the reliability of that information, e.g. the inherent quality of the exposure monitoring or modeling information, and the methods and procedures for collecting and describing the information to be able to give evidence of the clarity and plausibility of the findings. The guidance includes an approach for providing a "Reliability Score" for information reported in both Format B: Monitoring and Format C: Modeling.

7. There are 4 Annexes included in this document. Annex 1 includes a format that can be used when summary information on physical, or chemical properties are to be reported. Annex 2 provides a glossary of terminology. Annex 3 provides relevant resources for emission scenario documents, exposure factor references, function/product use descriptions, some available models, etc. Annex 4 includes a listing of Industrial Categories and Use Categories.

### **How to Use the Formats and Guidance**

8. As noted above, the formats are designed to be flexible and to accommodate both quantitative (e.g., release rate, exposure result) and qualitative information (e.g., description of source of release, description of control measures), to cover any chemical or category of chemicals from various sources, and could contain a variety of exposure scenarios ranging from site-specific to national or even regional summaries (See figure 1-1 for various sources and pathways). As a submitter, you may find it helpful to consult with individuals who collected the available information, occupational hygienists, engineers, or others who are familiar with the chemical and associated exposures and releases. The formats may be used to summarize information from existing exposure assessment reports, and/or information that has not previously been analyzed and characterized in an assessment. You will need to determine the purpose, scope, and level of detail of your summary and complete the formats accordingly. For example, if your report summarizes only those exposures associated with occupational activities, you would complete sections I through IV of the Format A and the relevant information in section V and VI. If there were monitoring or modeling information, Formats B and C would be completed as appropriate. Within each format, you will need to determine the level of detail appropriate to transparently communicate the summarized exposure information. Each format section includes hyperlinks—"See Guidance"—that take you to additional detail to aide you in completing the Format. From the guidance, a "**BACK**" hyperlink will take you back to the section in the Format. Helpful Tips are included at the beginning of each Format or section to assist you in

completing the format.

9. For each reported chemical or category of chemicals, a *Format A: General Information and Overview of Exposure* format will need to be completed, since it contains basic information about the chemical/category and overall perspective on potential exposures. Available monitoring or modeling data can be summarized in *Format B: Monitoring Evaluations* and/or *Format C: Modeling Evaluations*. A chemical may have been evaluated in one or more monitoring studies intended to measure human exposures, environmental media concentrations or for some other purpose. Likewise, more than one modeling study may have been conducted. *Monitoring Evaluations* and/or *Modeling Evaluations* formats may be provided for any activities for which there is a potential for human or ecological exposure (e.g., general environmental monitoring, outdoor air exposures to children in the communities where the production plant(s) are located, occupational exposure to workers involved in chemical production, etc.). Therefore, there may be multiple *Monitoring Evaluations* and *Modeling Evaluations* formats included with *Format A*. In some cases it may not be possible to relate the measured exposure or environmental media concentration from a monitoring study to a particular activity (i.e., to chemical production or to the industrial, commercial or consumer product uses of the chemical). However, such general monitoring data may still be useful for understanding overall exposures. In these cases, a *Monitoring Evaluations* format can be used to capture the information.

10. From a practical standpoint, data and information may be duplicated across the formats if it helps improve clarity, while in other cases a cross reference to information elsewhere in the formats may be used to prevent unnecessary duplication of data and information.

#### **Other Considerations in the Context of Exposure Reporting**

11. **Proprietary Information.** It may be necessary to establish mechanisms to share exposure information in a way that successfully addresses potential concerns about preserving the inherent value of this information. In some cases, detailed information relevant to assessments may be considered proprietary such that information providers may not want to (or even be able to) share it with competitors. In addition, you may be disinclined to share exposure data because of its value for potential use in a regulatory context, such as gaining product approvals (e.g., compensation for toxicity testing data, proprietary processes). The Alliance for Chemical Awareness has documented a variety of creative data sharing mechanisms that can help in meeting the goals of improved transparency, while maintaining protection of confidential information, found at : <http://chemicalawareness.org/resources/data.html>

12. **Communicating with the Public.** Obviously, the manner in which information is presented to the public can be expected to be of considerable interest and potential concern. Providing caveats regarding the limitations of data because of the scope and nature of the exposure assessment may be helpful but will not entirely address these problems. In some – but certainly not all – instances, you may be able to overcome or resolve these concerns. In most cases, you will have to assess these concerns as part of the cost-benefit analysis that will need to be undertaken in order to make a decision in the merits of providing summary exposure information. The Alliance for Chemical Awareness has also developed resources for such communications, which can be found at:

<http://chemicalawareness.org/resources/communications.html>

13. **Anti-trust implications.** Finally, discussions among companies choosing to collaboratively prepare exposure reports may include fairly detailed information on topics such as chemical products, uses and production volume. Depending upon the level of detail, content and context of those discussions, you may wish to consult with legal counsel on the potential for anti-trust issues and whether there are tools or techniques to avoid potential liability.

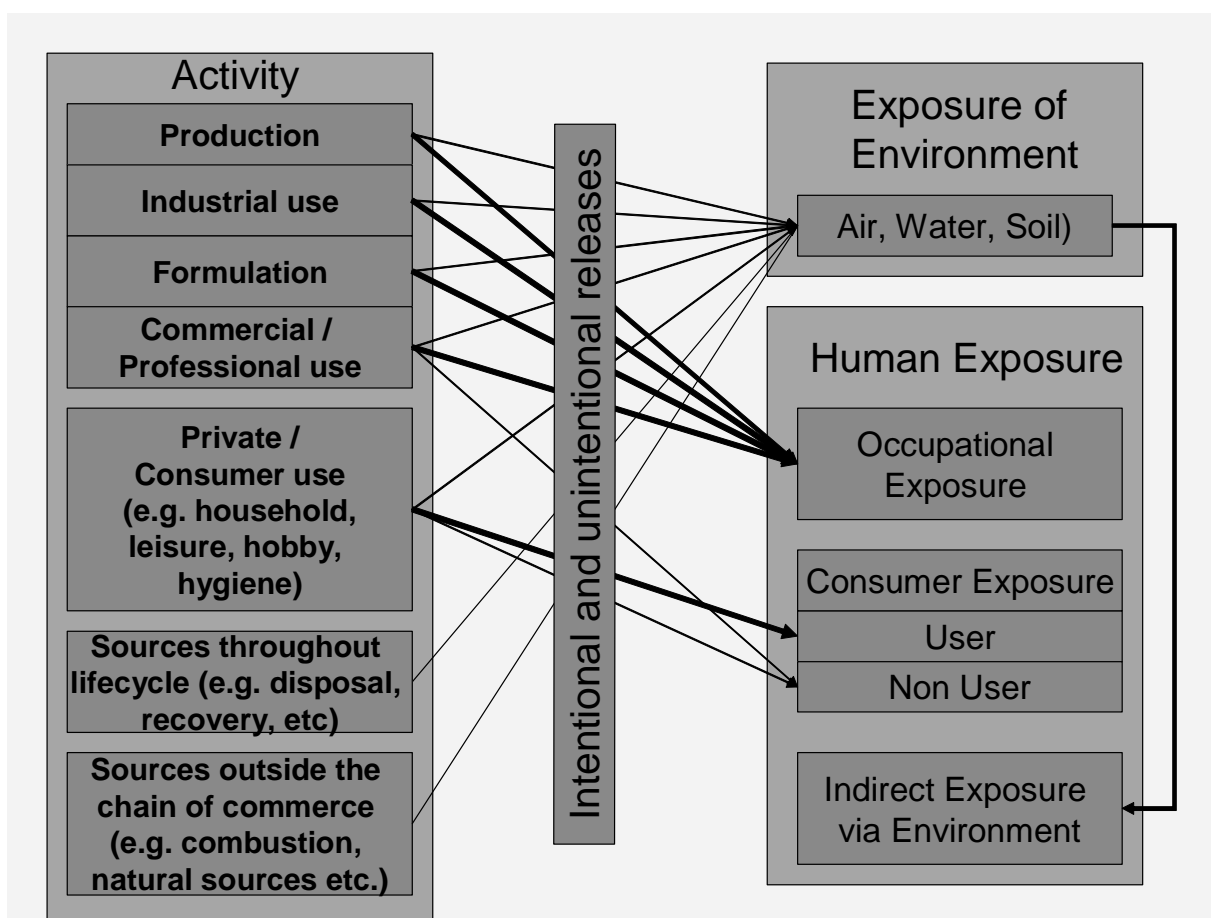


Figure 1-1. Routes of Chemical Exposure.

## CHAPTER 2. FORMATS

14. This Chapter presents the blank formats A, B and C, with helpful tips and [Hyperlinks](#) to the relevant section of the format-specific guidance (Chapter 3).

### Format A: General Information and Overview of Exposure [See Guidance](#)

**Report Title:** (Create a title that reflects the information provided in the formats.) [See Guidance](#)

*Helpful Tip: Information should be added under each section if that information is applicable to the Purpose and Coverage described in Format A, Section III. For example, if the summary includes information relevant only to worker exposure, data and information relevant to releases need not be included unless they are related to the worker exposures being summarized.*

*Helpful Tip: Data and information may be duplicated across the formats if it helps to improve the clarity, but a cross reference to information elsewhere in the formats may be used to prevent unnecessary duplication of data and information.*

*Helpful Tip: Available data tables may be attached either as an annex or within the relevant field.*

#### I. Identification Information

- |  |
|--|
| <b>(1) Date of Submission</b> (Provide the date on which the summary was completed.)   |
| <b>(2) Identity of Organization</b> (Provide the company name and technical contact information.) <a href="#">See Guidance</a>                         |
| <b>(3) Contents</b> (list of accompanying format(s) and annex(es) included) (List the formats completed, and any annexes) <a href="#">See Guidance</a> |

#### II. Substance information

- |   |
|---|
| <b>(1) Category Name or CAS Number(s)</b> (Provide CAS number(s) for the chemical and for each chemical in the category if a category approach is used.) <a href="#">See Guidance</a>         |
| <b>(2) Substance Name(s)</b> (List the chemical identities (trade names, common names, TSCA Inventory names, IUPAC names, and/or synonyms.) <a href="#">See Guidance</a>                      |
| <b>(3) Substance Formula and Structure</b> (Provide the chemical formula for the substance and a structural diagram, if available.) <a href="#">See Guidance</a>                              |
| <b>(4) Physical Form</b> (Enter the physical form of the pure chemical .) <a href="#">See Guidance</a>  |
| <b>(5) Other Constituents (If Applicable)</b> (List any other constituents of the substance, including the name, CAS number, percentage range, impurities, etc.) <a href="#">See Guidance</a> |



### III. Purpose and Coverage of this Report.

(1) <b>Purpose</b> (Provide a brief description of the purpose of the submission e.g., a post-SIDS submission.) <u>See Guidance</u>
(2) <b>Coverage</b> (Identify which exposures are covered in this summary, and which are not covered) <u>See Guidance</u>

### IV. Summary

(1) <b>Synthesis of Key Results</b> (Summarize the key results of the exposure assessment, including the most significant endpoints of exposure, and the methods by which they were identified and quantified.) <u>See Guidance</u>
(2) <b>Summary of Data Collection Efforts</b> (Describe the efforts to research and collect data for this summary.) <u>See Guidance</u>
(3) <b>Discussion of Key Uncertainties, Limitations, Data Gaps</b> (Describe the uncertainties and limitations of the information and data reported.) <u>See Guidance</u>
(4) <b>Table of Exposure Results</b> (List the exposure results and identify the exposed population(s).) <u>See Guidance</u>

### V. Production, Import/Export and Use Total Volumes

(1) <b>Estimated Total Produced, Imported, and Exported Volumes:</b> (Provide volumes in tonnes per year; indicate information source, the geographical area and year to which the value applies.) <u>See Guidance</u>
(2) <b>Industrial and Use Categories and Percent Volume for Each:</b> (For each Industrial Category or Use Category, provide the corresponding percentage of chemical used indicate source of information, the geographical area and year to which the value applies.) <u>See Guidance</u>
(3) <b>Remarks:</b> (Include any relevant information not included elsewhere in the format.) <u>See Guidance</u>

**VI. Life Cycle Steps Covered in this Report See Guidance**

**Production, Formulation, and Industrial/ Professional Use See Guidance**

*Helpful Tip: This section is designed to be applicable to Production, Formulation, and Use. Complete the section using information relevant to the applicable part of the life cycle.*

*Helpful Tip: This section may be copied multiple times to be used for each process and/or site you are including based on the Purpose and Coverage you've identified for this report.*

*Helpful Tip: Some chemicals are used in private businesses that may be characterized as industrial or non-industrial. You should determine whether the information and data are more appropriately placed in the format under the Industrial/Professional Use (this section of Format A) or under Private Use (next section of Format A). For example, an assessment of solvent release and exposure in dry cleaning businesses would generally be summarized under Industrial Use, whereas a solvent release from a household would be Private Use.*

**(1) Volumes and Related Information:** (Provide general or site-specific information on sites and volume produced, formulated, or used in this process) See Guidance

**(2) Process Description and Related Information:** (Describe the process and/or provide a process flow diagram and other relevant and available information.) See Guidance

**(3) General Description of Potential Releases and Exposures**

(a) Releases: (Describe and where possible quantify all potential sources of releases and each receiving media) See Guidance

(b) Exposures: (Describe and where possible quantify all potential exposures) See Guidance

*For any releases and exposures presented in Formats B and C provide a cross-reference, if applicable.*

**(4) Discussion of Factors that Decrease or Increase Releases and Exposures:** (Describe how engineering, administrative or work practice controls, personal protective equipment, and occupational and environmental regulations may affect releases and exposures.) See Guidance

**(5) Environmental Exposure:** (Describe and where possible quantify the discharges associated with the process) See Guidance

**(6) Information not Included and Rationale** Briefly describe and explain why available information relevant to the purpose and coverage of this summary is not included. See Guidance

**(7) Remarks:** (Include any relevant information not included elsewhere in the format.) See Guidance

**Private (Consumer) Use (copy for different use types)**

*Helpful Tip: Sections 8 through 11 below apply only to consumer products. If your report does not include consumer products, this section may be omitted.*

*Helpful Tip: Some chemicals are used in private businesses that may be characterized as industrial or non-industrial. You should determine whether the information and data are more appropriately placed in the format under the Industrial/Professional Use or under Private Use. For example, an assessment of solvent release and exposure in dry cleaning businesses would generally be summarized under Industrial Use, whereas a solvent release from a household would be Private Use.*

<p><b>(8) Function/ Product Use Category Description.</b> Identify each type of private (consumer) product use, function of the substance in the product, physical form of the product, concentration of the substance in the product and other relevant information. <u>See Guidance</u></p>
<p><b>(9) General Description of Direct Exposures to Private (Consumer) Products and of Potential Releases to the Environment leading to Ecological Exposures and Indirect Human Exposures</b></p> <p>(a) Exposures: (Describe and where possible quantify exposures to the products) <u>See Guidance</u></p> <p>(b) Releases: (Describe and where possible quantify releases from the products) <u>See Guidance</u></p> <p><i>For any exposures and releases presented in Formats B and C, provide a cross-reference, if applicable</i></p>
<p><b>(10) Discussion of Factors that Decrease or Increase Releases and Exposures:</b> Discuss the effects of use controls, personal protective equipment, and waste disposal requirements on the exposures and releases described in (9). <u>See Guidance</u></p>
<p><b>(11) Remarks:</b> (Use this area to include any relevant information not included elsewhere in the format.) <u>See Guidance</u></p>

#### VII. Unassociated Format B and/ or Format C

<p><b>(1) Notes and Remarks on Unassociated Format B and/ or Format C:</b> (List any copies of Format B and Format C that are not linked to a monitoring or modeling study listed in Format A.) <u>See Guidance</u></p>
---

#### VIII. References.

<p><b>Format A References</b> (Provide any relevant citations, resources, and references) <u>See Guidance</u></p>
---

**Format B: Monitoring Evaluations See Guidance**

**Report Title:** (Same as Format A Title.)

*Helpful Tip: If your submission included multiple studies, you will need to make multiple copies of this form and fill each copy out for an individual study.*

*Helpful Tip: Format B is designed to be flexible and to be applied to different types of monitoring evaluations (human and environmental monitoring.) Data can be duplicated in the formats if it serves the purpose of clarity, but a cross-reference to information elsewhere in the formats is sufficient to prevent unnecessary duplication of information. Also, there can be a great range of variability in the level of detail available for monitoring and modeling studies. If you do not have the information in the section, simply state this.*

*Helpful Tip: Available data tables may be attached either as an annex or within the relevant field.*

**I. Identification Information**

**(1) Study Title** (Brief description of Study)

**(2) Activity Associated with Monitoring Information:** (Identify the activity from Format A to which this release or exposure data applies) See Guidance

**II. Monitoring Study Design and Description of Scenario Monitored**

**(1) Monitoring Study Objective and Scenario Description:** (Describe the study's design, scope, and objectives and the scenario being monitored.) See Guidance

**III. Sampling and Analytical Methods**

**(1) Media Sampled** (Describe the media sampled e.g. personal inhalation monitoring, biomonitoring, general sample of water.) See Guidance

**(2) Sampling:** (Describe all aspects of the sampling procedure methodology and QA/QC) See Guidance

**(3) Method/ Procedure:** (Describe the analytical method used, including validation, detection limits, and QA/QC) See Guidance

**IV. Results and Reliability Description**

**(1) Results:** (Provide a summary of the results of the monitoring study and exposure estimates based on the monitoring data. See Guidance)

(2) **Reliability Score:** (Provide a score for each release, environmental concentration, or exposure (or intake or dose) estimate above.) See Guidance

(3) **Remarks:** (List resources used, applicable study notes, etc. for the monitoring study.) See Guidance

**V. References**

**Format B References** (Provide any relevant citations, resources, and references.) See Guidance

**Format C: Modeling Evaluations. See Guidance**

**Report Title:** (Same as Format A Title.)

*Helpful Tip: If your submission included multiple studies, you will need to make multiple copies of this form and fill each copy out for an individual study.*

*Helpful Tip: Format C is designed to be flexible and to be applied to different types of modeling evaluations (human and environmental modeling.) Data can be duplicated in the formats if it serves the purpose of clarity, but a cross-reference to information elsewhere in the formats is sufficient to prevent unnecessary duplication of information. Also, there can be a great range of variability in the level of detail available for monitoring and modeling studies. If you do not have the information in the section, simply state this.*

*Helpful Tip: Available data tables may be attached either as an annex or within the relevant field.*

**I. Identification Information**

**(1) Study Title** (Brief description of Study)

**(2) Activity Associated with Modeling Information:** (List the specific activity and description associated with the modeling information from Format A, (i.e., the cross-reference with Format A.) See Guidance)

**II. Modeling Objective and Description of Modeled Scenario**

**(1) Modeling Study Objective and Scenario Description:** (Explain the intent of the study and describe the scenario being modeled) See Guidance

**III. Description of Model and Status of Peer review and Validation**

**(1) Tool or Model:** (Provide the name of the model, a brief description, the model's version number, the basic algorithm if appropriate and the date on which the model was run.) See Guidance

**(2) Validation/ Peer Review:** (Describe any existing peer reviews and the scope of any validation of the model; provide references.) See Guidance

**(3) Availability and Documentation:** (Provide information on how to obtain the model and documentation.) See Guidance

**IV. Inputs, Outputs, and Reliability Description**

**(1) Media Modeled:** (Describe the type of medium or matrix modeled (e.g., soil, clothing or patches of cloth) and how the medium can affect the potential for exposure (e.g. transport through soil.)) See Guidance

<p><b>(2) Inputs:</b> (Provide the values of key input parameters. If the model's default values were changed, provide rationale.) <u>See Guidance</u></p>
<p><b>(3) Estimated Model Outputs:</b> (List the model results and the release medium or exposed population associated with each modeled value; characterize the results (i.e., average, conservative, etc.), and provide a basis) <u>See Guidance</u></p>
<p><b>(4) Reliability Score.</b> (Provide a reliability score for each release, environmental concentration, or exposure (or intake or dose) estimate above.) <u>See Guidance</u></p>
<p><b>(5) Remarks:</b> (Provide any resources used, applicable study notes, etc. for the modeling study and any associated exposure estimates.) <u>See Guidance</u></p>

## V. References

<p><b>(1) Format C References</b> (Provide any relevant citations, resources, and references) <u>See Guidance</u></p>
---

### CHAPTER 3. FORMAT-SPECIFIC GUIDANCE

15. This Chapter provides instructions for completing the exposure formats, resources and references, and glossary of terms. This also includes hyperlinks to the corresponding fields in Chapter 2.

#### **Format A: General Information - Instructions for Completing the Format. BACK**

16. The purpose of the Format A (General Information and Overview of Exposure) is to provide identification and background information such as the originator, chemical/category, purpose and coverage of the report, synthesis of results, volumes, activities (e.g. production, industrial use, commercial use, consumer product use), release and exposure information and measured data or estimates, and cross-references to Monitoring Evaluations format(s) (Format B) and/or Modeling Evaluations format(s) (Format C). Formats B and C are used to provide summary information on any quantitative exposure and release estimates, and the reliability of the estimates.

#### **Report Title BACK**

17. This field is for creating an overall title that reflects the scope of information provided in the format(s), for record-keeping purposes. You should use unique identifiers to help track records. If you submit monitoring or modeling summaries, you may also use this field as a means of linking the information provided in the other formats. For example, if a single substance is being evaluated, the chemical name can be used to coordinate the various formats. If a category approach is being used, then a category name or descriptor can be used.

#### **I. Identification Information**

##### **(1) Date of Submission**

18. To further enhance record-keeping, this field is to be filled out with the date on which the summary was completed.

##### **(2) Identity of Organization BACK**

19. This field is for logistical purposes, where the respondent and technical contact information is provided. The information can include the organization name and technical contact name(s), as well as addresses, phone numbers, e-mail, web site URLs, or other information the submitter deems relevant.

##### **(3) Contents (list of formats and annex included) BACK**

20. This field is for the reader's ease in understanding the layout of the information provided, by a listing and brief description of each format included in this report.

#### **II. Chemical Information**

##### **(1) Category Name or CAS Number(s) BACK**

21. The CAS number(s) should be used as a primary cross-referencing identifier for synonyms. If a category approach is used, the Category Name should be provided in this field.



**(2) Chemical Name(s)**      **BACK**

22. This field is for listing the various identities a product may have, including trade names, common names, TSCA Inventory names, IUPAC names, and synonyms. For consistency in other geographical areas, you can use the 9<sup>th</sup> Collective Index Chemical Abstracts index name or search the STN International for the name of the chemical. If a category approach is used, the name of each chemical in the category and its CAS number should be provided in this field.

**(3) Substance Formula and Structure**      **BACK**

23. This field is for providing the chemical formula for the substance and a structural diagram, if available.

**(4) Physical Form**      **BACK**

24. This field is for entering the physical form (e.g. solid, liquid, aerosol, suspension) of the pure chemical and, if applicable, of the mixture(s) containing the chemical. If a category approach is used, it is appropriate to provide the physical form for each chemical in the category. This information is important because the physical form of a product can influence the potential for exposure. For example, some chemicals can be distributed in different particle sizes, which would impact the likelihood of inhalation exposure. Also, in the case of product mixtures, other ingredients can lower the boiling point of the component being assessed, which could reduce the potential for inhalation exposure.

**(5) Other Constituents (If Applicable)**      **BACK**

25. This field is for listing any other constituents of the substance, including the name, CAS number, percentage range, impurities, etc, as applicable.

**III. Purpose and Coverage****(1) Purpose**      **BACK**

26. This field is for a brief description of the purpose of the submission (e.g., a post-SIDS summary report). This information will help guide you in determining which sections of the format to complete and assist the reader in understanding what type of information to expect.

**(2) Coverage**      **BACK**

27. This field is for characterizing the extent to which the summary covers the range of potential exposures from production, processing, use and disposal and what geographic range is addressed. In summarizing and reporting exposure information, it is important to communicate its thoroughness and scope. This information will also help guide the reader on what to expect and guide you in determining which sections of the format to complete. The extent of coverage provided by an exposure report may be evaluated by asking the following questions relating to the assessments that comprise the submission:

- Do the exposure studies provide a current total chemical volume, the assessed chemical volume, and how both of these volumes are broken out among uses? If they do not, do the summaries provide an explanation of why they did not provide this information
- Do the summaries estimate or otherwise address the range of exposure scenarios (source/pathway/route/population) that are possible (at least theoretically)? This range of exposure scenarios includes occupational exposures, consumer product exposures, indirect exposures to

humans from releases to the environment and environmental (ecological) exposures. If one or more of the scenarios were not addressed, does the summary provide an explanation of why it was not addressed? Does the summary address aggregate exposures?

#### **IV. Summary**

##### **(1) Synthesis of Key Results     BACK**

28. This field is for briefly summarizing the key results of the reported information. Indicate the most significant endpoints of exposure among the potential exposures to the chemical being evaluated.

##### **(2) Summary of Data Collection Efforts     BACK**

29. This field is for describing the extent of efforts involved in researching and collecting data for this exposure summary.

##### **(3) Discussion of Key Uncertainties, Limitations, and Data Gaps BACK**

30. This field is for discussing uncertainties, key data gaps, restrictions in the representativeness of the data, etc., and other limitations. For instance, it is understood that often 100% of total production volume or uses will not be precisely known. When this occurs, identify these limitations and the uncertainties that may stem from them.

##### **(4) Table of Exposure Results     BACK**

31. This field may be useful for providing a tabular summary of quantitative exposure information for important scenarios listing the acute and/or chronic exposures (mg/kg-day) and identifying the exposed population.

#### **V. Production, Import/Export and Use Total Volumes**

##### **(1) Estimated Total Produced, Imported, and Exported, Volumes (tonnes/year) BACK**

32. This field is for identifying the total estimated produced, imported, and exported chemical volume for the most recent calendar year available in tonnes/year. Specify what the numbers represent, such as production from one company versus total national or regional production, global production, etc and to identify the source of the information. Ranges may be used as necessary to avoid disclosure of confidential information. To adequately characterize the coverage of the report, and its transparency, it is important to describe what portion of the chemical volume has been accounted for.

##### **(2) Industrial and Use Categories and Total Percentage Volume for Each     BACK**

33. This field is for identifying the known Use Categories (e.g., surfactant, flame retardant, etc.) for the chemical and the percentage of estimated volume that is associated with each category (e.g., 10% - 20% used in Use Category X). Also, identify the primary Industrial Categories (end uses) of the chemical and the percentage of estimated volume associated with each use (e.g., 70% - 80% used in Industrial Category Y). It may be necessary to use estimates or ranges of volumes where exact information is unavailable or to avoid the disclosure of confidential information. Identify the geographic area where the information is applicable. Annex 4 provides a listing of the Industrial and Use Categories, which may be helpful.

**(3) Remarks BACK**

34. Use this field to include any information that would be useful to the submission but did not fit into any other sections in the format.

**VI. Life Cycle Steps Covered in this Report BACK**

35. This section of the format is designed to be applicable to four life cycle steps—production, formulation, industrial/professional use, and private/consumer use—to help you organize activity and use information. Subsections 1 through 7 are applicable to production, formulation, and industrial use; subsections 8 through 11 are applicable to private/consumer use. Fill out sections for the uses that pertain to the chemical of interest and/or the purpose of the summary. For example, an intermediate may be used only as a building block to make another chemical. Therefore, only information relating to its production and final use as an intermediate are relevant. The section for private/consumer use would not be filled out, nor would there be any discussion of formulation or professional uses. Also, for submissions containing quantitative information from modeling or monitoring data, you may use this section to specifically tie in studies summarized in Format B or Format C to particular uses or activities. For those studies that cannot be linked directly, you may provide references to the studies in Section VII, which follows this section.

36. To assist with organizing the information in this section, which will assist readers in following those exposures that could result from which processes, provide a thorough discussion of each process and use separately. Each process and use should be clearly labeled to avoid confusion, especially for chemicals that have multiple uses.

***Production/ Formulation/ Industrial/ Professional Use* BACK**

37. If relevant to the Purpose and Coverage section, the following sections for production, formulation, and industrial use may be copied and used to summarize information for each of these process types covered.

38. Some chemicals are used in private businesses that may be characterized as industrial or non-industrial. You should determine whether the information and data are more appropriately placed in the format under the Industrial Use (this section of Format A) or under Private Use (next section of Format A). For example, an assessment of solvent release and exposure in dry cleaning businesses would generally be summarized under Industrial Use, whereas a solvent release from a household use would be Private.

**(1) Volumes and Related Information BACK**

39. For each process, provide the volume (tonnes/yr) of *pure substance* produced, formulated, or used in this process and, if available, the number of sites. Ranges may be used as necessary to avoid disclosure of confidential information. If the substance is in a formulation or mixture, also indicate the percentage by weight of the pure substance in the formulation or mixture. If available, include site-specific information, including locations, geographic region or country,

**(2) Process Description and Related Information BACK**

40. A process description and related information can provide useful information on potential releases and exposures that are not sufficiently communicated just from chemical reactions. In this section a description and/or a diagram may be provided of the process of production, formulation, or industrial use of the chemical or mixture containing the chemical. It includes, if available, factors which can be relevant

to the description such as:

- where human intervention is involved, highlight activities/processes and/or tasks
- volume of the pure chemical and of the mixture containing the chemical, if applicable, produced, formulated, or used per day, per batch, or per year in tonnes. Ranges may be used as necessary to avoid disclosure of confidential information.
- whether the production process is continuous or batch;
- whether the process is open or closed;
- relevant changes in chemical's physical form or concentration;
- whether water is involved in the process;
- cleaning of the process equipment, and/ or in cleaning or rinsing of emptied transport containers;
- what is done with process and cleaning wastes; and
- what types of transport containers are used to deliver, store and ship the chemical or mixture containing the chemical.

The following questions can be helpful for completeness as they indicate the next step in the life cycle. Is the chemical or mixture containing the chemical:

- a. Consumed internally for other chemical production or use?
- b. Formulated or packaged by the producer?
- c. Sold to distributors?
- d. Sold for use in other chemical production (by the producer or by the distributor)?
- e. Sold to formulators or repackagers (by the producer or by the distributor)?

### **(3) General Description of Potential Releases and Exposures BACK**

41. This section is one of the most important in Format A, helping to address transparency and coverage. It provides an opportunity to describe potential releases and exposures so that readers have a clear understanding of which releases pertain to which exposures. The submitter should organize the information consistently throughout the section, whether describing each aspect separately or combining all relevant release, exposure and mitigation information in a continuous narrative.

42. a) Releases: Releases are described and cross referenced to related Format B and C estimates.

The summary identifies all likely sources, the likely receiving media, and whether the release would be periodic, accidental or expected. It also includes, if available:

- release volumes, from the production, formulation, or industrial use and any other parts of the life cycle of the chemical.
- list of point sources, release rate for each source and frequency of release (days/yr)
- the aggregate (sum total) release rates (daily or per batch releases in tonnes to surface water or to publicly owned treatment works, as fugitive or stack air releases or emissions, to on-site or off-site incineration, to landfill or applied to land on or off site, other transfer etc.)
- each medium to which one or more releases occurs

It is helpful to be as quantitative and precise as possible (i.e., avoid the use of words such as *significant*, *sufficient*, *low*, *negligible*, etc., unless such words can be backed up by explanatory text.) It may be helpful to describe if the chemical is directly released in the media (emission to surface/sea water or air without treatment) or if there is on-site treatment of the chemical (ventilation hoods, air pollution control equipment, a wastewater treatment plant, etc.).

For each individual point source estimate, provide:

- the year to which the estimate pertains (the most recent data available is usually most appropriate): and either:
- the basis (monitoring data, which is preferable, or other appropriate method), or:
- the cross-reference to Format B or C in which the estimate was reported.

43. b) Exposures: The summary identifies exposures from relevant sources and the likely exposed environmental species or human populations. It includes (if available):

- the exposed population(s)
- potential exposure by route and frequency (days/yr)
- aggregate exposure (sum total)
- tasks, processes, activities and equipment that contribute to the potential exposure.

For each exposure estimate, provide:

- the year to which the estimate pertains (the most recent data available is usually most appropriate):
- the cross-reference to Format B or C in which the estimate was reported.

44. If you are providing qualitative descriptions (e.g., for releases, media and sources without numerical release estimates; for exposures, routes and individual activities without numerical estimates), attention should be paid to thoroughness and clarity. It is helpful to be as quantitative and precise as possible (i.e., avoid the use of words such as *significant*, *sufficient*, *low*, *negligible*, etc., unless such words can be backed up by explanatory text.)

#### **(4) Discussion of Factors that Decrease or Increase Releases and Exposures BACK**

45. Other factors are described that may affect potential releases and exposures. Examples of helpful, relevant topics to include if available :

- physical and chemical properties of the chemical that have a significant effect on exposure,
- engineering controls (e.g. ventilation hoods, air pollution control equipment, on- or off-site treatment)
- administrative policies or work practice controls (e.g. work schedules, cleaning, maintenance and inspection procedures)
- personal protective equipment (e.g. gloves, goggles, respirators, chemical protective clothing)
- the nature of the wastewater treatment plant (biological, chemical etc) with information on its effluent flow and the flow of surface water body receiving its outflow.
- any international, national, regional, or local regulations that apply to the activities at the facility where the chemical is produced, formulated, or used industrially, including occupational standards (e.g., MAK, PEL, STEL, TLV) and environmental standards.

#### **(5) Environmental Exposure BACK**

46. Information on any discharges associated with the process are described, including if available :

- direct or indirect discharge rate (L/d),
- the parameters of any treatment processes, including if available flow rate (L/d), process type, influent and effluent concentrations, removal rate of the substance, biodegradation removal rate, sorption to sludge, sludge disposal information and dilution factor in the receiving water.
- parameters relative to air discharges and environmental fate, if appropriate.

**(6) Information Not Included and Rationale BACK**

47. This element provides an opportunity to briefly identify and explain why relevant point source, exposed population, or monitoring data, known to the submitter, is not included. For example, although a submitter may possess data covering years of monitoring, the precision may be lacking due to limits of the methodology or equipment used. Therefore, the submitter could instead provide modeling data for the scenario. A simple explanation letting the reader know why one data set was presented over the other should be provided. In another example, the protection of proprietary information may prevent the disclosure of company or site-specific information. The proprietary information may be aggregated to avoid disclosure, which can be explained in one or two sentences.

**(7) Remarks BACK**

48. Use this area to include any relevant information not included elsewhere in the format.

***Private/ Consumer Use***

**(8) Function/ Product Use Category Description BACK**

49. For chemicals with private (consumer) uses, identify (if available):

- the product categories where the chemical is used,
- the function of the substance in the products,
- the physical form of the products, and,
- the concentration of the substance in the product

50. When characterizing consumer uses and scenarios, it is important to understand the releases and exposures for each product category in which the chemical is used. The following questions can help in determining additional points that might be addressed for different product categories and are especially useful in developing estimates of exposure using Format B: Monitoring or Format C: Modeling:

- a. How frequently is each private and/or consumer product used?
- b. What is the duration of use?
- c. How much of the product is used?
- d. Is the product used “neat” or diluted? If diluted, what is the likely use concentration?
- e. Who are the potentially directly exposed populations during use and who are the potentially directly exposed populations after use? Adults? Children (ages)? Infants? Prenatal exposures to children?
- f. What are the activities associated with the exposures?
- g. What are the likely locations of exposure?
- h. Is the private (consumer) product likely to leave residuals after use?
- i. What are the likely disposal scenarios for the product?
- j. Who are the potentially indirectly exposed populations from release to the environment? Adults? Children (ages)? Prenatal exposures to children? Ecological exposures?

**(9) General Description of Direct Human Exposures to Consumer Products and of Potential Releases to the Environment Leading to Ecological Exposures and Indirect Human Exposures**

Direct Human Exposures                      BACK

51. a) Exposures: Potential human exposures from consumer uses are described. This may cover if available, for each consumer product/consumer population combination listed above the direct exposure to the chemical by route of exposure and the exposure frequencies (days/yr)

Specify the units (e.g., mg/m<sup>3</sup>, ppm, mg/day, mg/kg/day, etc.) used for any quantitative value and the year that is covered if relevant. Where relevant, provide the cross-references to a Format B or Format C. It is helpful to be as quantitative and precise as possible (i.e., avoid the use of words such as *significant*, *sufficient*, *low*, *negligible*, etc., unless such words can be backed up by explanatory text.)

**Potential Releases to the Environment leading to Ecological and Indirect Human Exposures BACK**

52. b) Releases: Releases are described and cross referenced to related Format B and C estimates.

The summary identifies all likely release scenarios from consumer products, the likely receiving media, and whether the release would be periodic, accidental or expected. It also includes, if available:

- each medium to which one or more releases occur from the consumer use of the chemical,
- the release rates (releases to surface water or to publicly owned treatment works, as air releases or emissions, to landfill),
- the media concentrations, and
- indirect exposures via the environment (inhalation exposures, dermal exposures, drinking water, etc.)

It is helpful to be as quantitative and precise as possible (i.e., avoid the use of words such as *significant*, *sufficient*, *low*, *negligible*, etc., unless such words can be backed up by explanatory text.) It may be helpful to describe if the chemical is directly released in the media (emission to surface/sea water or air without treatment) or if there treatment of the chemical (wastewater treatment plant, etc.) Specify the units in either in pounds or kilograms and maintain the same units throughout the summary for any quantitative value and the year that is covered if relevant.

**(10) Discussion of Factors that Decrease or Increase Releases and Exposures** BACK

53. Other factors are described that may affect potential releases and exposures. Examples of helpful, relevant topics to include if available :

- physical and chemical properties of the chemical,
- whether product packaging, labelling or use instructions are likely to reduce consumer exposure
- whether ventilation likely to be in place during the use
- whether consumers using the product likely to wear any personal protective equipment like gloves
- the likely nature of waste disposal

**(11) Remarks** BACK

54. Use this field to include any relevant information not included elsewhere in the format.

**VII. Unassociated Format B and/ or Format C**

**(1) Notes and Remarks on Unassociated Format B and/ or Format C** BACK

55. If one or more Format B or Format C cannot be linked to a particular production, industrial use,

commercial use, or consumer use, provide here a discussion and relevant citations, resources, references, etc. (e.g. national biomonitoring or environmental monitoring studies such as NHANES, MOE, USGS, provides results that, while useful for exposure assessments, cannot generally be related back to a specific activity.)

### **VIII. References**

#### ***Format A References* BACK**

56. This field is for any relevant citations, resources, and references.



**Format B: Monitoring Evaluation - Instructions for Completing the Format. BACK**

57. The monitoring evaluation format is to be used to provide *summary information* from monitoring studies for the chemical. The term monitoring covers studies in which data are the result of measurements of the chemical in environmental media (e.g., outdoor air, indoor air, surface water, soil, etc.) or a particular exposure scenario, such as inhalation or dermal exposure monitoring. It also includes biomonitoring data. The fields are flexible to be able to include monitoring in any type of medium, including simple environmental matrices such as air and water, or complex biological matrices like blood, urine or tissue. When estimates of environmental releases or exposures are based on a monitoring study, the monitoring evaluations format may be used to describe the data from that study.

**Report Title**

58. This field is for entering the title of the overall report, the same as that used in the associated Format A.

**I. Identification Information****(1) Study Title**

59. This field is for entering a brief title that describes the study

**(2) Activity Associated with Monitoring Information BACK**

60. This field is for entering the appropriate Format A, section IV number to which this release, environmental concentration, or exposure (or intake or dose) data applies, and the associated description from that section (i.e. the cross-reference in the General Description of Potential Releases and Exposures where some descriptions could include general environmental monitoring, worker exposure monitoring for production, drinking water monitoring, water release estimate from production, etc.)

**II. Monitoring Study Design and Description of Scenario Monitored****(1) Monitoring Study Objective and Scenario Description BACK**

61. In this section, describe the general scope and objectives of the monitoring study. This section also provides you with an opportunity to describe why the data are relevant.

62. Describe the objectives of the monitoring study to which the results apply (e.g. to determine estimates of average and high end release or exposures to the population of interest; for exploratory purposes relating to the population, release, or chemical of interest; as surrogate monitoring data that did not directly study the release, population, or chemical of interest; of an unknown study objective; etc.).

63. Listed below are statements that you might use to describe the objectives of a study:

- Monitoring data for the chemical of interest collected using a study design that will permit estimates of average and high-end release or exposure to the population of interest.
- Monitoring data for the chemical of interest collected on the release or population of interest for exploratory purposes but not for estimating average or high-end releases or exposures.

- Surrogate monitoring data (i.e. data not collected directly on the release or population or chemical of interest) but for a similar exposure scenario.
- Monitoring data that lack documentation on study objective and/or design.

64. Briefly describe the scenario monitored, location, dates, and study design. Depending on the scenario, other relevant information could include:

- frequency of release or exposure,
- amount of chemical / product used,
- physical form in which the chemical / product was used,
- information on existing exposure controls, etc.),
- whether the study assessed acute or chronic exposures,
- whether typical or conservative (i.e. protective) releases or exposures were estimated, and,
- the specific release source or population (e.g. occupational job descriptions or consumer) that was monitored and activities performed during monitoring, if applicable.

### **III. Sampling and Analytical Methods**

#### **(1) Media Sampled BACK**

65. This section should be used to describe the media that was sampled in the monitoring study [e.g. personal inhalation monitoring (air sampled from the breathing zone of a worker or consumer), personal dermal exposure monitoring (a wipe sample taken from the skin or gloves of a worker or consumer), biomonitoring (personal blood, urine or tissue sampling), or a general sample of air, water, wastewater, groundwater, soil, clothing, or work surfaces.]

#### **(2) Sampling BACK**

66. Provide information about the method used to collect the samples for the study. Include other relevant information such as:

- the dates in which samples were obtained,
- the duration of the study,
- number of samples,
- sampling periods,
- locations of sampling,
- sample storage and preservation,
- information on monitoring equipment instrumentation, documentation and variations from established procedures.

#### **(3) Method/Procedure BACK**

67. Describe the analytical method used to analyze the samples collected, including any number or standard affiliation and associated documentation. Include information on validation by an independent body (e.g. ASTM standard method xxxx, NIOSH method yyyy), or an individual company (e.g. method number 1234 developed by company ABC). Include the limit of detection and the limit of quantification of the chemical with the method and any evaluation of sampling and measurements parameters (e.g. overall uncertainty, overall precision, overall bias, accuracy, recovery from collection media, capacity of collection media, stability of collected analyte(s), sampling interferences, measurement range, measurement precision, measurement interferences).

68. Listed below are statements that you may wish to use to describe the methods or procedures of a study:

- Monitoring data collected and analyzed using sampling and analytical chemistry methods that have been validated and accepted by an independent body (e.g. ASTM, NIOSH, etc.).
- Monitoring data collected and analyzed using well-documented sampling and analytical chemistry methods.
- Monitoring data collection and analysis documentation is not available.

#### **IV. Results and Reliability Description**

##### **(1) Results BACK**

69. Summarize the results of a monitoring study. The numerical results and units should be provided and characterized (e.g. time-weighted averages, representative/typical conditions, worst-case scenario, conservative, grab sample, daily average concentration, etc.)

70. Unless you have very few data for a particular exposure scenario, it is likely that you will need to use some form of statistics to summarise them. It is suggested that the median and percentiles such as the 90<sup>th</sup> and 95<sup>th</sup> be used as measures of location, confidence intervals around these be used to indicate their uncertainty. These statistics are nonparametric, i.e., they do not rely on any assumptions about whether data are normal, lognormal or are from any other skewed distribution and are appropriate for all data sets. More conventional statistics (means, geometric means, standard deviations, geometric standard deviations etc) are inappropriate unless the assumptions about a distribution can be tested. Remember though, it can take a large number of data points (specific references) to test that your data fits a particular distribution at a reasonable level of confidence. The use of inappropriate statistics can lead to incorrect conclusions being drawn about exposures. So, whatever statistics are selected, it would be helpful to provide a brief rationale for your choice. Some helpful literature on summary statistics are included in the Annex 3 references.

71. Where there is a need to provide integrated data, for example if there is a desire to predict exposed dose, then the supporting equations should be given and reference made to the sources of input parameters (see Annex 3). There are a variety of equations and methods that may be used for providing estimates of exposure, such as an equation for estimating ppm x hours of exposure or selection of an estimate of peak exposure concentration over a specified time interval. In exposure assessment equations for providing estimates of dose and intake such as average daily dose (ADD), lifetime average daily doses (LADD), average daily intake, etc., are also used. The data provided by the monitoring study is one of the inputs. Other inputs could include parameters such as breathing rate, duration of exposure, body weight, skin surface area in contact with a contaminant, etc., and these parameters would depend upon the equation used. For information on the definitions and equations for these and other estimates of exposure, dose and intake, Annex 3 may be a valuable resource. If biological monitoring data are being used to reconstruct a dose, summarize how this was done and what assumptions were made.

72. Also describe here any relevant characteristics of the exposed population that is being assessed (e.g. size of the assessed population, age of the assessed population, location of the assessed population if that is relevant.). Remember that when exposure is characterized as being average, conservative, etc., that characterization applies to a specific population and to the type of exposure being estimated (i.e. acute or chronic exposure).

73. If data from two or more differently exposed populations are combined, this should be indicated and a rationale provided.

**(2) Reliability Score BACK**

74. Describe the reliability of each release or exposure estimate in the Results section above by selecting the appropriate reliability score below, with explanation of the reason why this score was selected.

**- 1 valid without restrictions**

All the following bullet points should be met.

- a valid analytical method including quality control was used for the intended matrix (water, sediment, soil, sludge, air etc) and which is sensitive enough for the intended purpose
- Representative data including quality controls are available for the population or scenario of interest to sufficiently describe the releases or exposures
- measured data are statistically analysed, outliers identified and eliminated
- The study design used to collect the data is appropriate and well documented (e.g. sampling location, description of matrix, sampling period etc)

**- 2 valid with restrictions**

All the following bullet points should be met.

- a valid analytical method including quality control was used for the intended matrix (water, sediment, soil, sludge, air etc) and which is sensitive enough for the intended purpose
- Representative data including quality controls are available for the population or scenario of interest to sufficiently describe the releases or exposures
- The study design used to collect the data is appropriate and well documented (e.g. sampling location, description of matrix, sampling period etc)

**- 3 not valid**

- measurements are available; however insufficient confidence can be invested in the measurements (e.g. no information is available on the sampling or analytical conditions)

OR

- The measurements are not representative of the population or scenario of interest

**- 4 not assignable**

- measurements are available, but without supporting documentation so that for the time being the reliability cannot be judged

**(3) Remarks BACK**

75. Include any relevant citations, resources used, applicable study notes, etc. for the monitoring study and any associated release or exposure estimates.

**V. References**

**(1) Format B References BACK**

76. This field is for any relevant citations, resources, and references.

**Format C: Modelling Evaluation – Instructions for Completing the Format BACK**

77. This format is to be used when modeling is done to estimate exposures (or intakes or doses) or to estimate releases or environmental concentrations, which can then be used to estimate exposure. Although the word model is often associated with scientific computer software applications, it can also be used to describe one or more algorithms or mathematical equations. Models can be used to make estimates of human exposure directly or estimates of chemical release or chemical concentration in an environmental media which can then be used to make subsequent estimates of exposure. It is also true that estimates of exposure (i.e. concentration x duration of contact) and dose (e.g. daily intake, absorbed dose) are usually generated using “models.”

78. Scientists routinely use data from monitoring studies to validate exposure models, although not necessarily for the specific chemical of interest. Monitoring data can also be used as an input for some models. There are also models that use the outputs of other models as inputs.

**Report Title**

79. This field is for entering the title of the overall report, the same as that used in the associated Format A.

**I. Identification Information****(1) Study Title**

80. This field is for entering a brief title that describes the study

**(2) Activity Associated with Modeling Information BACK**

81. This field is for entering the appropriate Format A, section IV number to which this release or exposure modelling data applies and the associated description from that section (i.e., the cross-reference in the General Description of Potential Releases and Exposures where some descriptions could include general environmental modelling, industrial use #2 worker inhalation exposure modelling, modelling for production releases from source x, etc.)

**II. Modeling Objective and Description of Modeled Scenario****(1) Modeling Study Objective and Scenario Description BACK**

82. This field is for explaining the general scope and objectives of the study; for instance, to state whether the objective was to provide a conservative estimate of release or exposure, a representative estimate of release or exposure or some other kind of estimate of release or exposure. This field is also for identifying the population being assessed and whether the study is intended to estimate acute or chronic exposures, or both. When using a model to estimate environmental media concentrations and exposures, it is common to do these at the same time and as part of the same study. In this case it is not necessary to separately discuss the objective for estimating the media concentration and the objective for the exposure assessment.

83. This field is also to be used to describe the scenario being modelled, which includes information like duration (hours/day) and frequency (days/yr) of release or exposure, amount of chemical/product used, physical form in which the chemical/product was used, information on exposure controls and whether the modelling assesses acute or chronic exposures. Include information on whether it was designed to estimate typical or conservative (i.e. protective) releases or exposures, and the basis for the characterization.

84. Identify the specific population (e.g. worker job descriptions or consumer) and activities performed, if applicable, for which the modelling is being done.

### **III. Description of Model and Model Validation**

#### **(1) Tool or Model BACK**

85. This field is for providing the name of the tool or model, including a brief description of the model algorithm (if appropriate), and its applicability to this assessment and the date(s) on which the model was run. If applicable, provide the version number of the model. Note that simple, first principle equations are often used, especially in screening level assessments which err on the side of being protective. In that case, the inputs, outputs, exposure factors, and other relevant information will be important for transparency.

#### **(2) Validation/Peer Review BACK**

*Note that the information in sections (2) and (3) need only be provided one time if the same model is used for multiple estimates.*

86. This field is for describing any model evaluations and/or peer reviews that have been performed or for providing citations of such evaluations/peer reviews. If the model has undergone an evaluation, information may be provided on how the model performed and some background information about the evaluation (i.e., how input data were selected, was the model validated against field observations or against other models, what type of expert(s) conducted the peer review? etc.). The extent to which a model is accepted for by the scientific and regulatory community may be noted. Example summary statements might include:

- The model has been validated with monitoring data that is directly relevant for the scenario of interest.
- The model has been evaluated with monitoring data but it has not been formally validated.
- The model has not been validated or evaluated with monitoring data.
- The model has been through a formal peer review process.
- The model has been informally peer reviewed.
- The model has not had any peer review.
- The model has (wide, limited, no) acceptance among the scientific and regulatory community.

#### **(3) Availability and Documentation BACK**

87. If applicable, provide information on how to obtain the model and documentation, and references to evaluations and reviews of the model that are not listed elsewhere. For example, you may provide information on how to obtain the model (e.g. private model with limited release, model with closed code available for purchase, model available at low or no cost with code available for inspection, model available at low or no cost with code available for inspection and modification, model available in

publication x, etc.), related guidance documents, evaluations and reviews that are not part of a peer review process, and any other information that may be relevant.

#### **IV. Inputs, Outputs, and Reliability Description**

##### **(1) Media Modeled BACK**

88. Describe the type of medium or matrix modeled (e.g., soil, clothing or patches of cloth) and how the medium can affect the potential for exposure (e.g. transport through soil.) Models can, and have been, developed to include specifics on the type of medium or matrix in which the chemical of interest is contained. Various media can include: air, water, soil, clothing or patches of cloth, work surfaces, specific solid materials, blood, tissue, and many others. You may also wish to include how the medium can affect the potential for exposure to the chemical of interest (e.g. transport through soil, diffusion through liquid, leaching from a solid).

##### **(2) Inputs BACK**

89. The values of key input parameters should be provided. If the model's default values have been changed, a reason should be provided. Many models use certain assumptions, which can appear as default values in specific equations. Other models do not use defaults but require the user to supply all of the inputs. In this field, list the key input values and units, and list any changes to the defaults. Also provide here your rationale for changing default values (e.g. direct measurements of habits and practices for the situation of interest). Some of the key inputs that are often encountered when performing a modeling study are: sources (e.g. release rates into the environment, the days of release, receiving stream flows, house volumes and air exchange rates, etc.); approximate percentage of aggregate product volume that goes into a specific product or use; physical form of the chemical; likely route of exposure; amount of product used per application, and the concentration of the chemical being studied; known or recommended dilution ratios for use; disposal routes; and others, depending on the model. You may choose to use certain inputs in the areas described above, or may elect to use the model's default values.

90. Listed below are statements that you may wish to include to describe various inputs used in a modeling study:

- measured site or scenario specific value.
- estimated site or scenario specific value.
- generic conservative default value.

##### **(3) Estimated Model Outputs BACK**

91. This section is for providing modeling results and the exposed population (e.g. size of the assessed population, age of the assessed population, location of the assessed population, if that is relevant) associated with each modeled value; for characterizing the results (i.e., average, conservative, etc.), and providing a basis for the characterization. Take care to ensure that: appropriate units are provided, dimensions are correct, conversion factors are used correctly, non-dimensional quantities are correctly expressed, and the number of significant figures given are correct. When summarizing the results of the model estimation of environmental media concentration, use this field to describe any equations used to estimate exposures (or intake, or dose) and the values and sources of the inputs to the equation. The numerical results, including the units, should be provided and characterized (e.g. average, conservative, etc.), along with the basis for the characterization (e.g. the inputs are intended to provide an estimate of average (acute or chronic) exposure, intake, or dose to the population being assessed.)

92. There are various equations and methods that may be used for providing estimates of exposure, such as an equation for estimating ppm x hours of exposure or selection of an estimate of peak exposure concentration over a specified time interval. In exposure assessment it is also common to use equations for providing estimates of dose and intake such as average daily dose (ADD), lifetime average daily doses (LADD), average daily intake, etc. The output provided by the model for an environmental media concentration may be an input to another model. Other inputs could include parameters such as breathing rate, duration of exposure, body weight, skin surface area in contact with a contaminant, etc., and these parameters would depend upon the equation used. For information on the definitions and equations for these and other estimates of exposure, dose and intake, Annex 3 is a valuable resource.

93. If data from two or more differently exposed populations are combined, this should be indicated and a rationale provided.

#### **(4) Reliability Score BACK**

94. Determine the reliability of each release, environmental concentration, or exposure (or intake or dose) estimate in the Results section (C.IV.3.) by selecting the most appropriate reliability score, with explanation of why this score was selected.

##### **- 1 valid without restrictions**

The first or second bullet point should be met. The third bullet point should also be met.

- the model has been validated for the scenario of interest, peer reviewed and well documented. Sufficient experience demonstrates its applicability for the intended use in exposure assessment and ultimately risk characterization. ;

OR

- model is sufficiently conservative, has undergone peer review *and* is generally accepted by authorities

AND

- exposure modelling for the given substance falls into the applicability domain of the model and appropriate inputs are used

##### **- 2 valid with restrictions**

The first or second bullet point should be met. The third bullet point should also be met.

- The model is accepted for the current purposes as a result of wide experience by scientists from the regulatory, industrial and academic community

OR

- model is sufficiently conservative, has undergone peer review *or* is generally accepted by authorities

AND

- modelling for the given substance falls into the applicability domain of the model and appropriate inputs are used

##### **- 3 not valid**

- model has not been confirmed by sufficient case studies or case studies suggest that it is not reliably applicable; application of the model would deliver results which would be “not valid”

OR

- model is accepted but the modelling for the given substance falls out of the applicability domain of the model and therefore the result would be “not valid”

OR

- model is accepted but the inputs are not appropriate or well documented and therefore the result would be “not valid”



**- 4 not assignable**

- model and/or input values are not described or documented sufficiently to judge if it can be applied for this scenario. Reliability of the results would be “not assignable”. Use of this model cannot provide useful results for exposure assessment and risk characterization until the missing facts on the model are made available.

**(5) Remarks BACK**

94. Include any relevant citations, resources used, applicable study notes, etc. for the modelling study and any associated release or exposure estimates.

**V. References**

**(1) Format C References BACK**

95. This field is for any relevant citations, resources, and references.

### ANNEX 1: INFORMATION ON PHYSICAL AND CHEMICAL PROPERTIES, EXPOSURE LIMITS

This annex provides a format that can be used when summary information on physical, chemical or hazard properties is to be reported in conjunction together with the Formats A-C. Alternatively, the Full SIDS Summary Format and SIAM dataset may be used.

	MEASURED/ CALCULATED	PROTOCOL/ SPECIES	DATA
<b>PHYSICAL-CHEMICAL</b>			
Molecular weight			
Physical form			
Melting Point			°C
Boiling Point			°C (at kPa)
Density			kg/m <sup>3</sup>
Vapour Pressure			kPa at °C
Henry's Law constant			
Partition Coefficient (Log Pow)			
Water Solubility			mg/l at °C
pH			at °C
pKa			
Oxidation: Reduction Potential			mV
<b>ENVIRONMENTAL FATE AND PATHWAY</b>			
Photodegradation			In air $t_{1/2}$ = hour
Stability in Water			$t_{1/2}$ = min
Adsorption/desorption to soil			at °C
Calculated distribution between environmental compartments	Calculated	(Fugacity Level 1 type)	In Air % In Water % In Sediment % In Soil % In Biota %
Bioconcentration Factor			
Biodegradation			
<b>EXPOSURE LIMITS</b>			
Occupational Exposure Limits			ppm or mg/m <sup>3</sup>
Others			

## ANNEX 2: GLOSSARY OF TERMINOLOGY

This annex provides definitions of key terms used in this document. These definitions originate from OECD (2003), “Descriptions of Selected Key Generic Terms Used in Chemical Hazard/Risk Assessment – Joint OECD/IPCS Project on the Harmonisation of Hazard/Risk Assessment Terminology”, Testing and Assessment Series No. 44.

<b>Term</b>	<b>Description</b>
<b><u>Analysis</u></b>	Detailed examination of anything complex, made in order to understand its nature or to determine its essential features.
<b><u>Assessment</u></b>	Evaluation or appraisal of an analysis of facts and the inference of possible consequences concerning a particular object or process.
<b><u>Concentration</u></b>	Amount of a material or agent dissolved or contained in unit quantity in a given medium or system.
<b><u>Dose</u></b>	Total amount of an agent administered to, taken up or absorbed by an organism, system or (sub) population.
<b><u>Effect</u></b>	Change in the state or dynamics of an organism, system or (sub) population caused by the exposure to an agent.
<b><u>Exposure</u></b>	Concentration or amount of a particular agent that reaches a target organism, system or (sub) population in a specific frequency for a defined duration.
<b><u>Exposure Assessment</u></b>	Evaluation of the exposure of an organism, system or (sub) population to an agent (including its derivatives).
<b><u>Exposure Scenario</u></b>	A set of conditions or assumptions about sources, exposure pathways, amount or concentrations of agent(s) involved, and exposed organism, system or (sub) population (i.e. numbers, characteristics, habits) used to aid in the evaluation and quantification of exposure(s) in a given situation.
<b><u>Fate</u></b>	Pattern of distribution of an agent, its derivatives or metabolites in an organism, system, compartment or (sub) population of concern as a result of transport, partitioning, transformation or degradation.
<b><u>Hazard</u></b>	Inherent property of an agent or situation having the potential to cause adverse effects when an organism, system or (sub) population is exposed to that agent.
<b><u>Hazard Assessment</u></b>	A process designed to determine the possible adverse effects of an agent or situation to which an organism, system or (sub) population could be exposed.  The process includes hazard identification and hazard characterization. The process focuses on the hazard in contrast to risk assessment where exposure assessment is a distinct additional step.

<b><u>Risk</u></b>	The probability of an adverse effect in an organism, system or (sub) population caused under specified circumstances by exposure to an agent.
<b><u>Risk Characterization</u></b>	The qualitative and, wherever possible, quantitative determination, including attendant uncertainties, of the probability of occurrence of known and potential adverse effects of an agent in a given organism, system or (sub)population, under defined exposure conditions.
<b><u>Uncertainty</u></b>	Imperfect knowledge concerning the present or future state of an organism, system or (sub) population under consideration.
<b><u>Validation</u></b>	<p>Process by which the reliability and relevance of a particular approach, method, process or assessment is established for a defined purpose.</p> <p>Different parties define “Reliability” as establishing the reproducibility of the outcome of the approach, method, process or assessment over time. "Relevance" is defined as establishing the meaningfulness and usefulness of the approach, method, process or assessment for the defined purpose.</p>

## ANNEX 3: RESOURCES

**Emission Scenario Documents:**

OECD, 2001	Use and Release of Industrial Chemicals, OECD's Database on Use and Release of Industrial Chemicals <a href="http://webdomino1.oecd.org/ehs/urchem.nsf">http://webdomino1.oecd.org/ehs/urchem.nsf</a>
EU, 2003	EU Technical Guidance Document in Support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation 1488/94/EEC for existing substances, and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, 2003 Part IV, Emission Scenario Documents; Source: <a href="http://ecb.jrc.it/Documents/TECHNICAL_GUIDANCE_DOCUMENT/EDITION_2/tgdpart4_2ed.pdf">http://ecb.jrc.it/Documents/TECHNICAL_GUIDANCE_DOCUMENT/EDITION_2/tgdpart4_2ed.pdf</a>

**Exposure Factors:**

Canada, 1993	Reference Values for Canadian Populations, May 1993
U.S. EPA, 1997	U.S. EPA/ORD Exposure Factors Handbook (1997); <a href="http://www.epa.gov/ncea/exposfac.htm">www.epa.gov/ncea/exposfac.htm</a>
U.S. EPA, 2000	U.S. EPA/ORD Child-Specific Exposure Factors Handbook (External Review Draft June 2000); <a href="http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=55145">http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=55145</a>
U.S. EPA, 1993	U.S. EPA/ORD Wildlife Exposure Factors Handbook (1993) <a href="http://cfpub.epa.gov/ncea/cfm/wefh.cfm">http://cfpub.epa.gov/ncea/cfm/wefh.cfm</a>
U.S. EPA, 1999	U.S. EPA/ORD Sociodemographic Data Used for Identifying Potentially Highly Exposed Populations (1999); <a href="http://cfpub.epa.gov/ncea/cfm/sociodeg.cfm">http://cfpub.epa.gov/ncea/cfm/sociodeg.cfm</a>
U.S. EPA,	U.S. EPA/ORD Volatilization Rates from Water to Indoor Air Phase II <a href="http://cfpub.epa.gov/ncea/cfm/volatiliz.cfm">http://cfpub.epa.gov/ncea/cfm/volatiliz.cfm</a>
Ausschuss für Umwelthygiene (AUH) (1994)	Standards zur Expositionsabschätzung. Arbeitsgemeinschaft der leitenden Medizinalbeamten und -beamtinnen der Länder, Behörde für Arbeit, Gesundheit und Soziales, Hamburg, 1995.
Bremmer HJ, van Veen MP (2000)	Factsheet algemeen. Randvoorwaarden en betrouwbaarheid, ventilatie kammergrootte, lichaamsoppervlak. RIVM report 612810009
ECETOC	Exposure Factors Sourcebook for European Populations (with focus on UK Data) ECETOC Technical Report No. 79
Bremmer HJ, Van Veen MP (2000) Factsheet	Verf. Ten behoeve van de schatting van de risico's voor de consument. RIVM Report No. 612810010 <a href="http://www.rivm.nl/bibliotheek/rapporten/612810010.html">http://www.rivm.nl/bibliotheek/rapporten/612810010.html</a>
Bremmer HJ, Van Veen MP (2002)	Children's Toys Fact Sheet. To assess the risks for the consumer. RIVM Report No. 612810012 <a href="http://www.rivm.nl/bibliotheek/rapporten/612810012.html">http://www.rivm.nl/bibliotheek/rapporten/612810012.html</a>
AIHC (1994).	Exposure Factors Handbook, Update. American Industrial Health Council (AIHC), Washington, DC

**Summary Statistics**

Hoaglin DC, Mosteller F, Tukey JW, eds	Understanding Robust and Exploratory Data Analysis, John Wiley and Sons, Inc, New York, NY, USA, 1983
Sprent P, Smeeton NC	Applied Nonparametric Statistical Methods, 3 <sup>rd</sup> Edition, Chapman and Hall, CRC, London, 2001
Sprent P	Data Driven Statistical Methods, Chapman and Hall, London, 1998
Hollander M, Wolfe DA	Nonparametric Statistical Methods, 2 <sup>nd</sup> Edition, John Wiley and Sons, Inc, London, 1999
Hettmansperger TP, McKean JW	Robust Nonparametric Statistical Methods, Arnold, Hodder Headline Group, London, 1998, Chapter 1
Efron B, Tibshirani, RJ	An Introduction to the Bootstrap, Chapman and Hall, London, 1993

**Function/Product Use Description**

Environmental Defense	Environmental Defense Fund website with over 6,000 chemical profiles <a href="http://www.scorecard.org/chemical-profiles/">http://www.scorecard.org/chemical-profiles/</a>
ChemExpo	Profiles of industrial chemicals <a href="http://www.chemexpo.com">http://www.chemexpo.com</a>
SPIN Database	Nordic product register database <a href="http://www.spin2000.net/spin.html">http://www.spin2000.net/spin.html</a>

**Models:**

Alliance for Chemical Awareness	Alliance for Chemical Awareness website <a href="http://www.chemicalawareness.org">http://www.chemicalawareness.org</a>
California EPA, 1994	CalTox (TM), Multimedia Total Exposure Model for Hazardous Waste Sites, California EPA, 1994, Version 1.5, latest version 2.3  <a href="http://www.dtsc.ca.gov/ScienceTechnology/ctox_dwn.html">http://www.dtsc.ca.gov/ScienceTechnology/ctox_dwn.html</a>
ECETOC, 1992	ECETOC Report No. 50, Estimating Environmental Concentrations of Chemicals using Fate and Exposure Models, November 1992, ISSN-0773-8072-50
ECETOC, 1994	ECETOC Special Report No. 8, HAZCHEM, A mathematical model for use in Risk Assessment of Substances, October 1994, ISSN -0773-8072-8
EUSES, 1997	EUSES, European Union System for the Evaluation of Substances, Software Version 1.01, 1997 <a href="http://ecb.jrc.it/existing-chemicals/">http://ecb.jrc.it/existing-chemicals/</a>
OECD , 1993a	Report of the OECD Workshop on the Application of simple models for Environmental Exposure Assessment, 1993, OCDE/GD (93)127 <a href="http://www.oecd.org/env/riskassessment">http://www.oecd.org/env/riskassessment</a>
OECD, 1993b	OECD Environment Monographs, No. 70, Occupational and Consumer Exposure Assessments, 1993, OCDE/GD (93)128
OECD, 2003	OECD Database on Models <a href="http://webdomino1.oecd.org/comnet/env/models.nsf">http://webdomino1.oecd.org/comnet/env/models.nsf</a>
OECD, 2002	Report of the OECD/UNEP Workshop on the Use of Multimedia Models for Estimating Overall Environmental Persistence and Long-

	range Transport in the Context of PBTs/POPs Assessment, ENV/JM/MONO(2002)15, <a href="http://www.oecd.org/env/riskassessment">http://www.oecd.org/env/riskassessment</a>
OECD, 2003	Guidance Document on the Use of Multimedia Models for Estimating Overall Environmental Persistence and Long-range Transport, <a href="http://www.oecd.org/env/riskassessment">http://www.oecd.org/env/riskassessment</a>
RIVM, 2001	van Veen, M.P., Consexpo 3.0, Consumer exposure uptake models, RIVM Report No. 612810011, May 2001; <a href="http://www.rivm.nl/bibliotheek/rapporten/612810011.html">http://www.rivm.nl/bibliotheek/rapporten/612810011.html</a>
Trent University	Fugacity models from Mackay's research group at Trent University <a href="http://www.trentu.ca/cemc/models/models.html">http://www.trentu.ca/cemc/models/models.html</a>
U.S. EPA	U.S. EPA/OPPT Exposure Assessment Tools and Models Web Page; <a href="http://www.epa.gov/oppt/exposure">www.epa.gov/oppt/exposure</a>
ELPOS	A. Bayer; Environmental Long-range Transport and Persistence of Organic Substances; Institute of Environmental System Research; University of Osnabrück <a href="http://www.usf.uos.de/projects/elpos/">http://www.usf.uos.de/projects/elpos/</a>
Chemrange	Martin Scheringer, ETH Zürich, <a href="mailto:scheringer@tech.chem.ethz.ch">scheringer@tech.chem.ethz.ch</a> <a href="http://www.tech.chem.ethz.ch/hungerb/research/product/chemrange.html">http://www.tech.chem.ethz.ch/hungerb/research/product/chemrange.html</a>
RIVM, 1991	Jaaps Struis, Simple Treat, RIVM Report No. 670208002 <a href="http://www.rivm.nl/bibliotheek/rapporten/670208002.html">http://www.rivm.nl/bibliotheek/rapporten/670208002.html</a>
RIVM, 1996	Brandes LJ, den Hollander H, van de Meent D., Simple Box, RIVM Report No. 719101029; <a href="http://www.rivm.nl/bibliotheek/rapporten/719101029.html">http://www.rivm.nl/bibliotheek/rapporten/719101029.html</a>
OPS-Model	EU - Technical Guidance Document Support of Commission Directive 93/67/EEC, Commission Regulation 1488/94/EEC and Directive 98/8/EC, 2003 Van Jaarsveld, J.A. (1990). An operational atmospheric transport model for Priority Substances; specifications and instructions for use. RIVM report no. 222501002.
Indirect Exposure	EU - Technical Guidance Document Support of Commission Directive 93/67/EEC, Commission Regulation 1488/94/EEC and Directive 98/8/EC, 2003, Part I, Chapter 2 <a href="http://ecb.jrc.it/cgi-bin/reframer.pl?A=ECB&amp;B=/tgd/doc/">http://ecb.jrc.it/cgi-bin/reframer.pl?A=ECB&amp;B=/tgd/doc/</a>

## ANNEX 4: LISTING OF INDUSTRIAL CATEGORIES AND USE CATEGORIES.

### List of Industry Categories

(Manual for Investigation of HPV Chemicals, Chapter 2 Annex 1)

#### 1. Agricultural industry

Agricultural industry deals with the activities of growing crops (vegetables, grains, etc.) and raising cattle (for dairy products, meat and wool). It also comprises all allied activities such as pest control (application of pesticides, veterinary medicines), manuring, etc.

#### 2. Chemical industry: basic chemicals

There are two different ICs for chemical industry, the industry where substances are produced through chemical reactions. The raw materials for chemical industry come from petrochemical industry (IC 9 'Mineral oil and fuel industry'), from plant or animal materials, or coal. IC 2 is dedicated to *basic chemicals*, which are substances used generally throughout all branches of chemical industry and usually in considerable amounts. Important basic chemicals are solvents (UC 48) and pH-regulating agents (UC 40) (acids, alkalis).

#### 3. Chemical industry: chemicals used in synthesis

Chemicals used in synthesis are substances either regulating the chemical reaction process (e.g. catalysts) or being used as an intermediate (i.e. chemicals that are formed and can be isolated at an intermediate step between starting material and the final product in a sequence of chemical processes).

#### 4. Electrical/electronic industry

In electrical/electronic industry production of a wide range of products is manufactured. It comprises both the manufacture of components like resistors, transistors, capacitors, diodes, lamps, etc. and the production of televisions, radios, computers (PC's as well as mainframes), radar installations, complete telephone exchanges, etc. In the manufacturing processes constituent processes may take place. The main constituent processes are electroplating, polymer processing, and paint application.

#### 5. Personal/domestic

In this IC the use and application of substances in household for maintenance and care of houses, furniture, kitchenware, gardens, etc., and personal care (hygiene, make-up, etc.) is covered. Chemicals used in this IC in many cases will be present in formulations, e.g. in cleaners (soaps, detergents, washing powders, etc.), cosmetics, and products for the care of leather, textile and cars.



## 6. Public domain

This IC covers application and use of substances in a variety of places by skilled workers, such as offices, public buildings, waiting rooms, various workshops like garages, professional cleaning and maintenance of buildings, streets, parks, etc. Also in this IC most chemicals will be present in formulations, e.g. in “cleaners” (UC = 9 ‘Cleaning and washing agents and disinfectants’), non-agricultural biocides (UC = 39 ‘Biocides, non-agricultural’), and products for the maintenance of roads, buildings, etc.

## 7. Leather processing industry

Leather processing industry is considered as the industries where leather is made out of raw hides, leather is dyed and where products are made out of leather (e.g. shoe manufacture).

## 8. Metal extraction, refining and processing industry

This IC covers the extraction of metals from the ores, the manufacture of primary/secondary steel and non-ferro metals (as well “pure” metals as alloys), and the manifold of metal working processes (“shaping”) like cutting, drilling, rolling, etc.

## 9. Mineral oil and fuel industry

Mineral oil and fuel industry involves the so-called *petrochemical* industry, which processes crude mineral oil. By means of physical and chemical processes (e.g. separation by means of distillation, cracking and platforming) they produce a wide range of hydrocarbons serving as raw materials for chemical industry and (often after adding a series of additives) fuels for heating and combustion engines.

## 10. Photographic industry

Photographic industry is the industry where photographic materials are manufactured (“solid” materials like films and photographic “papers”, but also preparations - either in a solid or a liquid form - for film and paper processing baths. Also the processing of films and photographic paper is accounted to photographic industry, including professional processing in so-called printshops.

## 11. Polymers industry

Polymers industry comprises the branch of chemical industry where ‘plastics’ (thermoplastics) are chemically produced and industries where processing of thermoplastics and prepolymers takes place by means of a wide range of techniques.

## 12. Pulp, paper and board industry

Production of pulp, paper and cardboard out of wood or waste paper belongs to this IC, but also chemicals used in reprographic industry.

## 13. Textile processing industry

This IC covers treatment of fibres (“cleaning”, spinning, dyeing, etc.), weaving, and finishing (e.g. impregnation, coating, etc.).

14. Paints, lacquers and varnishes industry

Apart from the manufacture of coating products (stage of formulation) like paints this IC also covers application of these products.

16. Engineering industry: civil and mechanical

To this IC industrial activities belong such as wood processing industries (e.g. wooden furniture), motor car manufacture, building industry, etc.

0. Others

All processes and activities, which can not be placed in one of the previous ICs, belong to this IC. An example is food processing industry.

**List of Use Categories**  
(Manual for Investigation of HPV Chemicals, Chapter 2 Annex 1)

The Use Categories (UC) described below (left column), as they are proposed by IUCLID can be used for that purpose. The corresponding functions as proposed by ChemUSES (US-EPA, 1980) are listed in the right column. A list of synonyms for functions according to ChemUSES vs. IUCLID Use category No is also presented below.

No. USE CATEGORY (IUCLID)	No. Function (ChemUSES)
1 Absorbents and adsorbents	131 Absorbents 60 Adsorbents 213 Dehumidifiers
2 Adhesive, binding agents	302 Adhesives 143 Binders 92 Spreaders 165 Stickers 280 Tackifiers
3 Aerosol propellants	178 Aerosol propellants
4 Anti-condensation agents	
5 Anti-freezing agents	77 Antifreezes 74 De-icers 52 Deodorants 313 Functional fluids
6 Anti-set-off and anti-adhesive agents	104 Abherents 63 Antiblocking agents 188 Anticaking agents 300 Detackifiers 233 Dusting agents 144 Parting agents 7 Soil retardants
7 Anti-static agents	328 Antistatic agents 89 Electroconductive coating agents 318 Humectants
8 Bleaching agents	304 Bleaching assistants 132 Bleaching agents
9 Cleaning/washing agents and additives	293 Antiredeposition agents 180 Boil-off assistants 242 Cleaners 173 Detergents 78 Pre-spotting agents 274 Scouring agents 261 Shrinkage controllers 14 Soaping-off assistants 294 Soil release agents
10 Colouring agents	5 Bloom agents 86 Colouring agents 174 Coupling agents (dyes) 267 Dyes

	20	Fluorescent agents
	248	Lakes
	381	Luminescent agents
	235	Mercerising assistants
	128	Opacifiers
	139	Pearlizing agents
	125	Pigments
	83	Stains
11	Complexing agents	177 Antiprecipitants 124 Complexing agents 10 Sequestering agents
12	Conductive agents	161 Electrical conductive agents 383 Electrode materials 245 Electrolytes 313 Functional fluids
13	Construction materials and additives	324 Case-hardening agents 355 Concrete additives 361 Embrittlement inhibitors 375 Materials for shaping 250 Reinforcing agents 349 Water-reducing agents
14	Corrosion inhibitors	230 Antioxidants 64 Antiscaling agents 323 Corrosion inhibitors
15	Cosmetics	301 Antiperspirants 167 Cosmetic ingredients
16	Dust binding agents	26 Dust control agents
17	Electroplating agents	353 Brighteners 32 Fume suppressants
18	Explosives	179 Detonators 363 Explosion inhibitors 158 Explosives 27 Incendiaries
19	Fertilisers	34 Fertilisers
20	Fillers	351 Fillers (augmentation) 212 Fillers (patching) 371 Surface coating additives 127 Swelling agents 58 Weighting agents (textile technology)
21	Fixing agents	291 Anticrock agents 347 Antistripping agents 268 Barrier coating agents 295 Fixatives 134 Fixing agents (fragrances) 112 Fixing agents (textile technology) 227 Mordents
22	Flame retardants and fire preventing agents	25 Fire extinguishing agents 332 Flame retardants

23	Flotation agents	163	Activators (ore processing)
		190	Flocculating agents
		297	Flotation agents
		360	Modifiers
24	Flux agents for casting		
25	Foaming agents	358	Blowing agents
		133	Chemical blowing agents
		94	Frothers
		50	Physical blowing agents
26	Food/feedstuff additives	214	Acidulants
		66	Feed additives
		145	Food additives
		80	Sweeteners (taste)
27	Fuels	247	Fuels
28	Fuel additives	329	Antifouling agents
		76	Antiknock agents
		183	Deposit modifiers
		306	Fuel additives
		138	Sweeteners (petroleum technology)
29	Heat transferring agents	72	Coolants
		313	Functional fluids
		199	Heat transfer agents
		216	Quenchers
		208	Refrigerants
30	Hydraulic fluids and additives	313	Functional fluids
		65	Hydraulic fluids
		256	Transmission fluids
31	Impregnation agents	102	Delustrants
		98	Sizes
		258	Water repellents
		23	Waterproofing agents
32	Insulating materials	254	Acoustical insulating material
		311	Electrical insulating material
		314	Heat insulating materials
		162	Insulating materials
33	Intermediates	146	Inorganic intermediates
		115	Monomers
		290	Organic intermediates
		43	Prepolymers
34	Laboratory chemicals	238	Analytical and product testing
		122	Chelating agents
		107	Deionisers
		373	Extraction agents
		69	Indicators
		325	Oxidation-reduction indicators
		374	Reagents
35	Lubricants and additives	119	Antiseize agents
		313	Functional fluids

	148	Internal lubricating agents
	195	Lubricant additives
	364	Lubricating agents
	346	Oiliness agents
	249	Penetrants
	312	Slip agents
36	Odour agents	79 Flavours and fragrances 339 Odorants
37	Oxidising agents	149 Oxidisers
38	Plant protection products, agricultural	166 Animal repellents 333 Bactericides 108 Biocides 97 Decontaminants 270 Fumigants 362 Fungicides 275 Herbicides 155 Insect attractants 348 Insect repellents 330 Insecticides 252 Nematocides 253 Pesticides 264 Rodenticides
39	Biocides, non-agricultural	287 Algicides 1 Antifouling agents 140 Disinfectants 118 Preservatives 116 Slime preventatives
40	pH-regulating agents	172 Laundry sours 266 pH control agents 191 pH indicators
41	Pharmaceuticals	
42	Photochemicals	122 Chelating agents 198 Desensitisers (explosives) 299 Desensitisers (photography) 182 Developers 286 Intensifiers (photography) 285 Light stabilisers 344 Photosensitive agents 303 Sensitisers
43	Process regulators	321 Accelerators 46 Activators (chemical processes) 239 Activators (enzymes) 110 Adhesion promoters 4 Antifelting agents 352 Antislip finishing agents 206 Antistaining agents 194 Antiwebbing agents 281 Builders 222 Carbonising agents 164 Carriers 19 Catalyst supports

	170	Catalysts	
	31	Chain extenders	
	113	Chain terminators	
	141	Chain transfer agents	
	122	Chelating agents	
	114	Coagulants	
	278	Coalescents	
	357	Coalescing agents	
	315	Crabbing assistants	
	228	Crosslinking agents	
	226	Curing agents (concrete)	
	369	Curing agents (polymer technology)	
	18	Currying agents	
	236	Deasphalting agents	
	342	Defoamers	
	365	Degumming agents	
	137	Dehairing agents	
	73	Dehydrating agents	
	366	De-inkers	
	84	Delignification agents	
	30	Depolymerisation agents	
	367	Depressants	
	292	Desising agents	
	259	Dispersants	
	317	Dryers	
	150	Dye carriers	
	255	Dye levelling agents	
	307	Dye retardants	
	211	Dye retention aids	
	341	Enzyme inhibitors	
	157	Enzymes	
	284	Finishing agents	
	337	Formation aids	
	331	Fuel oxidisers	
	117	Fulling agents	
	103	Initiators	
	359	Intensifiers (printing)	
	171	Kier boiling assistants	
	24	Nucleating agents	
	96	Peptising agents	
	75	Pitch control agents	
	121	Polymerisation additives	
	209	Polymerisation inhibitors	
	21	Prevulcanisation inhibitors	
	153	Refining agents	
	223	Repulping aids	
	136	Retarders	
	296	Retention aids	
	338	Rubber compounding agents	
	51	Scavengers	
	326	Solubilising agents	
	310	Weighting agents (petroleum technology)	
44	Reducing agents	244	Reducers
45	Reprographic agents	225	Toners
46	Semiconductors	202	Semiconductors
		378	Photovoltaic agents

47	Softeners	269	Bates
		231	Devulcanising agents
		28	Elasticisers
		265	Emollients
		185	Plasticisers
		29	Softeners
		147	Water softeners
48	Solvents	229	Degreasers
		82	Dewaxing solvents
		373	Extraction agents
		320	Paint and varnish removers
		16	Reaction media
		271	Solvents
49	Stabilisers	277	Anticracking agents
		12	Antifume agents
		129	Antihydrolysis agents
		168	Antiozonants
		230	Antioxidants
		120	Antilivering agents
		282	Anti-plasticisers
		160	Antisagging agents
		68	Antisettling agents
		88	Bloom inhibitors
		123	Coupling agents (polymers)
		159	Emulsifiers
		87	Heat stabilisers
		54	Stabilisers
		36	Ultraviolet absorbers
50	Surface-active agents	41	Antifloating agents
		234	Antifogging agents
		109	Surfactants
		243	Wetting agents
51	Tanning agents	316	Tanning agents
52	Viscosity adjustors	152	Antiflooding agents
		120	Antilivering agents
		343	Antiskinning agents
		221	Gelling agents
		262	Pour point depressants
		272	Thickeners
		334	Thixotropic agents
		240	Turbulence suppressors
		135	Viscosity adjustors
		15	Viscosity index improvers
53	Vulcanising agents	288	Vulcanising agents
54	Welding and soldering agents	101	Brazing agents
		22	Fluxing agents
0	Other	204	Ablatives
		105	Abrasives
		196	Activators (luminescence)
		354	Aerating agents



47	Air entraining agents
376	Alloying agents
90	Anticratering agents
48	Anticreasing agents
99	Antifogging agents
218	Antipilling agents
350	Antiskid agents
6	Blasting abrasives
70	Bluing agents
220	Bright dips
93	Chemical raw materials
298	Clarifiers
260	Cloud point depressants
130	Coating agents
283	Collectors
335	Coupling agents (solutions)
215	Culture nutrients
81	Deaerating agents
309	Debloating agents
85	Dechlorinating agents
73	Dehydrating agents
107	Deionisers
232	Demulsifiers
200	Denaturants
49	Descaling agents
205	Dewatering aids
356	Discharge printing agents
38	Drainage aids
44	Drilling mud additives
322	Dry strength additives
39	Dye stripping agents
100	Electron emission agents
340	Eluting agents
372	Embalming agents
186	Encapsulating agents
57	Enhanced oil recovery agents
308	Entraining agents
319	Etching agents
336	Evaporation control agents
373	Extraction agents
207	Fiber-forming compounds
368	Filtration aids
56	Flattening agents
79	Flavours and fragrances
142	Fluid loss additives
313	Functional fluids
193	Greaseproofing agents
184	"Grinding, lapping, sanding and"
192	Hormones
246	Humidity indicators
210	Hydrotropic agents
181	Impact modifiers
380	Incandescent agents
69	Indicators
2	Ion exchange agents
91	Lachrymators
33	Latex compounding agents
53	Leaching agents
156	Leather processing agents

370	Liquid crystals
381	Luminescent agents
379	Magnetic agents
67	Mar proofing agents
289	Metal conditioners
95	Metal strippers
37	Metal treating agents
327	Milling aids
237	Obscuring agents
197	Oil repellents
62	Optical quenchers
382	Osmotic membranes
17	Papermaking agents
55	Phosphatising agents
203	Phosphorescent agents
59	Pickling agents
217	Pickling inhibitors
251	Plant growth regulators
176	Plastics additives
224	Plastics for shaping
169	Plating agents
8	Poison gas decontaminants
3	Polymer strippers
111	Pore forming agents
151	Precipitating agents
106	Protective agents
45	Radioactivity decontaminants
374	Reagents
219	Refractive index modifiers
241	Refractories
154	Resists
9	Rinse aids
71	Ripening agents
187	Rubber for shaping
201	Rubber reclaiming agents
189	Rubbing fastness agents
276	Rust inhibitors
11	Rust removers
263	Scrooping agents
42	Sealants
98	Sizes
126	Slime control agents
305	Soil conditioners
61	Strippers
40	Tar removers
345	Tarnish inhibitors
13	Tarnish removers
279	Textile specialities
257	Vat printing assistants
273	Wax strippers
35	Well treating agents
175	Wet strength additives
377	X-ray absorbents

**List of synonyms for functions according to ChemUSES (US-EPA, 1980) vs. IUCLID Use category No.**

No.	ChemUSES Function	Use category IUCLID (No.)	No.	ChemUSES Function	Use category IUCLID (No.)
104	Abherents	6	108	Biocides	38
204	Ablatives	55	6	Blasting abrasives	0
105	Abrasives	0	132	Bleaching agents	8
131	Absorbents	1	304	Bleaching assistants	8
321	Accelerators	43	5	Bloom agents	10
214	Acidulants	26	88	Bloom inhibitors	49
254	Acoustical insulating material	32	358	Blowing agents	25
46	Activators (chemical processes)	43	70	Bluing agents	0
163	Activators (ore processing)	23	180	Boil-off assistants	9
196	Activators (luminescence)	55	101	Brazing agents	54
239	Activators (enzymes)	43	220	Bright dips	0
110	Adhesion promoters	43	353	Brighteners	17
302	Adhesives	2	281	Builders	43
60	Adsorbents	1	222	Carbonising agents	43
354	Aerating agents	0	164	Carriers	43
178	Aerosol propellents	3	324	Case-hardening agents	13
47	Air entraining agents	0	170	Catalysts	43
287	Algicides	39	19	Catalyst supports	43
376	Alloying agents	0	31	Chain extenders	43
238	Analytical and product testing	34	113	Chain terminators	43
166	Animal repellents	38	141	Chain transfer agents	43
63	Antiblocking agents	6	122	Chelating agents	34, 42, 43
188	Anticaking agents	6	133	Chemical blowing agents	25
277	Anticracking agents	49	93	Chemical raw materials	0
90	Anticratering agents	0	298	Clarifiers	0
48	Anticreasing agents	0	242	Cleaners	9
291	Anticrock agents	21	260	Cloud point depressants	0
4	Antifelting agents	43	114	Coagulants	43
41	Antifloating agents	50	278	Coalescents	43
152	Antiflooding agents	52	357	Coalescing agents	43
234	Antifogging agents	50	130	Coating agents	0
99	Antifogging agents	0	283	Collectors	0
1	Antifouling agents	39	86	Colouring agents	10
329	Antifouling agents	28	124	Complexing agents	11
77	Antifreezes	5	355	Concrete additives	13
12	Antifume agents	49	72	Coolants	29
129	Antihydrolysis agents	49	323	Corrosion inhibitors	14
76	Antiknock agents	28	167	Cosmetic ingredients	15
120	Antilivering agents	49, 52	123	Coupling agents (polymers)	49
230	Antioxidants	14, 49	174	Coupling agents (dyes)	10
168	Antiozonants	49	335	Coupling agents (solutions)	55
301	Antiperspirants	15	315	Crabbing assistants	43
218	Antipilling agents	55	228	Crosslinking agents	43
282	Antiplasticisers	49	215	Culture nutrients	0
177	Antiprecipitants	11	226	Curing agents (concrete)	43
293	Antiredeposition agents	9	369	Curing agents (polymer technology)	43
160	Antisagging agents	49	18	Currying agents	43
64	Antiscalting agents	14	366	De-inkers	43
119	Antiseize agents	35	81	Deaerating agents	0
68	Antisettling agents	49	236	Deasphalting agents	43
350	Antiskid agents	0	309	Debloomng agents	0
343	Antiskinning agents	52	85	Dechlorinating agents	55
352	Antislip finishing agents	43	97	Decontaminats	38
206	Antistaining agents	43	342	Defoamers	43
328	Antistatic agents	7	229	Degreasers	48
347	Antistripping agents	21	365	Degumming agents	43
194	Antiwebbing agents	43	137	Dehairing agents	43
333	Bactericides	38	213	Dehumidifiers	1
268	Barrier coating agents	21	73	Dehydrating agents	0, 34
269	Bates	47	74	Deicers	5
143	Binders	2	107	Deionizers	0, 34

84	Delignification agents	43	332	Flame retardants	22
102	Delustrants	31	56	Flatting agents	0
232	Demulsifiers	0	79	Flavours and fragrances	0, 36
200	Denaturants	0	190	Flocculating agents	23
52	Deodorants	5	297	Flotation agents	23
30	Depolymerisation agents	43	142	Fluid loss additives	0
183	Deposit modifiers	28	20	Fluorescent agents	10
367	Depressants	43	22	Fluxing agents	54
49	Descaling agents	0	145	Food additives	26
198	Desensitisers (explosives)	42	337	Formation aids	43
299	Desensitisers (photography)	42	94	Frothers	25
292	Desizing agents	43	306	Fuel additives	28
300	Detackifiers	6	331	Fuel oxidisers	43
173	Detergents	9	247	Fuels	27
179	Detonators	18	117	Fulling agents	43
182	Developers	42	32	Fume suppressants	17
231	Devulcanising agents	47	270	Fumigants	38
205	Dewatering aids	0	313	Functional fluids	0, 5, 12, 29, 30, 35
82	Dewaxing solvents	48	362	Fungicides	38
356	Discharge printing agents	0	221	Gelling agents	52
140	Disinfectants	39	193	Greaseproofing agents	0
259	Dispersants	43	184	Grinding, lapping, sanding and polishing abrasives	0
38	Drainage aids	0	199	Heat transfer agents	29
317	Dryers	43	314	Heat insulating materials	32
44	Drilling mud additives	0	87	Heat stabilisers	49
322	Dry strength additives	0	275	Herbicides	38
26	Dust control agents	16	192	Hormones	0
233	Dusting agents	6	318	Humectants	7
150	Dye carriers	43	246	Humidity indicators	0
255	Dye leveling agents	43	65	Hydraulic fluids	30
307	Dye retardants	43	210	Hydrotropic agents	0
211	Dye retention aids	43	181	Impact modifiers	0
39	Dye stripping agents	0	380	Incandescent agents	0
267	Dyes	10	27	Incendiaries	18
28	Elasticisers	47	69	Indicators	0, 34
161	Electrical conductive agents	12	103	Initiators	43
311	Electrical insulating material	32	146	Inorganic intermediates	33
89	Electroconductive coating agents	7	155	Insect attractants	38
383	Electrode materials	12	348	Insect repellents	38
245	Electrolytes	12	330	Insecticides	38
100	Electron emission agents	0	162	Insulating materials	32
340	Eluting agents	0	286	Intensifiers (photography)	42
372	Embalming agents	0	359	Intensifiers (printing)	43
361	Embrittlement inhibitors	13	148	Internal lubricating agents	35
265	Emollients	47	2	Ion exchange agents	0
159	Emulsifiers	49	171	Kier boiling assistants	43
186	Encapsulating agents	0	91	Lachrymators	0
57	Enhanced oil recovery agents	0	248	Lakes	10
308	Entraining agents	0	33	Latex compounding agents	0
341	Enzyme inhibitors	43	172	Laundry sours	40
157	Enzymes	43	53	Leaching agents	0
319	Etching agents	0	156	Leather processing agents	0
336	Evaporation control agents	0	285	Light stabilisers	42
363	Explosion inhibitors	18	370	Liquid crystals	0
158	Explosives	18	195	Lubricant additives	35
373	Extraction agents	34, 48	364	Lubricating agents	35
66	Feed additives	26	381	Luminescent agents	0, 10
34	Fertilisers	19	379	Magnetic agents	0
207	Fiber-forming compounds	0	67	Mar proofing agents	55
212	Fillers (patching)	20	375	Materials for shaping	13
351	Fillers (augmentation)	20	235	Mercerising assistants	10
368	Filtration aids	0	289	Metal conditioners	0
284	Finishing agents	43	37	Metal treating agents	0
25	Fire extinguishing agents	22	95	Metal strippers	0
295	Fixatives	21	327	Milling aids	0
112	Fixing agents (textile technology)	21	360	Modifiers	23
134	Fixing agents (fragrances)	21			

115	Monomers	33	187	Rubber for shaping	0
227	Mordents	21	201	Rubber reclaiming agents	0
252	Nematocides	38	189	Rubbing fastness agents	0
24	Nucleating agents	43	11	Rust removers	0
237	Obscuring agents	0	276	Rust inhibitors	0
339	Odorants	36	51	Scavengers	43
197	Oil repellents	0	274	Scouring agents	9
346	Oiliness agents	35	263	Scrooping agents	0
128	Opacifiers	10	42	Sealants	0
62	Optical quenchers	0	202	Semiconductors	46
290	Organic intermediates	33	303	Sensitisers	42
382	Osmotic membranes	0	10	Sequestering agents	11
325	Oxidation-reduction indicators	34	261	Shrinkage controllers	9
149	Oxidisers	37	98	Sizes	0, 31
320	Paint and varnish removers	48	126	Slime control agents	0
17	Papermaking agents	0	116	Slime preventatives	39
144	Parting agents	6	312	Slip agents	35
139	Pearlising agents	10	14	Soaping-off assistants	9
249	Penetrants	35	29	Softeners	47
96	Peptising agents	43	305	Soil conditioners	0
253	Pesticides	38	294	Soil release agents	9
191	pH indicators	40	7	Soil retardants	6
266	pH control agents	40	326	Solubilising agents	43
55	Phosphatising agents	0	271	Solvents	48
203	Phosphorescent agents	0	92	Spreaders	2
344	Photosensitive agents	42	54	Stabilisers	49
378	Photovoltaic agents	42	83	Stains	10
50	Physical blowing agents	25	165	Stickers	2
217	Pickling inhibitors	0	61	Strippers	0
59	Pickling agents	0	371	Surface coating additives	20
125	Pigments	10	109	Surfactants	50
75	Pitch control agents	43	138	Sweeteners (petroleum technology)	28
251	Plant growth regulators	0	80	Sweeteners (taste)	26
185	Plasticisers	47	127	Swelling agents	20
176	Plastics additives	0	280	Tackifiers	2
224	Plastics for shaping	0	316	Tanning agents	51
169	Plating agents	0	40	Tar removers	0
8	Poison gas decontaminants	0	13	Tarnish removers	0
3	Polymer strippers	0	345	Tarnish inhibitors	0
121	Polymerisation additives	43	279	Textile specialities	0
209	Polymerisation inhibitors	43	272	Thickeners	52
111	Pore forming agents	0	334	Thixotropic agents	52
262	Pour point depressants	52	225	Toners	45
78	Pre-spotting agents	9	256	Transmission fluids	30
151	Precipitating agents	0	240	Turbulence suppressors	52
43	Prepolymers	33	36	Ultraviolet absorbers	49
118	Preservatives	39	257	Vat printing assistants	0
21	Prevulcanisation inhibitors	43	135	Viscosity adjustors	52
106	Protective agents	0	15	Viscosity index improvers	52
216	Quenchers	29	288	Vulcanising agents	53
45	Radioactivity decontaminants	0	147	Water softeners	47
16	Reaction media	48	258	Water repellents	31
374	Reagents	0, 34	349	Water-reducing agents	13
244	Reducers	44	23	Waterproofing agents	31
153	Refining agents	43	273	Wax strippers	0
219	Refractive index modifiers	0	310	Weighting agents (petroleum technology)	43
241	Refractories	0	58	Weighting agents (textile technology)	20
208	Refrigerants	29	35	Well treating agents	0
250	Reinforcing agents	13	175	Wet strength additives	0
223	Repulping aids	43	243	Wetting agents	50
154	Resists	0	377	X-ray absorbents	0
136	Retarders	43			
296	Retention aids	43			
9	Rinse aids	0			
71	Ripening agents	0			
264	Rodenticides	38			
338	Rubber compounding agents	43			

**Category of Product/ general characterisation Subcategories  
(EU Technical Guidance Document Chapter 2 Appendix II)**

**1. CLEANER / POLISH**

The category covers all products that are used in the household for cleaning, polishing and care. Some subcategories can be defined by different use characteristics. A comprehensive overview on household cleaners and its subcategories has been published by the IKW (IKW,2001)

- Cleaning of machines and vehicles (e.g. cars, bikes, motorbikes)
- General household (All Purpose Cleaners)
- Dish washing, manual
- Dish washing, machine
- Sanitary cleaners
- Textile cleaners e.g. Powder Laundry Detergents, Laundry Liquid Detergents
- Oven cleaners
- Shoe and leather cleaner
- Furniture cleaners
- Drain cleaners
- Metal cleaners

**2. ADHESIVE / SEALANT**

The category covers all products that are used in the household as adhesives or sealants. Some subcategories can be defined by different use characteristics (The list of subcategories of adhesives has been prepared by the WHO/IPCS).

- General purpose adhesive
- Floor covering adhesives
- Dental plate cement
- Fabric adhesive
- Film cement, photographic
- Leather adhesive
- Metal adhesive
- Paper adhesive
- Plastic adhesive
- Rubber adhesive
- Wallboard joint cement
- Wallpaper adhesive
- Wood adhesive

**3. PRINTING / WRITING MATERIAL**

The category covers all products that are used in the household for writing and printing. Some subcategories can be defined by different use characteristics: (The list of subcategories of adhesives has been prepared by the WHO/IPCS).

- •Dye
- •Ink
- •Etching fluid
- •Correction fluid
- •Crayon
- •Pen marker
- •Toner

**PAINTING MATERIAL AND ADDITIVES**

The category covers all products that are painted to an area for renewing, or to protect the areas against wetness or corrosion etc. Some subcategories can be defined by different use characteristics. The classification of subcategories has been prepared according to Baumann & Muth (1997) and Bremmer and van Veen (2000a).

- Solvent based paint
- Water based paint
- Resin based paints
- Aerosol paints
- Paints for special purposes
- Industrial paints
- Varnish
- Bleaching paints
- Paints for conservation
- Thinner
- Paint remover

**4. FUELS**

This category covers products that are used for feed machines (cars, motorbikes) or lamps or to lighten fires.

- Gasoline
- Fuel oil
- Liquid lamp oils and grill lighters

- Solid grill lighters
- Solid lighteners, other

#### 5. BLEACH / DISINFECTANT / STERILIZER

The category covers all products that are used in the household as a bleach or for sterilisation. Some subcategories can be defined by different use characteristics.

- Bleaches
- Sterilisers

#### 6. REMOVERS

The category covers all products that are used in the household to remove substances, from surfaces and thus cleaning them. Some subcategories can be defined by different use characteristics:

- Adhesive/glue remover
- Dye/ink remover
- Seal remover
- Polish remover
- Limescale remover/descaler
- Oil/grease remover
- Rust remover
- Stain remover
- Wall paper remover

#### 7. PHOTOGRAPHIC CHEMICAL

The category covers all products in the household that are referred to photography. Some subcategories can be defined by different use characteristics:

- Photographic chemicals
- Photographic paper

#### 8. TEXTILE CHEMICAL

The category covers all products that are exposure related to the use of textiles. Some subcategories can be defined by different use characteristics.

- Textile colours/dyes
- Emission from textiles
- Residues from cleaning textiles
- Fabric softeners
- Fire protecting agents in textiles

#### 9. VEHICLE MAINTENANCE

The category covers all products that are used in the household to make vehicles (cars, bikes, motorbikes, caravans, boats etc.) ready for use. Cleaning is covered by the category "cleaner/polish". Some subcategories can be defined by different use characteristics:

- Lubricants
- Repairing material
- Antifreeze (vehicle)
- Screen wash
- Brake fluid
- Fuel additive
- Radiator fluid
- Transmission fluid

#### 10. COSMETIC / PERSONAL HYGIENE PRODUCT

The category covers all products that are used in the household to clean and care the body in particular e.g. hair and skin. Some subcategories can be defined by different use characteristics. Categories of cosmetics are extensively described by the compilation of cosmetic frame formulations (COLIPA, 2000).

- Rinse off products (e.g. Hand Dishwashing Liquids)
- Non-rinse products
- Spraying
- Products that can contact mucous membranes

#### 11. CONTAMINATION OF FOOD

The category covers exposures that can be referred to the consumption of food. In particular, it is referred to contaminations of food and is subcategorised to the different kinds of food. Most of the data referring to this type of exposure are available from food surveillance studies (e.g. BGVV, 1995). Categories of food consumption should be taken according to the EFG food grouping system (EFCOSUM, 2001).

- Contamination of food by processing and packaging material

#### 12. AIR CONTAMINANT / POLLUTANT

The category covers all exposures that are referred to the emission of chemicals from materials in the household except textiles

- Furniture chemicals
- Building chemicals
- Emissions from vehicles (e.g. cars)

**13. TOY / JOKE / CHILDREN'S PLAYTHING**

(Bremmer and van Veen, 2001)

**14. OTHER CATEGORIES NOT MENTIONED OTHERWISE •**

- Refrigerant, coolant
- Solvent
- Water softener
- Aerosol propellant
- Aquarium product
- Art/craft material
- Deodorizer/air freshener
- Sports product
- Swimming pool product
- Waterproofing compound
- Agricultural products other than pesticides
- Medical devices
- Piercings



**EU Categories for biocidal Products and Substances  
(EU Directive 98/8/EC)**

Number	Product Type	Description
Main Group 1:	Disinfectants & General Biocidal Products	
1	Human hygiene biological products	Used for human hygiene purposes.
2	Private and public health area disinfectants and other biocidal products	Used for the disinfection of air, surfaces, materials, equipment and furniture which are not used for direct food or feed contact in private, public or industrial areas, including hospitals, as well as products used as algacides. Usage areas include swimming pools, aquariums, bathing and other waters; air-conditioning units; walls and floors in health and other institutions; chemical toilets, waste water, hospital waste, soil and other substrates (in playgrounds).
3	Veterinary hygiene biocidal products	Includes products used in areas in which animals are housed, kept or transported.
4	Food and feed area disinfectants	Used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage, or consumption of food, feed or drink (including drink water) for humans and animals.
5	Drinking water disinfectants	For both humans and animals.
Main Group 2 Preservatives		
6	In-can preservatives	Used for the preservation of manufactured products, other than foodstuffs or feeding stuffs, in containers by the control of microbial deterioration to ensure their shelf life.
7	Film preservatives	Used for the preservation of films or coatings by the control of microbial deterioration in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works etc.
8	Wood preservatives	For wood from and including saw-mill stage, and wood products (including preventative and curative products).
9	Fibre, leather, rubber and polymerised materials preservatives	Includes the preservation of fibrous materials, such as paper or textile products.
10	Masonry preservatives	Used for the preservation and remedial treatment of masonry or other construction materials other than wood by the control of microbiological algal attack.
11	Preservatives for liquid-cooling and processing systems	Use for the preservation of water and other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels (not drinking water preservation products).
12	Slimicides	Used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and

		paper pulp, and porous sand strata in oil extraction.
13	Metalworking-fluids preservatives	Products used for the preservation of metalworking fluids by the control of microbial deterioration.
Main Group 3: Pest Control		
14	Rodenticides	Control of mice, rats or other rodents.
15	Avicides	control of birds.
16	Molluscicides	Control of molluscs, e.g. snails that may clog pipes.
17	Piscicides	Control of fish; excludes products for the treatment of fish diseases.
18	Insecticides, acaricides and to control other arthropods	e.g. insects arachnids and crustaceans
19	Repellents or attractants	Used to control, harmful organisms (invertebrates such as fleas, vertebrates such as birds), by repelling or attracting, including those that are used for human or veterinary hygiene either directly or indirectly.
Main Group 4: Other Biocidal Products		
20	Preservatives for food and feedstocks	Used for the preservation of food or feedstuffs by the control of harmful organisms.
21	Antifouling products	Used to control growth and settlement of fouling organisms (microbes and higher forms of plant and animal species) on vessels, aquaculture equipment or other structures used in water.
22	Embalming or taxidermist fluids	Used for the disinfection and preservation of human or animal corpses, or parts thereof.
23	Control of vertebrates	i.e. vermin