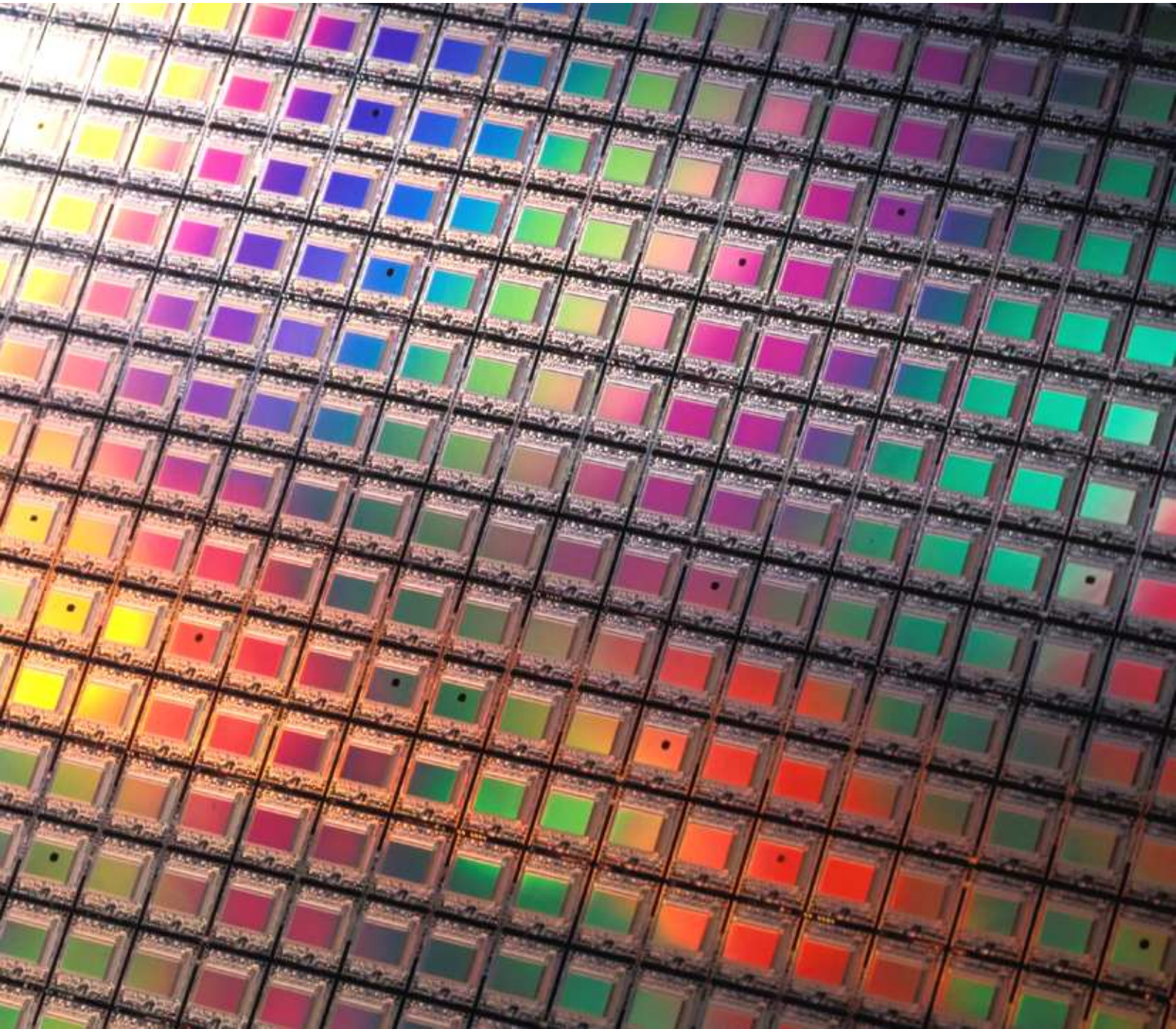
EECA ESIA

European Semiconductor Industry Association

ECHA

European Chemicals Agency

# Exposure Scenarios for the Semiconductor Industry Examples



**Exposure Scenarios for the Semiconductor Industry Examples**

**Reference:** ECHA-10-R-005-EN

**Date:** 5 August 2010

**Language:** EN

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## Overview

The European Chemicals Agency (ECHA)/semiconductor industry collaboration was established to gain practical experience in generating exposure scenarios (ESs) that would be integral elements of the chemical safety report (CSR). The examples are related to industrial use of three substances in production of semiconductor devices (“microchips”).

Project participants strove to achieve a high level of understanding of semiconductor (SC) processes through information sharing and a site visit to observe actual semiconductor manufacturing operations. Although not all the details were required or utilised, it established a common understanding of the SC industry to allow estimation of exposure to environment and workers and to take into account risk management measures (RMM) typically used.

The three examples of ES identify how each substance is used, the operational conditions (OC) and RMM in place and any potential exposures resulting to the environment and workers. Those factors, along with specific Predicted No-Effects-Concentration for environment (PNEC) and Derived No–effect-Level for human health (DNEL) of the substances are required to assess risk and to calculate the Risk Characterisation Ratio (RCR).

In these examples, the waste stage has not yet been addressed since ECHA’s draft guidance on exposure assessment for the waste life stage is still under consultation with ECHA’s Committees and the EU Member States.

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# 1. INTRODUCTION

## 1.1 Background

The European Chemicals Agency approached the European Semiconductor Industry Association (ESIA) to collaborate over creating an example ES. ESIA agreed to participate along with the International Sematech Manufacturing Initiative (ISMI) - an international consortium of semiconductor manufacturers - and semiconductor chemical suppliers.

The project team selected three substances that represent generic classes of chemicals used in semiconductor manufacturing as well as typical OC and RMM. These example exposure scenarios can serve as a standardised format for suppliers to use in their development of CSRs.

The examples relate to industrial manufacture of semiconductor devices ('microchips') on silicon wafers[1] in fabrication areas (Fab) called 'clean rooms' in which the temperature, humidity and airborne particle contamination are strictly controlled. The Fab environment is, in most cases, thousands of times cleaner than a hospital operating room. Uncontrolled chemical vapours and gases are equally controlled as their presence is unacceptable due to their potential for contaminating products, as well as for occupational health and safety concerns.

In Fabs a number of RMM are used to prevent and control chemical release to the environment and exposure of workers. Chemical dispensing may be totally contained, equipment is often enclosed and extraction removes fumes and vapours to air abatement systems such as water scrubbers or thermal oxidisers. In many cases secondary and even tertiary redundancy to controls ensure that, in the event that one control fails, other will continue to provide the necessary protection. Numerous voluntary guidelines developed by the industry promote manufacturing equipment design that minimises risk to workers during normal operation and maintenance procedures. Although maintenance may require bypass of some RMM, additional design, interlocks and deactivation of the equipment prevents chemical release and exposure. Local exhaust ventilation (LEV) is often used, where there is a risk of exposure to chemical substances present in the workplace atmosphere and, with personal protective equipment (PPE), reduces the exposure of the worker.

## 1.2 Building the exposure scenario and exposure estimation

The Exposure Scenario was developed using ECHA guidance. Information on the OC and RMM were provided by industry stakeholders. Chemical suppliers provided substance specific information to allow derivation of substance DNEL and PNEC. Suitable quality, representative measured exposure data was not available for the conditions described in the ESs; therefore the expected exposure concentration for workers and the predicted environmental concentration (PEC) were calculated using "ECETOC TRA[2]" and "EUSES 2.1[3]", two TIER 1 computer models. These two models can make exposure assessments based upon assumptions on conditions of use, including those encoded in given process categories (PROCs) or environmental release categories (ERCs)[4], and substance characteristics. If the predicted exposure is below DNEL/PNEC (i.e., the RCR is less than 1),

[1] A **wafer** is a thin slice of semiconductor material, such as a silicon crystal, used in the fabrication of integrated circuits and other microdevices ( Source Wikipedia : http://en.wikipedia.org/wiki/Silicon_Wafer)
[2] www.ecetoc.org/tra
[3] www.ecb.jrc.ec.europa.eu/euses
[4] PROCs and ERCs are elements of the use descriptor system contained in the ECHA Guidance Document R.12 ( http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf ). Other relevant input parameters to run the TIER 1 models are for example: the substance amount (EUSES), indication whether the use takes place under industrial conditions or not and whether an LEV is present or not.

the conditions of use assumed for the TIER 1 exposure estimate may be used in the ES. Otherwise, higher TIER model or actual monitoring data for environmental releases and worker exposure is required. The TIER 1 modelling approach was seen as appropriate for the three example substances and the data (including RCR) for each ERC and PROC are provided at the end of each ES.

Selection of use descriptors is required to roughly characterise how the substance is used and to determine exposure of the environment and worker. Assigning the PROCs and ERCs proved to be a challenge because no single descriptor appeared to fit well without adding qualifiers. The following PROCs and ERCs were chosen from the descriptor pick-list contained in Appendix R.12.1 to R.12.6 of the ECHA Guidance on Use Descriptor System (R12). Please note that since none of these pick-list categories was 100 percent applicable, the project team described the process and assigned the best fitting PROC/ERC. Also note that other descriptors could apply to different applications within SC manufacturing.

- PROC 1 was used to describe the use of reactive processing aids within rigorously contained equipment and delivery systems.
- PROC 8b was used to describe manual dispensing of the chemical into process equipment, typical maintenance activities, cleaning of equipment, and sampling.
- PROC 13 was used to describe dipping of wafers into open baths.
- ERC 6b was used to describe the enclosed use of reactive processing aids.
- ERC 4 was used to describe general use of processing aids.

## 1.3 Selection of examples

The project team selected three substances that represent generic classes of chemicals used in semiconductor manufacturing as well as typical OC and RMM. Derivation of PNEC and DNEL has been performed based on available information on toxic and ecotoxic effects of the substances. For local effects a qualitative assessment has been performed. In all cases, the most conservative approach has been taken in calculating DNELs and PNECs. DNELs and PNECs have been used to calculate the RCR in order to demonstrate safe use of the substance.

An exposure estimation and risk characterisation table has been attached to each exposure scenario document in order to provide scientific background of the assumptions. The summary table is not in the format required for the CSR and it has to be interpreted only as supporting information, not as a reference document.

**Please note**: All information reported in this document, including the calculated DNELs and PNECs, are functional only within the scope of the project (exemplification of exposure scenario), and do not expose ECHA or other project participants to any legal obligation.

## 1.4 Project Outcome

Exposure scenarios form the foundation of chemical safety assessments and CSR under REACH. Based on the risk characterisation for human health and environment in the three completed exposure scenarios, the risks are controlled adequately for the three example substances. The results of the project are available in the standard format of a final exposure scenario for chemical safety report as described in the ECHA's Guidance on information requirements and chemical safety assessment, part D: exposure scenario building[5]. The three exposure scenarios finalised in this joint project, are a first practical example published

[5] http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_ESformat_en.pdf?vers=27-05-10

by ECHA on how exposure scenarios for hazardous substances under REACH could look like[6]. Other examples may follow. The joint project team evaluated the applicability of the strictly controlled conditions[7] (SCC) concept to the semiconductor manufacturing process, and came to the conclusion that SCCs are, in some cases, applicable to workers protection (PROC 1 activities) but not to the environment in the three examples evaluated.

## General considerations

The initial ECHA guidance questionnaire to gather industry and process information was drafted based on the model of the questionnaire used for the update of the Guidance on intermediates. It proved to be very informative but more extensive than required to assess risk and complete the final ES. The exercise brought all participants up to a common understanding of the potential information requirements of an ES and the semiconductor industry processes.

Although the semiconductor industry's production processes, manufacturing tool sets, and environmental health and safety (EHS) standards are uniform to a great degree, some differences exist and agreeing on a single data set to represent all semiconductor manufacturing operations was difficult. For example, the majority of sites discharge to a municipal sewage treatment plant (STP); however, a few sites directly discharge after on-site wastewater treatment. In order to reflect the worst-case realistic scenario, the STP was not considered in calculations of exposure estimations. Additionally, some sites used enclosed, fully automated process equipment with robotics to handle the wafers and chemicals, while other sites use manual operations with administrative controls.

[6] Please note: The operational conditions and risk management measures are not yet presented in standardised and harmonised phrasing, since the standardisation of risk management phrases at EU level is still at a relatively early stage of development.

[7] Please note that the term 'Strictly Controlled Conditions' is not used here in relation to intermediates

# 2 ISSUES AND LESSONS LEARNED

## 2.1 Issue 1: Site specific conditions and general conditions of use

Environmental mass balance data required for calculating releases to air, water and waste on a substance and SC process basis are difficult to obtain; moreover, it is difficult to determine a single set of conditions that are reflective of every semiconductor facility.

Duration and frequency of activities are different across the industry sector; therefore, it is difficult to establish a single set of conditions reflective of every semiconductor facility.

Agreement on a single realistic data set across the industry was a big challenge because manufacturing sites vary in age, loading, process technology and operational conditions.

### Lesson Learned

The description of generic and representative conditions of use vs. site-specific conditions is one of the major challenges that registrants have to face when preparing the CSR dossiers under REACH.

The analysis of specific cases of use for substances in the SC industry led to the conclusion that one of several approaches could be followed (e.g. worst case, average or default assumptions). The industry and suppliers decided that, because conditions varied from site to site, the representation of general conditions would be based on the least controlled condition or worst case.

## 2.2 Issue 2: Exposure estimation

The TIER 1 tool used for predicting worker exposure – ECETOC TRA – does not model 'clean room' conditions (controlled environment, high air exchange rates, etc.) and therefore overestimates exposure, resulting in higher RCR.

The selection of appropriate PROCs for specific processes proved to be difficult. This was especially difficult for non-manufacturing activities such as maintenance operations. This problem can result in the TIER 1 tool over-estimating risk and not modelling true to the operational conditions.

While a significant amount of monitoring data was available from some sites, it was not representative for all semiconductor operations due to differences in processes and risk management measures.

### Lesson Learned

Computer based TIER 1 exposure tools were used. For these examples, the TIER 1 exposure estimation compared with DNELs and PNECs showed control of risks. Thus no further refinement was needed. The TIER 1 tools are very conservative and, for other processes and substances used in semiconductor manufacturing, may not demonstrate safe use. In those instances, the use of monitoring data may be necessary.

## 2.3 Issue 3: Risk management measures

The semiconductor industry applies certain standard RMM which do not target a specific substance but a group of substances with similar hazard characteristics. For example, most major production sites are equipped with air abatement systems (water scrubbers and

thermal oxidisers) that are designed to reduce air emissions for a variety of substances. It was a challenge to specify a generic removal efficiency for a specific substance.

In most cases, permit limits vary, based on local operations and permit requirements

### Lesson Learned

When TIER 1 modelling tools are used for exposure estimation, a default value is used for the expected effectiveness of RMM[8]. If default estimations are not adequate to guarantee control of risk, then the use of higher TIER models or measured data is recommended.

## 2.4 Issue 4: RMM and risk characterisation

In some cases (e.g., substance in Example 1) it was also discovered that, where standard air abatement were applied, these RMM could generate a secondary impact on the water compartment by transferring the substance and reactive by-products from air to water. The impact to water was estimated to be higher than the impact of the substance directly released to air without any RMM; however, safe use was still demonstrated (in part due to a very low volume of the substance used).

### Lessons Learned

It is not uncommon that the application of a standard RMM for air emission could generate a risk to the water compartment.

[8] Please note: For the environmental TIER 1 exposure estimate based on EUSES it is always assumed that no risk management measures are applied (and thus the effectiveness of RMM is zero).

# 3 EXAMPLES

## 3.1 Example 1 (substance A)

Example 1 is representative of a substance in liquid form that is classified harmful (Xn) - risk phrases: R10 (Flammable), R20 (Harmful by inhalation), R36 (Irritating to eyes), R37 (Irritating to respiratory system). The substance does not meet the criteria for being classified as hazardous for the environment. It hydrolyses quickly (4.4 h half-life at pH 7) and is readily biodegradable.

The substance is used in a vapour form. It reacts on use and it is applied in enclosed system. The un-reacted portion of the substance (<10% worst case assumption) is initially discharged to air abatement system (water scrubber at pH 4, hydrolysis half-life – 0.1 hour)) where it is quickly and almost completely hydrolysed. It has been estimated that <1% of the initial amount of the substance is discharged from the scrubber to the receiving water body. No relevant waste stream to treat.

### 3.1.1 Exposure Scenario

| **9.1 "Industrial use of reactive processing aids in production of semiconductor devices"** | |
|---|---|
| List of all use descriptors from the stage and all uses under it (from life cycle tree) | *ERC6b, SU16; PROC1* |
| **Contributing environmental scenario:** reaction (gaseous) on use in batch process for production of semiconductor devices (industrial) | *ERC 6b* |
| **Contributing worker scenario::** reaction (gaseous) on use in rigorously contained batch process | *PROC1* |

| **9.1.1 Exposure Scenario** |
|---|
| ***Explanation on technical processes and activities covered:*** |
| *production of semiconductor devices in batch process with low pressure chemical vapour deposition (LPCVD) and plasma enhanced (PECVD) in dedicated equipment to deposit thin films of silicon dioxide onto the surface of silicon wafers (including substance supply system feeding the reaction chamber). "Clean room environment" conditions apply.* |
| **9.1.1.1 Control of environmental exposure : Reaction (gaseous) on use in batch process for production of semiconductor devices (industrial) - ERC6b** |
| ***Further specifications:*** |
| **Product characteristics** |
| *Physical state of the substance (at 25˚C and atmospheric pressure): liquid*<br>*Physical state of the substance when used: vapour with inert carrier gas (fed into chamber at negative pressure)*<br>*Closed loop supply system, rigorously contained coupling to production equipment* |
| **Amounts used** |
| *0.03 kg/day – 10 ton/year per site* |
| **Frequency and duration of use / exposure** |
| *Continuous* |

| |
|---|
| **Environment factors not influenced by risk management** |
| *Receiving river flow rate ≥18000 $m^3$/day, (default assumption)* |
| **Other given operational conditions affecting environmental exposure** |
| *>90% of substance A reacts on use: <10% initially sent to air abatement system (scrubber)*<br>*Effluent flow rate: 2000 $m^3$/day (default assumption)* |
| **Technical conditions and measures at process level (source) to prevent release** |
| |
| **Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil** |
| *Substance A hydrolyses in the scrubber[9] (efficiency 90%) and <1% of substance A is released to waste water Products of hydrolysis are substances D and E, not meeting the criteria to be classified as hazardous for human health and the environment* |
| **Organisational measures to prevent/limit release from site** |
| *A combination of organisational and technical measures (spill containment and leak detection) should be used to prevent and detect unexpected releases* |
| **Conditions and measures related to municipal sewage treatment plant** |
| *N/A* |
| **Conditions and measures related to external treatment of waste for disposal** |
| *Not addressed* |
| **Conditions and measures related to external recovery of waste** |
| *Not addressed* |
| **Additional good practice advice beyond the REACH CSA**<br>**Note: The measures reported in this section have not been taken into account in the exposure estimates related to the exposure scenario above. They are not subject to obligation laid down in Article 37 (4) of REACH** |
| *Biological water treatment plant should be considered as good practice for waste water treatment when no municipal STP is available. Water scrubber is suggested to reduce emission of substance A in air* |

[9] If a scrubber is applied as an industry default RMM, then impact on water compartment has to be evaluated.

| 9.1.1.2. Control of workers exposure: reaction (gaseous) on use in rigorously contained batch process - PROC1 |
|---|
| ***Further specification:***<br>▪ *loading and unloading of wafers to/ from production equipment*<br>▪ *maintenance*<br>▪ *connecting and disconnecting of containers to/from delivery system* |
| **Product characteristic** |
| *See above* |
| **Amounts used** |
| *Not relevant* |
| **Frequency and duration of use/exposure** |
| *>4 hr/day* |
| **Human factors not influenced by risk management** |
| *Default ECETOC modelling values were used in calculation of workers exposures* |
| **Other given operational conditions affecting workers exposure** |
| *N/A* |
| **Technical conditions and measures at process level (source) to prevent release** |
| *Rigorously contained production process*<br>▪ *Processes take place in enclosed process chambers under vacuum conditions*<br>▪ *Process chambers are to be automatically purged with an inert gas (Nitrogen or Helium), until all traces of substance A are removed before they are opened for process or maintenance purpose*<br>*Rigorously contained supply containers changeover*<br>▪ *Substance A delivery system and pipe system must be purged with inert gases, e.g. Nitrogen or Helium, before containers are changed* |
| **Technical conditions and measures to control dispersion from source towards the worker** |
| |
| **Organisational measures to prevent /limit releases, dispersion and exposure** |
| *Containers and valves must be visually checked before they are connected to line of the Substance A delivery system*<br>*Substance A containers and bubblers must be provided with delivery valves that must be kept closed when they are being connected or disconnected to the delivery system* |
| **Conditions and measures related to personal protection, hygiene and health evaluation** |
| |
| **Additional good practice advice beyond the REACH CSA**<br>**Note: The measures reported in this section have not been taken into account in the exposure estimates related to the exposure scenario above. They are not subject to obligation laid down in Article 37 (4) of REACH** |
| *Leak sensors and automatic shut-off valves can be installed to protect workers against accidental, uncontrolled leak/release of the substance*<br>*Workers training should include information about the risks related to chemical substance/s they may be exposed to and safe operation procedures*<br>*While skin and inhalation exposure are not expected, safety glasses, viton, rubber or other suitable gloves, and half-face respirator with multipurpose or type A cartridge (or other suitable respiratory protection) with 90% efficiency can be used during container change-out and equipment maintenance* |

## 3.1.2 Substance information -substance A- reactive processing aid

| | | |
|---|---|---|
| **General properties** | | |
| 1 | IUPAC name | |
| 2 | Chemical Abstract Number | |
| 3 | Chemical formula | |
| 4 | Molecular weight | |
| 5 | Physical state (solid, liquid, gas) at 20ºC and 101.3 Pa | Liquid |
| 6 | Melting/freezing point | ~ -80ºC |
| 7 | Boiling point | 163-168ºC |
| 8 | Vapor pressure (20ºC) | 2.5 hPa |
| 9 | Water solubility | 1490 mg/l |
| 10 | Octanol Water partitioning coefficient (log Kow) | 0.04@ 40ºC |
| 11 | Information on stability (biological degradation, hydrolysis, photo-degradation, atmospheric degradation (half-life in water, soil, air) | Hydrolysis half life:<br>0.1 h @ pH 4; 4.4 h @ pH 7;<br>0.2 h @ pH 9 |
| **Classification and labelling** | | |
| 12 | substance classified as CMR PBT/vPvB | NO |
| 13 | Substance classification (R phrases) | R10 (Flammable)<br>R20 (Harmful by inhalation)<br>R36 (Irritating to eyes)<br>R37 (Irritating to respiratory system) |
| **Toxicological information** | | |
| 14 | DNEL Long-term inhalation systemic | 2.47 mg/m$^3$ |
| 15 | DNEL Long-term dermal systemic | 11.3 mg/kg bw/d |
| 16 | DNEL oral exposure, consumer | 10 mg/kg/day |
| 17 | DNEL Man via environment | 1.24 mg/m$^3$ |
| **Ecotoxicological information** | | |
| 18 | Acute aquatic toxicity fish (LC50) | >245 mg/l |
| 19 | Acute aquatic toxicity Daphnia (EC50) | >75 mg/l |
| 20 | Acute aquatic toxicity Algae (IC50) | >22 mg/l |
| 21 | Fate and behaviour in the environment | readily biodegradable; not bio-accumulative |
| 22 | Degradation (abiotic) | rapid hydrolysis |
| 23 | PNEC freshwater | 0.02 mg/l |
| 24 | PNEC freshwater sediment | 0.1 mg/kg dw |
| 25 | PNEC marine water | 0.002 mg/l |
| 26 | PNEC marine water sediment | 0.01 mg/kg dw |
| 27 | PNEC agricultural soil | 0.01 mg/kg dw |

## 3.1.3 Environmental exposure estimation and risk characterization

### 3.1.3.1 Contributing scenario: reaction on use in batch process (ERC6b)

Main assumptions made in the exposure scenario driving the exposure estimation:

- amount used at the site: 0.03 ton/day (10 ton/year)
- no municipal STP available
- effluent flow rate (2.000 $m^3$/day) and river flow rate (18.000 $m^3$/day) - default assumptions
- 90% of substance A reacts on use

Two worst case discharge conditions have been investigated:
Case A) 10% of substance A is directly discharged into air - No RMM
Case B) 10% of substance A is initially discharged into air scrubber with all substance transferred into the aqueous phase and partially hydrolyzed (90% of effectiveness) inside the scrubber before being discharged into surface water. The exposure scenario is based on case B.

**Environmental assessment - Case A**

| Endpoint | Exposure concentration | PNEC* | Risk Characterisation Ratio |
|---|---|---|---|
| PEC_fw | 6.22E-08 mg/l | 0.02 mg/l | 3.11E-06 |
| PEC_fw sed | 2.92E-07 mg/kg dw | 0.1 mg/kg dw | 2.92E-06 |
| PEC_mw | 1.53E-08 mg/l | 0.002 mg/l | 7.65E-06 |
| PEC_mw sed | 7.19E-08 mg/kg dw | 0.01 mg/kg dw | 7.19E-06 |
| PEC_fw predator | not required | not bio-accumulative | not required |
| PEC_mw predator | not required | not bio-accumulative | not required |
| PEC_mw top pre. | not required | not bio-accumulative | not required |
| PEC_terrestrial pre. | not required | not bio-accumulative | not required |
| PEC soil | 7.23E-05 mg/kg dw | 0.01 mg/kg dw | 0.007 |

** PNEC fresh and marine water have been calculated on the basis of ecotoxicological information provided by industry. Conservative assessment factors were used. PNEC soil and sediments were calculated from equilibrium partitioning equation.*

**Men via environment – Case A**

| Endpoint | Exposure concentration | DNEL** | Risk Characterisation Ratio |
|---|---|---|---|
| Total daily dose | 8.79E-06 mg/kg/d | 10 mg/kg/d | 8.79E-07 |
| PEC air | 7.62E-04 mg/$m^3$ | 1.24 mg/$m^3$ | 6.14E-04 |

*** DNEL has been calculated on the basis of toxicological information provided. Conservative assessment factors were used.*

### Environmental assessment - Case B

| Endpoint | Exposure concentration | PNEC* | Risk Characterisation Ratio |
|---|---|---|---|
| PEC_fw | 0.015 mg/l | 0.02 mg/l | 0.75 |
| PEC_fw sed | 0.07 mg/kg dw | 0.1 mg/kg dw | 0.705 |
| PEC_mw | 0.0015 mg/l | 0.002 mg/l | 0.75 |
| PEC_mw sed | 0.007 mg/kg dw | 0.01 mg/kg dw | 0.705 |
| PEC_fw predator | not required | not bio-accumulative | not required |
| PEC_mw predator | not required | not bio-accumulative | not required |
| PEC_mw top predator | not required | not bio-accumulative | not required |
| PEC_terrestrial predator | not required | not bio-accumulative | not required |
| PEC soil | 6.97E-10 mg/kg dw | 0.01 mg/kg dw | 6.97E-08 |

** PNEC fresh and marine water have been calculated on the basis of ecotoxicological information provided by industry. Conservative assessment factors were used. PNEC soil and sediments were calculated from equilibrium partitioning equation.*

### Men via environment – Case B

| Endpoint | Exposure concentration | DNEL** | Risk Characterisation Ratio |
|---|---|---|---|
| Total daily dose | 4.23E-04 mg/kg/d | 10 mg/kg/d | 4.23E-05 |
| PEC air | 1.19E-08 $mg/m^3$ | 1.24 $mg/m^3$ | 9.59E-09 |

*** DNEL has been calculated on the basis of toxicological information provided. Conservative assessment factors were used*

## 3.1.4 Workers exposure estimation and risk characterization

### 3.1.4.1 Contributing scenario: reaction on use in rigorously contained batch process (PROC1)

Main assumptions made in the exposure scenario driving the exposure estimation

- rigorous containment
- frequency and duration of use/exposure >4h/d
- no PPE required to control risk; availability of suitable PPE is recommended as good practice
- LEV not required to control risk

| Mode and route of exposure | Exposure concentration | DNEL* | Risk Characterisation Ratio |
|---|---|---|---|
| Long-term inhalation systemic | 0.087 mg/m$^3$ | 2.47 mg/m$^3$ | 0.035 |
| Long term dermal systemic | 0.343 mg/kg bw/d | 11.3 mg/kg bw/d | 0.031 |
| Long-term inhalation local | not available** | not derived** | qualitative assessment |
| Long-term dermal local | not available*** | not derived*** | qualitative assessment |
| Acute inhalation local | not available** | not derived** | qualitative assessment |
| Acute inhalation systemic | not available** | not derived** | qualitative assessment |
| Acute dermal local | not available** | not derived** | qualitative assessment |
| Acute dermal systemic | not required**** | not required**** | not required |
| Oral exposure, consumer | use not assessed | 10 mg/kg/day | not assessed |

** DNEL has been calculated on the basis of toxicological information provided. Conservative assessment factors were used*
*** No data available. Qualitative assessment performed based on OC and RMM*
**** No data available. Qualitative assessment performed based on OC and RMM (for risk to eyes)*
***** The substance does not meet the criteria to be classified for dermal systemic effects*

**Qualitative assessment**[10]

Risk of adverse effects due to long term local inhalation and dermal exposure, acute local exposure to skin, eyes and respiratory tract and systemic effects due to acute inhalation exposure is controlled by rigorous containment as described in contributing scenario 1.

[10] This qualitative assessment has not been fully conducted during the project. The statement is to be understood as an example of information that could be part of a qualitative risk characterisation.

## 3.2 Example 2 (substance B)

Example 2 is representative of an inorganic acid used in liquid form. The substance is classified corrosive (C) with risk phrase: R34 (Causes burns). The substance does not meet the criteria for being classified as hazardous for the environment. This substance is used in enclosed (no likelihood of exposure for workers) and partially open equipment (some potential for exposure). The substance is a processing aid and does not react on use. Used acid is discharged to waste water neutralisation system where 95% of it is neutralised (worst case assumption) before being discharged to receiving water body. A small fraction of the substance (less than 0.1%) is discharged to air.

### 3.2.1 Exposure Scenario

| **9.1 "Surface treatment with inorganic acids in production of semiconductor devices"** | |
|---|---|
| List of all use descriptors from the stage and all uses under it (from life cycle tree) | *ERC 4, SU16, PROC 1, PROC 8b, PROC 13* |
| **Contributing environmental scenario:** surface treatment of wafers with water borne acids in production of semiconductor devices | *ERC 4* |
| **Contributing worker scenario 1:** use in rigorously contained processes (automatic equipment) | *PROC 1* |
| **Contributing worker scenario 2:** transfer of acid from bottles to process tanks, cleaning of equipment, maintenance and sampling | *PROC 8b* |
| **Contributing worker scenario 3**: treatment of wafers by dipping in acid bath | *PROC 13* |

| 9.1.1 Exposure Scenario |
|---|
| ***Explanation on technical processes and activities covered:***<br>*production of semiconductor devices in batch processes in dedicated equipment (wet benches, spin etchers) by dipping and pouring. Equipment could be operated:*<br>• *automatically (rigorously contained process) or*<br>• *manually (partially open process).*<br>*"Clean room environment" conditions apply.* |
| **9.1.1.1 Control of environmental exposure : Industrial surface treatment of silicon wafers - ERC 4** |
| **Further specifications:** |
| **Product characteristics** |
| *Physical state of the substance when purchased and used (at 25˚C and atmospheric pressure): liquid*<br>*Concentration 85% w/w* |
| **Amounts used** |
| *0.1 ton/day – 30 ton/year per site* |
| **Frequency and duration of use** |
| *Continuous process* |
| **Environment factors not influenced by risk management** |
| *Receiving river flow rate ≥18000 $m^3$/day, (default assumption)* |
| **Other given operational conditions affecting environmental exposure** |
| *Evaporation loss <0.1% of acid used*<br>*99.9% of acid is discharged to waste water*<br>*Effluent flow rate: 2000 $m^3$/day (default assumption)* |
| **Technical conditions and measures at process level (source) to prevent release** |
| *N/A* |
| **Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil** |
| *Water**:** waste water neutralisation system (effectiveness >95%) must be installed before discharging to river*<br>*Waste: sludge from water treatment to be collected onsite as waste* |
| **Organisational measures to prevent/limit release from site** |
| *A combination of organisational and technical measures (spill containment and leak detection)should be used to prevent and detect unexpected releases* |
| **Conditions and measures related to municipal sewage treatment plant** |
| *N/A* |
| **Conditions and measures related to external treatment of waste for disposal** |
| *Closed loop supply system used for large containers (>200l)*<br>*Not further adressed* |
| **Conditions and measures related to external recovery of waste** |
| *Not addressed* |

| |
|---|
| **Additional good practice advice beyond the REACH CSA**<br>**Note: The measures reported in this section have not been taken into account in the exposure estimates related to the exposure scenario above. They are not subject to obligation laid down in Article 37 (4) of REACH** |
| |

| |
|---|
| **9.1.1.2. Control of workers exposure: contributing scenario 1**<br>**use in rigorously contained processes - PROC 1** |
| ***Further specifications:***<br>*loading/unloading of wafers to/from automatic equipment* |
| **Product characteristic** |
| *See above* |
| **Amounts used** |
| *Not relevant* |
| **Frequency and duration of use/exposure** |
| *>4 hr/day (default assumption)* |
| **Human factors not influenced by risk management** |
| *Default ECETOC modelling values were used in calculation of workers exposures* |
| **Other given operational conditions affecting workers exposure** |
| *None* |
| **Technical conditions and measures at process level (source) to prevent release** |
| *Rigorously contained production process:*<br>▪ *processes take place in enclosed, automated process equipment,*<br>▪ *rinsing and drying steps are to be automatically performed to guarantee that no residue of the inorganic acid is present on the wafer when they are downloaded from the equipment* |
| **Technical conditions and measures to control dispersion from source towards the worker** |
| |
| **Organisational measures to prevent /limit releases, dispersion and exposure** |
| |
| **Conditions and measures related to personal protection, hygiene and health evaluation** |
| *Not relevant. No skin or inhalation exposure during normal operation* |
| **Additional good practice advice beyond the REACH CSA**<br>**Note: The measures reported in this section have not been taken into account in the exposure estimates related to the exposure scenario above. They are not subject to obligation laid down in Article 37 (4) of REACH** |
| *Leak sensors and automatic shut-off valves can be installed to protect workers against accidental, uncontrolled leak/release of the substance*<br>*Workers training should include information about the risks related to chemical substance/s they may be exposed to and safe operation procedures*<br>*While skin and inhalation exposure are not expected, safety glasses, acid-resistant gloves, and half-face respirator fitted with multipurpose or other cartridge suitable for acid vapours (or other suitable respiratory protection) with 90% efficiency can be used* |

| **9.1.1.3. Control of workers exposure: contributing scenario 2**<br>**manual transfer of bottled acid to process tanks, maintenance, containers handling/connection and sampling - PROC 8b** |
|---|
| ***Further specifications:***<br>▪ *filling of process tanks - transfer of acid from plastic bottle/s to process tanks*<br>▪ *maintenance of equipment*<br>▪ *sampling*<br>▪ *connecting and disconnecting of containers to/from delivery system* |
| **Product characteristic** |
| *See above* |
| **Amounts used** |
| *Not relevant* |
| **Frequency and duration of use/exposure** |
| *>4 hr/day (default assumption)* |
| **Human factors not influenced by risk management** |
| *Default ECETOC modelling values were used in calculation of workers exposures* |
| **Other given operational conditions affecting workers exposure** |
| *Indoor use* |
| **Technical conditions and measures at process level (source) to prevent release** |
| |
| **Technical conditions and measures to control dispersion from source towards the worker** |
| *Equipment must be provided with LEV (Effectiveness of 97% - Default ECETOC modelling value)*<br>*Acid baths should be covered when not in direct use* |
| **Organisational measures to prevent /limit releases, dispersion and exposure** |
| *Operators should be fully trained*<br>*Containers are to be checked for integrity and cleanliness upon arrival at the site*<br>*Regular check and maintenance of delivery lines must be performed* |
| **Conditions and measures related to personal protection, hygiene and health evaluation** |
| *Acid resistant gloves, face shield, chemical resistant aprons/suits and foot protection* [11]*.* |
| **Additional good practice advice beyond the REACH CSA**<br>**Note: The measures reported in this section have not been taken into account in the exposure estimates related to the exposure scenario above. They are not subject to obligation laid down in Article 37 (4) of REACH** |
| *Leak sensors and spill containment structures can be installed to protect workers against accidental, uncontrolled leak/release of acid*<br>*Workers training should include information about the risks related to chemical substance/s they may be exposed to and safe operation procedures*<br>*Half-face respirator fitted with multipurpose or other cartridge suitable for acid vapours (or other suitable respiratory protection with efficiency of 90% or more) can be used* |

[11] Use of skin protection is required as a result of the qualitative assessment – due to corrosive properties of the substance. Note that this recommendation is not a result of the assessment with the TIER 1 tool.

| **9.1.1.4. Control of workers exposure: contributing scenario 3<br>treatment of wafers by dipping in acid bath - PROC 13** |
|---|
| ***Further specifications:***<br>*dipping of silicon wafer into acid bath* |
| **Product characteristic** |
| *See above* |
| **Amounts used** |
| *Not relevant* |
| **Frequency and duration of use/exposure** |
| *>15 to 60 min/day* |
| **Human factors not influenced by risk management** |
| *None* |
| **Other given operational conditions affecting workers exposure** |
| *Default ECETOC modelling values were used in calculation of workers exposures* |
| **Technical conditions and measures at process level (source) to prevent release** |
| *Indoor use* |
| **Technical conditions and measures to control dispersion from source towards the worker** |
| *Workers exposure has been evaluated under the assumption that LEV is installed and operational with 90% effectiveness (default ECETOC modelling value)*<br>*Special handling tools should be used to prevent direct skin contact with the acid and minimise respiratory exposure* |
| **Organisational measures to prevent /limit releases, dispersion and exposure** |
| *Operators must be fully trained. All equipment, including LEV and PPE used, must be well-maintained* |
| **Conditions and measures related to personal protection, hygiene and health evaluation** |
| *Acid resistant gloves, face shield, chemical resistant aprons/suits and foot protection*[12] |
| **Additional good practice advice beyond the REACH CSA**<br>**Note: The measures reported in this section have not been taken into account in the exposure estimates related to the exposure scenario above. They are not subject to obligation laid down in Article 37 (4) of REACH** |
| *Leak sensors and spill containment structures should be installed to protect workers against accidental, uncontrolled leak/release of acid*<br>*Workers training should include information about the risks related to chemical substance/s they may be exposed to and safe operation procedures*<br>*Half-face respirator fitted with multipurpose or other cartridge suitable for acid vapours (or other suitable respiratory protection with efficiency of 90% or more) can be used* |

[12] Use of skin protection is required as a result of the qualitative assessment – due to corrosive properties of the substance. Note that this recommendation is not a result of the assessment with the TIER 1 tool.

## 3.2.2 Substance information - substance B- inorganic acid

| | | |
|---|---|---|
| | **General properties** | |
| 1 | IUPAC name | |
| 2 | Chemical Abstract Number | |
| 3 | Chemical formula | |
| 4 | Molecular weight | |
| 5 | Physical state (solid, liquid, gas) at 20ºC and 101.3 Pa | Liquid |
| 6 | Melting/freezing point | - 20 ºC |
| 7 | Boiling point | 158 ºC |
| 8 | Vapor pressure (20ºC) | 2 hPa |
| 9 | Water solubility | 750000 mg/l |
| 10 | Octanol Water partitioning coefficient (log Kow) | -0.77 |
| | **Classification and labelling** | |
| 11 | substance classified as CMR PBT/vPvB | NO |
| 12 | Substance classification (R phrases) | R34 (causes burns) |
| | **Toxicological information** | |
| 13 | DNEL Long-term inhalation local | 1.4 $mg/m^3$ |
| 14 | DNEL Long-term inhalation systemic | 1.8 $mg/m^3$ |
| 15 | DNEL Long-term dermal systemic | 14.0 mg/kg/d |
| 16 | DNEL oral exposure, consumer | 2.55 mg/kg/d |
| 17 | DNEL inhalation exposure, consumer | 0.815 $mg/m^3$ |
| | **Ecotoxicological information** | |
| 18 | Fate and behaviour in the environment | not biodegradable; not bio-accumulative |
| 19 | PNEC freshwater | 0.4 mg/l |
| 20 | PNEC freshwater sediment | 1.6 mg/kg dw |
| 21 | PNEC marine water | 0.04 mg/l |
| 22 | PNEC marine water sediment | 0.16 mg/kg dw |

## 3.2.3 Environmental exposure estimation and risk characterization

### 3.2.3.1 Contributing scenario: industrial use as processing aid (ERC4)

Main assumptions made in the exposure scenario driving the exposure estimation:

- amount used at the site: 0.1 ton/day - 30 ton/year
- no municipal STP available
- effluent flow rate 2.000 m3/day and river flow rate 18.000 m3/day) set equal to default assumptions
- 0.1% of inorganic acid evaporate to air
- Neutralisation treatment of the water phase with minimum effectiveness of 95%

**Environmental assessment**

| Endpoint | Exposure concentration | PNEC* | Risk Characterisation Ratio |
|---|---|---|---|
| PEC_fw | 0.251 mg/l | 0.4 mg/l | 0.628 |
| PEC_fw sed | 1.01 mg/kg dw | 1.6 mg/kg dw | 0.631 |
| PEC_mw | 0.025 mg/l | 0.04 mg/l | 0.628 |
| PEC_mw sed | 0.101 mg/kg dw | 0.16 mg/kg dw | 0.631 |
| PEC_fw predator | not required | not bio-accumulative | not required |
| PEC_mw predator | not required | not bio-accumulative | not required |
| PEC_mw top pre. | not required | not bio-accumulative | not required |
| PEC_terrestrial pre. | not required | not bio-accumulative | not required |
| PEC soil | 1.99E-05 mg/kg dw | no hazard for soil | Qualitative |

** PNEC fresh and marine water have been calculated on the basis of ecotoxicological information provided. Conservative assessment factors were used. PNEC sediment was calculated using equilibrium partitioning equation*

**Men via environment**

| Endpoint | Exposure concentration | DNEL** | Risk Characterisation Ratio |
|---|---|---|---|
| Total daily dose | 0.006 mg/kg/d | 2.55 mg/kg/d | 0.0024 |
| PEC air | 2.3E-05 mg/m$^3$ | 0.815 mg/m$^3$ | 2.82E-05 |

*** DNEL has been calculated on the basis of toxicological information provided. Conservative assessment factors were used.*

## 3.2.4 Workers exposure estimation and risk characterization

### 3.2.4.1 Contributing scenario 1 – use in rigorously contained batch process (PROC 1)

Main assumptions made in the exposure scenario driving the exposure estimation

- rigorous containment
- frequency and duration of use/exposure >4h/day
- no PPE required to control risk; availability of suitable PPE is recommended as good practice
- LEV not required to control risk

| Endpoint | Exposure concentration | DNEL* | Risk Characterisation Ratio |
|---|---|---|---|
| Long-term inhalation systemic effect | 0.041 mg/m$^3$ | 1.8 mg/m$^3$ | 0.023 |
| Long-term inhalation local effect | 0.041 mg/m$^3$ | 1.4 mg/m$^3$ | 0.029 |
| Long-term dermal systemic effect | 0.0343 mg/kg bw /d | 14 mg/kg/d | 0.024 |
| Long-term dermal local | not available** | not derived** | qualitative assessment |
| Acute inhalation local | not required *** | not required *** | not required |
| Acute inhalation systemic | not required **** | not required **** | not required |
| Acute dermal local | not available** | not derived** | qualitative assessment |
| Acute dermal systemic | not required***** | not required***** | not required |

** DNEL has been calculated on the basis of toxicological information provided. Conservative assessment factors were used.*
*** No data available. Qualitative assessment performed, based on OC and RMM*
**** The substance does not meet the criteria to be classified for local respiratory effects*
***** The substance does not meet the criteria to be classified for systemic effects due to respiratory exposure*
****** The substance does not meet the criteria to be classified for systemic effects due to dermal exposure*

**Qualitative assessment**[13]

Risk of adverse effects of acute and long term local exposure to skin and eyes is controlled by rigorous containment as described in contributing scenario 1.

[13] This qualitative assessment has not been fully conducted during the project. The statement is to be understood as an example of information that could be part of a qualitative risk characterisation.

### 3.2.4.2 Contributing scenario 2 – manual transfer of bottled acid to process tanks, maintenance, containers handling/connection and sampling (PROC 8b)

Main assumptions made in the exposure scenario driving the exposure estimation

- frequency and duration of use/exposure: 1-4h/d
- LEV is present, efficiency 97%
- PPE required to control risk related to dermal exposure[14]; availability of suitable respiratory PPE is recommended.

| Endpoint | Exposure concentration | DNEL* | Risk Characterisation Ratio |
|---|---|---|---|
| Long-term inhalation systemic | 0.368mg/m$^3$ | 1.8 mg/m$^3$ | 0.204 |
| Long-term inhalation local effect | 0.368mg/m$^3$ | 1.4 mg/m$^3$ | 0.262 |
| Long-term dermal systemic | 0.686 mg/kg bw/d | 14 mg/kg/d | 0.049 |
| Long-term dermal local | not available** | not derived** | qualitative assessment |
| Acute inhalation local | not required *** | not required *** | not required |
| Acute inhalation systemic | not required **** | not required **** | not required |
| Acute dermal local | not available** | not derived** | qualitative assessment |
| Acute dermal systemic | not required***** | not required***** | not required |

** DNEL has been calculated on the basis of toxicological information provided. Conservative assessment factors were used.*
*** No data available. Qualitative assessment performed, based on OC and RMM*
**** The substance does not meet the criteria to be classified for local respiratory effects*
***** The substance does not meet the criteria to be classified for systemic effects due to respiratory exposure*
****** The substance does not meet the criteria to be classified for systemic effects due to dermal exposure*

**Qualitative assessment[15]**

Risk of adverse effects of acute and long term local exposure to skin and eyes is controlled by operational conditions and risk management measures as described in contributing scenario 2.

[14] Use of skin protection is required as a result of the qualitative assessment – due to corrosive properties of the substance. Note that this recommendation is not a result of the assessment with the TIER 1 tool.

[15] This qualitative assessment has not been fully conducted during the project. The statement is to be understood as an example of information that could be part of a qualitative risk characterisation.

### 3.2.4.3 Contributing scenario 3 – treatment of wafers by dipping in acid bath (PROC 13)

Main assumptions made in the exposure scenario driving the exposure estimation

- frequency and duration of use/exposure: 15-60 min/day
- LEV is present , efficiency 90%
- PPE required to control risk related to dermal exposure[16]; availability of suitable respiratory PPE is recommended.

| Endpoint | Exposure concentration | DNEL** | Risk Characterisation Ratio |
|---|---|---|---|
| Long-term inhalation systemic | 0.817 mg/m3 | 1.8 mg/m3 | 0.454 |
| Long-term inhalation local | 0.817 mg/m3 | 1.4 mg/m3 | 0.583 |
| Long-term dermal systemic | 0.686 mg/kg bw/d | 14 mg/kg/d | 0.049 |
| Long-term dermal local | not available** | not derived** | qualitative assessment |
| Acute inhalation local | not required *** | not required *** | not required |
| Acute inhalation systemic | not required **** | not required **** | not required |
| Acute dermal local | not available** | not derived** | qualitative assessment |
| Acute dermal systemic | not required***** | not required***** | not required |

** DNEL has been calculated on the basis of toxicological information provided. Conservative assessment factors were used.*
*** No data available. Qualitative assessment performed, based on OC and RMM*
**** The substance does not meet the criteria to be classified for local respiratory effects*
***** The substance does not meet the criteria to be classified for systemic effects due to respiratory exposure*
****** The substance does not meet the criteria to be classified for systemic effects due to dermal exposure*

**Qualitative assessment[17]**

Risk of adverse effects of acute and long term local exposure to skin and respiratory tract is controlled by operational conditions and risk management measures as described in contributing scenario 3.

[16] Use of skin protection is required as a result of the qualitative assessment – due to corrosive properties of the substance. This recommendation is not a result of the assessment with the TIER 1 tool.

[17] This qualitative assessment has not been fully conducted during the project. The statement is to be understood as an example of information that could be part of a qualitative risk characterisation.

## 3.3 Example 3 (substance C)

Example 3 is representative of a liquid organic solvent. The solvent is classified Xi (Irritant) with risk phrases R10 (flammable), R41 (risk of serious damage to eyes), R37 (irritating to respiratory system). The substance does not meet the criteria for being classified as hazardous for the environment. It is readily biodegradable, and hydrolises in water. The substance is used in liquid form as such or in mixture with other substances in enclosed (no likelihood of exposure for workers) and partially open equipment (some potential for exposure). It is a solvent and it does not react on use. In semiconductor process, about 90-95% of used solvent is collected for offsite incineration, 5-10 % evaporates and <0.5% is discharged to waste water.

### 3.3.1 Exposure Scenario

| **9.1 "Surface treatment of wafers with organic solvents in production of semiconductor devices"** | |
|---|---|
| List of all use descriptors from the stage and all uses under it (from life cycle tree) | *ERC 4, SU16; PROC 1; PROC 8b* |
| **Contributing environmental scenario :** Industrial use as processing aid for surface treatment of wafer in production of semiconductor devices | *ERC 4* |
| **Contributing worker scenario 1:** Use in rigorously contained processes – automatic equipment | *PROC 1* |
| **Contributing worker scenario 2:** Loading/unloading of wafers to/from partially closed equipment and cleaning of equipment, maintenance and sampling | *PROC 8b,* |

| 9.1.1 Exposure Scenario |
|---|
| ***Explanation on technical processes and activities covered:***<br>*production of semiconductor devices in batch processes in dedicated equipment (litho track tools) in a photolithography process.*<br>*The substance is used as processing aid in pure form or in mixture with other substances (photoresist, BARC and TARC).*<br>*Equipments are operated automatically and they can be totally or partially enclosed. .*<br>*"Clean room environment" conditions apply.* |
| **9.1.1.1 Control of environmental exposure : Industrial use as processing aid for surface treatment of wafers in production of semiconductor devices** |
| **Further specifications:** |
| **Product characteristics** |
| *Physical state of the substance when purchased and used (at 25°C and atmospheric pressure): liquid*<br>*Packaging for transportation:*<br>▪ *small containers (glass or plastic bottles 2.5 – 10 l)*<br>▪ *big containers (200 to 1000 litres)* |
| **Amounts used** |
| *1.1 ton/day - 400 ton/year per site* |
| **Frequency and duration of use** |
| *Continuous process***.** |
| **Environment factors not influenced by risk management** |
| *Receiving river flow rate 18000 $m^3$day (default assumption)* |
| **Other given operational conditions affecting environmental exposure** |
| *Discharge to air: 8-9%*<br>*Discharged to water <0.5%*<br>*Effluent flow rate: 2000 $m^3$/day (default assumption)* |
| **Technical conditions and measures at process level (source) to prevent release** |
| *N/A* |
| **Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil** |
| *Waste: Liquid waste must be collected on site* |
| **Organisational measures to prevent/limit release from site** |
| *A combination of organisational and technical measures (spill containment and leak detection) should be used to prevent and detect unexpected releases* |
| **Conditions and measures related to municipal sewage treatment plant** |
| *N/A* |
| **Conditions and measures related to external treatment of waste for disposal** |
| *Closed loop supply system used for large containers (>200 l)*<br>*Not further addressed* |
| **Conditions and measures related to external recovery of waste** |
| *Not addressed* |

| Additional good practice advice beyond the REACH CSA<br>**Note: The measures reported in this section have not been taken into account in the exposure estimates related to the exposure scenario above. They are not subject to obligation laid down in Article 37 (4) of REACH** |
|---|
| |

| 9.1.1.2. Control of workers exposure : Contributing scenario 1: Use in rigorously contained batch processes - PROC 1 |
|---|
| ***Further specifications:***<br>*loading/unloading of wafers to/from automatic equipment.* |
| **Product characteristic** |
| *See above* |
| **Amounts used** |
| *Not relevant* |
| **Frequency and duration of use/exposure** |
| *>4hr/day (default assumption)* |
| **Human factors not influenced by risk management** |
| *Default ECETOC modelling values were used in calculation of workers exposures.* |
| **Other given operational conditions affecting workers exposure** |
| *Indoor operations* |
| **Technical conditions and measures at process level (source) to prevent release** |
| *Rigorously contained production process:*<br>▪ *processes take place in enclosed, fully automated process equipment, ensuring that no residue of the substance is present on the wafers when they are downloaded from the equipment* |
| **Technical conditions and measures to control dispersion from source towards the worker** |
| |
| **Organisational measures to prevent /limit releases, dispersion and exposure** |
| |
| **Conditions and measures related to personal protection, hygiene and health evaluation** |
| *Not relevant. No skin or inhalation exposure during normal operation* |
| **Additional good practice advice beyond the REACH CSA**<br>**Note: The measures reported in this section have not been taken into account in the exposure estimates related to the exposure scenario above. They are not subject to obligation laid down in Article 37 (4) of REACH** |
| *Leak sensors and automatic shut-off valves can be installed to protect workers against accidental, uncontrolled leak/release of the substance*<br>*Workers training should include information about the risks related to chemical substance/s they may be exposed to and safe operation procedures*<br>*While skin and inhalation exposure are not expected, nitrile, natural rubber or nitrile and neoprene blend or other suitable gloves, eye protection and half face respirator with multipurpose cartridge or other cartridge suitable for solvents (or other suitable respiratory protection) with efficiency of 90% or more can be used* |

| 9.1.1.2. Control of workers exposure : contributing scenario 2<br>loading/unloading of wafers to/from partially closed equipment, maintenance, containers handling/connection and sampling - Proc 8b |
|---|
| ***Further specifications:***<br>▪ *operation (loading and unloading of wafers) into partially enclosed equipment.*<br>▪ *maintenance and cleaning of equipment*<br>▪ *handling and connection of containers*<br>▪ *sampling* |
| **Product characteristic** |
| *See above* |
| **Amounts used** |
| *Not relevant* |
| **Frequency and duration of use/exposure** |
| *>4 hr/day* |
| **Human factors not influenced by risk management** |
| *Default ECETOC modelling values were used in calculation of workers exposures.* |
| **Other given operational conditions affecting workers exposure** |
| *Indoor use* |
| **Technical conditions and measures at process level (source) to prevent release** |
| |
| **Technical conditions and measures to control dispersion from source towards the worker** |
| *LEV must be installed, with 97% effectiveness (Default ECETOC modelling value)*<br>*Before maintenance tasks, equipment should be emptied of the substance and rinsed.* |
| **Organisational measures to prevent /limit releases, dispersion and exposure** |
| |
| **Conditions and measures related to personal protection, hygiene and health evaluation** |
| *Safety glasses or face shield*[18] |
| **Additional good practice advice beyond the REACH CSA**<br>**Note: The measures reported in this section have not been taken into account in the exposure estimates related to the exposure scenario above. They are not subject to obligation laid down in Article 37 (4) of REACH** |
| *Leak sensors and spill containment structures can be installed to protect workers against accidental, uncontrolled leak/release of acid*<br>*Workers training should include information about the risks related to chemical substance/s they may be exposed to and safe operation procedures*<br>*Half-face respirator fitted with multipurpose or other cartridge suitable for solvent vapours (or other suitable respiratory protection) with efficiency of 90% or more and nitrile, natural rubber or nitrile and neoprene blend or other suitable gloves can be used* |

[18] Use of eye protection is required as a result of the qualitative assessment – due to properties of the substance (R-41). Note that this recommendation is not a result of the assessment with the TIER 1 tool.

## 3.3.2 Substance information - substance C- organic solvent

| | | |
|---|---|---|
| | **General properties** | |
| 1 | IUPAC name | |
| 2 | Chemical Abstract Number | |
| 3 | Chemical formula | |
| 4 | Molecular weight | |
| 5 | Physical state (solid, liquid, gas) at 20ºC and 101.3 Pa | Liquid |
| 6 | Melting/freezing point | -3 to -26ºC |
| 7 | Boiling point | 153 ºC |
| 8 | Vapor pressure (20ºC) | 220 Pa |
| 9 | Water solubility | Completely soluble (1.00E+06 mg/L @20ºC) |
| 10 | Octanol Water partitioning coefficient (log Kow) | 0.06 |
| | **Classification and labeling** | |
| 11 | substance classified as CMR PBT/vPvB | NO |
| 12 | Substance classification (R phrases) | R10 (Flammable)<br>R37 (Irritating to respiratory system)<br>R41 (Risk of serious damage to eyes) |
| | **Toxicological information** | |
| 13 | DNEL Long-term inhalation local | 4 $mg/m^3$ |
| 14 | DNEL Long-term inhalation systemic | 1 $mg/m^3$ |
| 15 | DNEL Long-term dermal systemic | *27.22 mg/kg bw /d* |
| 16 | DNEL acute inhalation local | 12 $mg/m^3$ |
| 17 | DNEL oral exposure, consumer | 3.33 mg/kg bw /d |
| 18 | DNEL Man via environment | 0.5 $mg/m^3$ |
| | **Ecotoxicological information** | |
| 19 | Fate and behaviour in the environment | Readily biodegradable – Not bioccumulative. |
| 20 | PNEC freshwater | 0.3 mg/l |
| 21 | PNEC freshwater sediment | 1.42 mg/kg dw |
| 22 | PNEC marine water | 0.03 mg/l |
| 23 | PNEC* arine water sediment | 0.142 mg/kg dw |
| 24 | PNEC agricultural soil | 0.16 mg/kg dw |

## 3.3.3 Environmental exposure estimation and risk characterization

### 3.3.3.1 Contributing scenario: Industrial use as processing aid (ERC 4)

Main assumption in the Exposure Scenario driving the exposure estimation
Amount used at the site: 1.1 ton/day (400 ton/year)
No Municipal STP available
Effluent (2.000 m3/day) and river flow rate (18.000 m3/day) set equal to default assumptions
8% of the solvent evaporate and is discharged to air without any treatment
0.5% of solvent is removed from the wafer and sent to surface water without any specific treatment

**Environmental assessment**

| Endpoint | Exposure concentration | PNEC* | Risk Characterisation Ratio |
|---|---|---|---|
| PEC_fw | 0.276 mg/l | 0.3 mg/l | 0.92 |
| PEC_fw sed | 1.3 mg/kg dw | 1.42 mg/kg dw | 0.916 |
| PEC_mw | 0.028 mg/l | 0.03 mg/l | 0.92 |
| PEC_mw sed | 0.13 mg/kg dw | 0.142 mg/kg dw | 0.916 |
| PEC_fw predator | not required | not bio-accumulative | not required |
| PEC_mw predator | not required | not bio-accumulative | not required |
| PEC_mw top pre. | not required | not bio-accumulative | not required |
| PEC_terrestrial pre. | not required | not bio-accumulative | not required |
| PEC soil | 0.005 mg/kg dw | 0.16 mg/kg dw | 0.028 |

** PNEC fresh and marine water have been calculated on the basis of ecotoxicological information provided by industry. Conservative assessment factors were used. PNEC soil and sediments were calculated from equilibrium partitioning equation*

**Men via environment**

| Endpoint | Exposure concentration | DNEL** | Risk Characterisation Ratio |
|---|---|---|---|
| Total daily dose (mg/kg/d) | 0.056 mg/kg/d | 3.33 mg/kg/d | 0.017 |
| PEC air (mg/m3) | 0.024 mg/m3 | 0.5 mg/m3 | 0.049 |

*** DNEL has been calculated on the basis of toxicological information provided by the manufacturer of the substance. Conservative assessment factors were used*

## 3.3.4 Workers exposure estimation and risk characterization

### 3.3.4.1 Contributing scenario 1 – use in rigorously contained batch process (PROC 1)

Main assumptions made in the exposure scenario driving the exposure estimation

- rigorous containment
- frequency and duration of use/exposure >4h/day
- no PPE required to control risk; availability of suitable PPE is recommended as good practice
- LEV not required to control risk

| Route and mode of exposure | Exposure concentration | DNEL** | Risk Characterisation Ratio |
|---|---|---|---|
| Long term inhalation systemic | 0.049 mg/m$^3$ | 1 mg/m$^3$ | 0.049 |
| Long term inhalation local | 0.049 mg/m$^3$ | 4 mg/m$^3$ | 0.012 |
| Long term dermal systemic | 0.343 mg/kg bw/d | 27.22 mg/kg bw/d | 0.012 |
| Long-term dermal local | not available** | not derived** | qualitative assessment |
| Acute inhalation local | not required *** | not required *** | not required |
| Acute inhalation systemic | not required **** | not required **** | not required |
| Acute dermal local | not available** | not derived** | qualitative assessment |
| Acute dermal systemic | not required***** | not required***** | not required |

** DNEL has been calculated on the basis of toxicological information provided. Conservative assessment factors were used.*
*** No data available. Qualitative assessment performed, based on OC and RMM*
**** The substance does not meet the criteria to be classified for local respiratory effects*
***** The substance does not meet the criteria to be classified for systemic effects due to respiratory exposure*
****** The substance does not meet the*

**Qualitative assessment**[19]

Risk of adverse effects of acute and long term local exposure to skin and eyes is controlled by operational conditions and risk management measures as described in contributing scenario 1.

[19] This qualitative assessment has not been fully conducted during the project. The statement is to be understood as an example of information that could be part of a qualitative risk characterisation.

### 3.3.4.2 Contributing scenario 2 – loading/unloading of wafers to/from partially enclosed equipment, maintenance and container handling/changing (PROC 8b)

Main assumptions made in the exposure scenario driving the exposure estimation

- LEV is present with efficiency of 97%
- frequency and duration of use/exposure: >4 h/day
- eyes protection required[20]; availability of suitable skin and respiratory PPE is recommended.

| Route and mode of exposure | Exposure concentration | DNEL** | Risk Characterisation Ratio |
|---|---|---|---|
| Long term inhalation systemic | 0.738 mg/m3 | 1 mg/m3 | 0.738 |
| Long term inhalation local | 0.738 mg/m3 | 4 | 0.184 |
| Long term dermal systemic | 0.686 mg/kg bw/d | 27.22 mg/kg bw/d | 0.025 |
| Long-term dermal local | not available** | not derived** | qualitative assessment |
| Acute inhalation local | not required *** | not required *** | not required |
| Acute inhalation systemic | not required **** | not required **** | not required |
| Acute dermal local | not available** | not derived** | qualitative assessment |
| Acute dermal systemic | not required***** | not required***** | not required |

** DNEL has been calculated on the basis of toxicological information provided. Conservative assessment factors were used.*
*** No data available. Qualitative assessment performed, based on OC and RMM*
**** The substance does not meet the criteria to be classified for local respiratory effects*
***** The substance does not meet the criteria to be classified for systemic effects due to respiratory exposure*
****** The substance does not meet the criteria to be classified for systemic effects due to dermal exposure*

**Qualitative assessment[21]**

Risk of adverse effects of acute and long term local exposure to skin and eyes is controlled by operational conditions and risk management measures as described in contributing scenario 2.

[20] Use of eye protection is required as a result of the qualitative assessment – due to properties of the substance (R-41). Note that this recommendation is not a result of the assessment with the TIER 1 tool.
[21] This qualitative assessment has not been fully conducted during the project. The statement is to be understood as an example of information that could be part of a qualitative risk characterisation.

# Annex I : acronyms

CSR - Chemical Safety Report

DNEL - Derived No Effect Level

EHS - Environmental Health and Safety

ERC - Environmental Release Categories

ECHA - European Chemicals Agency

ESIA - European Semiconductor Industry Association

ES - Exposure Scenario

ISMI - International Sematech Manufacturing Initiative

LEV - Local Exhaust Ventilation

OC – Operational Conditions

PNEC - Predicted No Effects Concentration

PPE - Personal Protective Equipment

PEC - Predicted Environmental Concentration

PROC - Process Category

REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals

RCR - Risk Characterisation Ratio

RMM - Risk Management Measures

SC - Semiconductor

STP - Sewage Treatment Plant

SCC - Strictly Controlled Conditions