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Supplement to the methodology for risk evaluation of biocides

Environmental Emission Scenarios for biocides used as human hygiene biocidal products (Product type 1)

European Commission DG ENV / RIVM

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EUBEES

This report has been developed in the context of the EU project entitled "Gathering, review and development of environmental emission scenarios for biocides" (EUBEES 2).
The contents have been discussed and agreed by the EUBEES 2 working group, consisting of representatives of some Member States, CEFIC and Commission. The Commissions financial support of the project is gratefully acknowledged (Ref. B4-3040/2001/326154/MAR/C3).

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FOREWORD

The European Parliament and the Council adopted in 1998 the Directive 98/8/EC on the placing of biocidal products on the market (Biocidal Products Directive, BPD). The background for the directive is a need for harmonisation of the legislation of the Member States regarding this type of chemicals, which are intended for exerting a controlling effect on higher or lower organisms. The Directive requires an authorisation process for biocidal products containing active substances listed in positive lists (Annex I and IA). Active substances may be added to the positive lists after evaluation of the risks to workers handling biocides, risks to the general public and risks to the environment. The risk assessments are carried out for the life cycle of the biocide: risks during and resulting from the application, risks associated with (the use of) the treated product and risks resulting from the disposal of the biocide and the treated product.

For the environmental risk assessment the environmental exposure needs to be evaluated. Within the risk assessment of industrial chemicals, emission scenario documents have been developed for a number of Industrial Categories (IC) that are included in section IV of the Technical Guidance Document (EC 2003a). For Product type 1 covering human hygiene biocidal products, various applications and processes are expected to be similar to those for the industrial chemicals. These emission scenario documents were checked on their suitability for use in the context of the BPD and some adaptations were recommended.

This report has been developed by Royal Haskoning, The Netherlands, in the context of the EU project entitled "Gathering, review and development of environmental emission scenarios for biocides" (EUBEES 2). The contents have been discussed and agreed by the EUBEES 2 working group, consisting of representatives of some Member States, CEFIC and the Commission. The Commissions financial support of the project is gratefully acknowledged (Ref. B4-3040/2001/326154/MAR/C3).

For quick reference the recommendations are given in Section 4.

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1 INTRODUCTION

1.1 Background

In the Technical Guidance Document on risk assessment (EU-TGD, EC 2003a) emission scenarios are described that can be used to evaluate the environmental emission of chemical substances. In this document the suitability of the emission scenarios for industrial chemicals is checked for use in the evaluation of biocidal products covered by Product type 1 (PT1), Human hygiene biocidal products as distinguished in the Biocidal Products Directive (BPD).

Biocidal products of Product type 1 are biocidal products used for human hygiene purposes with an anti-microbial claim. Many products used for this purpose could also be classified as a cosmetic or a medical product. The discussion of these so-called borderline cases is documented in several Guidance documents agreed between the Commission services and the competent authorities of Member States for the BPD and (1) for the Cosmetic Products Directive 76/768/EEC (draft, EC 2002b) and (2) for the Proprietary Medicinal Products Directive 2001/83/EC and Veterinary Medicinal Products Directive 2001/82/EC (EC 2002a). The discussions are reflected in the Manual of decisions for the implementation of the BPD: for medicinal products (EC 2003b). These document are available on: http://europa.eu.int/comm/environment/biocides/index.htm.

In the EU TGD various documents are available on Industrial Categories (IC) that may include the use of disinfectants: IC-5 – Personal/domestic and IC-6 – Public domain. In addition, also in other projects in EU member states environmental emission scenarios were developed for activities that include the use of biocides that have been taken into consideration in this report.

According to Annex VI of the Biocidal Products Directive the risk assessment shall cover the proposed normal use of the biocidal product together with a ‘realistic worst case scenario’. The focus is on methods to estimate the emission rate of Human hygiene biocidal products to the primary receiving environmental compartments. The calculation of a realistic worst case PEC using environmental interactions, for example subsequent movement of emissions to secondary environmental compartments (e.g. from soil to ground water), is the result of fate and behaviour calculations and models and is therefore considered to be outside the scope of this document.

The report was discussed in the working group for the EU project “Gathering, review and development of environmental emission scenarios for biocides (EUBEES 2)”.

1.2 Available scenario descriptions

The following documents are the main sources of information for the present document:

1) *EU TGD PART IV. IC-5 Personal/domestic and IC-6 Public domain. Assessment of the environmental release of soaps, fabric washing, dish cleaning and surface cleaning substances.*

This document contains a simple scenario for the release of detergents to raw sewage water during the use of these cleaning products.

2) *Baumann et al. 2000, p.6 (Institute for Environmental Research (INFU), University of Dortmund, UBA Berlin: Gathering and review of Environmental Emission Scenarios for biocides (2000))*

This document contains some information about the products in PT1 and the emission routes for biocides used in these products. Furthermore a simple emission scenario for the release of biocides in PT1 is suggested.

3) *Van der Poel and Bakker 2002, RIVM report 601 450 009. Emission Scenario Document for Biocides: Emission Scenarios for all 23 Product types of EU Directive 98/8/EEC.*

Van der Poel and Bakker 2002 provides three scenarios for PT1: two scenarios for private use of products from PT1 and one scenario for industrial use of these products.

1.3 Harmonised presentation

In this report, the emission scenarios are presented in text and Tables. In the Tables, the input and output data and calculations are specified, and units according to (E)USES are used. The input and output data are divided into four groups:

S	data Set	parameter must be present in the input data set for the calculations (no method has been implemented in the system to estimate this parameter; no default value is set, data either to be supplied by the notifier or available in the literature);
D	Default	parameter has a standard value (most defaults can be changed by the user);
O	Output	parameter is the output from another calculation (most output parameters can be overwritten by the user with alternative data);
P	Pick list	parameter values to be chosen from a pick list with values.

2 DESCRIPTON OF PRODUCT TYPE 1

2.1 Description of use area and processes

Biocidal products of Product type 1 are biocidal products used for human hygiene purposes with an anti-microbial claim. They are mainly used in relation to care, examination and treatment of patients in the public health service sector, in private medical and dental clinics, nursing homes, in the food processing industry and other food handling areas. A limited number of products are used in private homes and workplaces with the purpose of avoiding contamination and preventing infections in relation to cuts, abrasions and the like (Lassen et al. 2001).

Biocides in cosmetic products and products specifically intended for medicinal purposes are not covered by the Biocide Directive. First the definition of human hygiene products covered by the directive was, in accordance with the available borderline documents from the Commission, that they were products mainly intended for application on intact skin or for general hygiene purposes, which are not defined as 'medicinal' use. Later on this was replaced by a border based on the purpose and the use of the products. Disinfectants specifically aimed at treating or preventing disease in human beings and animals are regarded as medicinal products (Lassen et al. 2001, EC 2002). Products used for general disinfection for hygiene purposes without therapeutic claim may be considered under PT 1. Examples are hand disinfectants and fresh-up towels with a general disinfecting claim (EC 2002a).

Products for treatment of acne and shampoos to control dandruff are considered to be cosmetic products covered by the Cosmetics Directive (76/768/EEC) or in special cases to be medicinal products and covered by the Medicinal Products Directive, when a therapeutic claim is made. Suntan products containing anti-microbial ingredients, antiperspirants, deodorants, and mouth and denture products are considered to be cosmetic products (Lassen et al. 2001).

The manual of decisions for the implementation of the BPD gives the following examples for PT1 products:

- Hand disinfectants, disinfectant soap, antiseptic soap, antibacterial or antimicrobial soap, antibacterial or antimicrobial cleaning gel, antibacterial or antimicrobial cleaning solution
  (Remark: if used, e.g., to avoid cross contamination in the food industry)
- Fresh-up towels with a general disinfecting claim
- Detergents and cleaning products (auxiliary aids for washing processes like fabric conditioners are included) intended to have a biocidal activity (reliably controlling micro-organisms like fungi and bacteria)
- Disinfectant mouth solution, antiseptic mouth solution (no therapeutic claims)

“Borderline case disclaimer”
The reader should check the original borderline guidance documents in each case if his product falls under the scope of the BPD because in this ESD for PT 1 the scope borderlines are not presented in detail and also because the scope borderline documents may have changed in time. The hierarchy is that the Guidance Documents (on Medicinal Products, EC 2002b, on Cosmetics, in draft) sets the general rules and the Manual of Decisions summarises the discussions on various

issues on a case by case basis. All documents are available on the website: http://europa.eu.int/comm/environment/biocides/index.htm.

Skin disinfectants or antiseptics are used for human hygiene purposes in order to destroy micro-organisms that could cause infections or have a detrimental effect on human activities, for example spoiling or contaminating food or for general hygiene purposes in the health care sector. Skin disinfectants either inhibit the growth (micro-biostatic effect) or kill micro-organisms (microbiocidal effect) on the surface of the skin. These products contain an anti-microbial chemical substance, with a broad spectrum of activity, rapid action and a certain degree of persistence (Lassen et al. 2001; van Dokkum et al., 1998 in Baumann et al., 2000).

The scheme of the life cycle for products belonging to Product type 1 consists of two parts (see figure 2.1) distinguishing between 'leave-on' and 'rinse-of' products.

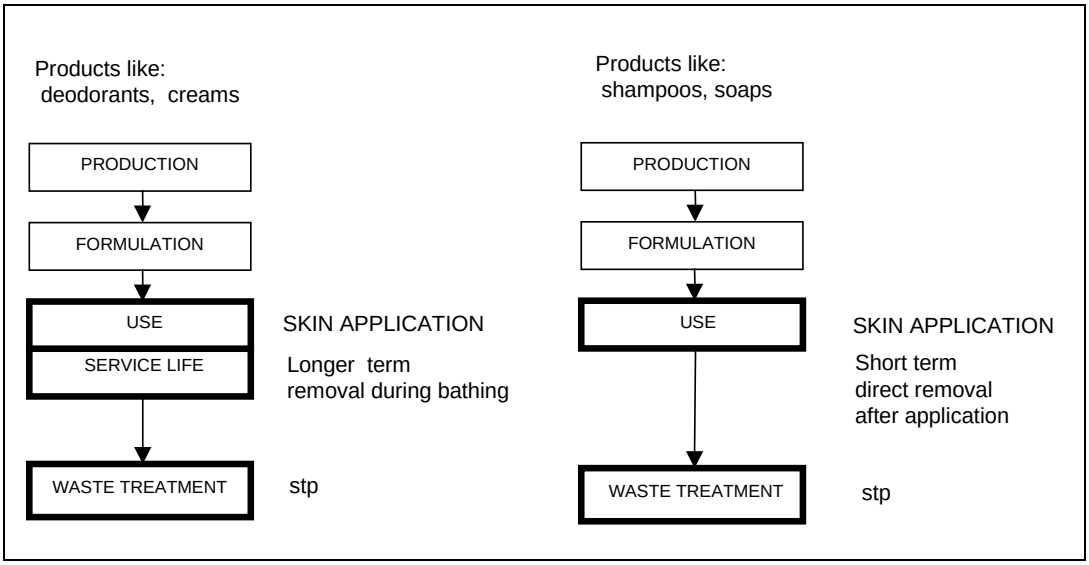

Figure 2.1 Life cycle scheme (after: Van der Poel and Bakker, 2002)

The emission scenario only includes the life cycle stages application (or use), service life and waste treatment (see boxes outlined in bold in figure 2.1).

Skin antiseptics are used professionally (in hospitals) as well as privately. Some skin antiseptics like products for bathing are applied and used in the very short term. After this short service life the products are rinsed off with fresh water or released with wastewater after washing and bathing. Other skin antiseptics may stay on the human skin for a longer period after application. During this period of 'service life' the product may transfer to the clothing and is removed when clothing is washed. Remains of the product on the human skin are removed during showering or bathing. Products are applied as solutions, soaps, creams, gels, lotions and aerosols (Van der Poel and Bakker, 2002).

Anti-microbial soap and lotions are used for disinfection purposes professionally (in hospitals) as well as privately. These soaps are applied and rinsed off after a very short time or released with wastewater after washing or bathing.

Health care personnel hand wash includes hand wash products used for disinfection on a professional basis (in hospitals). Like the anti-microbial soap products, health care personnel hand wash products are rinsed off after a very short term of use.

2.2 Examples of substances used

Human hygiene biocidal products are characterised by a large number of different products and active substances. Some examples for products and active substances under this Product type are described here (Lassen et al. 2001):

Chlorhexidine is rapidly bactericidal and persistent and is recommended as a relatively non-toxic skin antiseptic for general use. It is most active against Gram-positive organisms and fairly effective against Gram-negative bacteria and many viruses. It is inactivated by soap and organic matter and is therefore used in aqueous or alcoholic solutions for topical application, hand and skin washing. Chlorhexidine and alcohol are often used together for skin disinfection.

Iodine is mostly used in solutions with water and detergents (iodophors) together with alcohol. Iodine complexes with the detergents and exists in equilibrium with a small amount in the water phase. Iodophors are slowly sporicidal but rapidly effective against vegetative organisms including fungi and *Trichomonas*. The microbiocidal effect, especially against viruses, is however varying.

Iodine in alcohol solutions (tincture of iodine) are powerful and efficient skin disinfectants, but also rather irritant to skin. Free iodine may cause toxic dermatitis and is easily absorbed through injured skin. Previously these tinctures were widely used.

Alcohols like isopropyl alcohol and ethanol are optimally bactericidal in aqueous solution at concentrations of 70 to 75%, and have very little bacteriocidal effect outside this range, e.g. when 'absolute' or diluted too much. Alcohols represent the group of substances which most rapidly and efficiently reduces the number of microorganisms on the skin. They are microbiocidal against bacteria including mycobacteria, fungi and especially lipid containing virus. They are not active against spores and non-lipid containing viruses.

Triclosan has been widely used as an antimicrobial agent in consumer goods including cosmetics for many years. Recently it was discovered that triclosan has a very specific mode of action, as is the case for antibiotics. Triclosan is fat-soluble and crosses easily cell-membranes. Once inside the cell, triclosan blocks the active site of an enzyme called enoyl-acyl carrier-protein reductase, preventing the bacteria from producing fatty acids needed for building cell membranes and other vital functions. As a preservative in soaps, triclosan is added in low concentrations (<0.3%). In order to obtain an antiseptic effect, the concentration must typically be up to 3%.

Other substances in this product type are, e.g., the groups of quats, guanidines and compounds generating oxygen or halogen. A list of active substances currently notified under the Second Review Regulation according to the BPD can be found on the ECB Website: http://ecb.jrc.it/biocides/.
For PT1, around 100 substances have been notified.

2.3 Information on the scale or size of the application and use area

The Scientific Committee on Cosmetic Products and Non-Food Products (SCCNFP) intended for Consumers gave some relevant amounts per application and frequency of application per day in the notes of guidance for testing of cosmetic ingredients for their safety evaluation (SCCNFP, 2000). General purpose cream is applied twice per day, with 1.2 g applied per application, whereas Body lotion would be applied once per day using 8 gram.

According to Van der Poel and Bakker (2002) creams may be applied by 10% of the inhabitants, using 0.8 g per application twice per day.

2.4 Identification of the potential points of release in the application and use area

The environmental exposure of Product type 1 is very diffuse. The products are available as soap bars or liquid soap, sprays, gels, pastes, etc, all in small quantities. A distinction may be made between ‘rinse-off’ and ‘non-rinse-off’ or ‘leave-on’ products. After application ‘rinse-off’ products will usually be rinsed or washed off directly and most of the material will be discharged to the sewage treatment plant. For ‘leave-on’ products it may be assumed that they will be washed off later of be rubbed of by clothing to be washed to the sewer at a later stage. In exceptional cases, they directly, after application, reach the fresh and marine surface water or the indoor air.

A special case is the application of volatile substances such as ethanol antiseptics. This use will cause an emission to air implying that only a small fraction might go to wastewater.

Another potential route of emission is the disposal of the packaging material together with remnants of the product, or the disposal of outdated products to a waste dump via the normal route of municipal waste.

3 EMISSION SCENARIOS FOR HUMAN HYGIENE BIOCIDAL PRODUCTS

3.1 Description of available scenarios

For the product group “Human hygiene biocidal products” two main types of scenarios are available. The ones for private use are based on the IC5&6 scenario in the EU-TGD (EC 2003a). Some specification may be added to enable the integration of more substance-specific details. A scenario for professional use is described by Van der Poel and Bakker (2002). Both scenarios assume that the wastewater is eventually treated in a STP.

It should be kept in mind that all emission scenarios will develop over time and therefore the reader should always refer to the latest version of the original documents (e.g, the EU Technical Guidance Document) to find out whether adaptations have been introduced.

3.2 EU TGD IC5&6

This document contains a simple scenario for the release of detergents to raw sewage water during the use of these cleaning products. The scenario assumes that 100% of the used chemicals ends up in sewage water. However, a fraction ($F_{wastewater}$) describing the emission to wastewater is not incorporated in the scenario. The content of active ingredient in the product is also not incorporated in the scenario.

Table 3.1 Emission scenario for calculating the release of chemicals used in human hygiene biocidal products (IC5&6 in the EU-TGD, EC 2003a)

Variable/parameter	Unit	Symbol	Default	S/D/O/P
Input				
Population of an area or number of inhabitants consuming hygiene products containing biocides	[cap]	$N_{inhabitant}$		S
Consumption of human hygiene biocides (in a certain market area)	[tonnes.yr^{-1}]	TONNAGE		S
Number of emission days per year	[d.yr^{-1}]	Temission	365	D
Output				
Emission rate to wastewater per (consuming) inhabitant	[g.cap^{-1}.d^{-1}]	$Einhabitant_{water}$		
Calculations				
$Einhabitant_{water}$ = (TONNAGE * 10^6) / ($N_{inhabitant}$ * Temission)				

The ESD for IC-5&6 describes the calculation of an average consumption per capita in a certain area. This is calculated using actual tonnage data (the quantity of the

human hygiene biocide) and the related population ($N_{inhabitant}$). Following the scenario this may be a known market area or population area. The scenario does not provide default values for $N_{inhabitant}$.

Following the TGD and the USES/EUSES manual, TONNAGE is regional or continental. The regional tonnage may be derived from the continental figure: TONNAGEregional = 0.1 * TONNAGEcontinental. According to the TGD the population of a region (Nregional) is 20.10^6, the population to calculate a local emission (Nlocal) is 10,000 (the amount of inhabitants discharging to one waste water treatment plant). For the calculation of a local or regional emission these values may be used as default values for $N_{inhabitant}$ in the ESD for IC-5&6.

3.3 Baumann et al. 2000

A simple emission scenario for the release of biocides in PT1 is suggested by Baumann et al. (2000). This scenario is largely similar to the scenario for IC-5&6 as described in table 3.1. In contrast to the scenario "EU TGD IC5&6", where it is implicitly assumed that 100% of the used detergent chemicals ends up in wastewater, in the scenario-calculation of Baumann et al. a "fraction released to wastewater" is integrated. This fraction is normally 0 by default, but for the 'non-rinse-off' products, this fraction may be below 1, because a part of these 'non-rinse-off' products may be released to the air. A second difference is that, in contrast to the scenario "EU TGD IC5&6", the content of active ingredient in the product is incorporated in the scenario of Baumann et al. (2000).

Table 3.2 Emission scenario for calculating the release of chemicals used in human hygiene biocidal products

Variable/parameter	Unit	Symbol	Default	S/D/O/P
Input				
Number of inhabitants	[cap]	Ninhabitant		S
Consumption per inhabitant	[$l.cap^{-1}.d^{-1}$]	Q_{prod}		S
Active substance in the product	[$kg.l^{-1}$]	C_{prod}		S
Fraction released to wastewater	[-]	F_{water}	1	D/S[1)]
Output				
Emission rate to wastewater	[$kg.d^{-1}$]	$Einhabitant_{water}$		
Calculation				
$Einhabitant_{water} = N_{inhabitant} * Q_{prod} * C_{prod} * F_{water}$				

1) F_{water} = 1 by default, but the user may alter this value in case of 'non-rinse-off' products (in that case this fraction may be below 1)

The information on Nregional and Nlocal according to the TGD and the USES/EUSES manual, as described in the last paragraph of section 3.2, also applies on the scenario of Baumann et al. (2000).

3.4 Van der Poel and Bakker 2002

Van der Poel and Bakker (2002) distinguish between private use and industrial use of the products. The scenarios are an elaboration of IC5&6. By calculating the consumption for the local scenario, it is made applicable to biocides.

There are two scenarios for PT1 products for private use. The first scenario uses the annual tonnage applied. A second scenario was developed for cases where the tonnage would not be available. This scenario uses post-consumer release prediction and consumption data as applied in the ESD IC5&6 (TGD, EC 2003a).

The scenario for industrial use calculates the releases of disinfectants used for skin and hand application in hospitals. A distinction is made between the calculation method using the annual tonnage applied (as for private use) and the method using the average consumption per hospital bed.

3.4.1 Private use

The first scenario for private use uses the regional tonnage and follows the scenario approach as in EUSES for cleaning products in industrial category 5 (Personal/ domestic) at the stage of private use. This means that the standard STP of EUSES is considered as a point source where a fraction of 0.002 (Fmainsource) of the disinfectant ends up. This scenario is presented in Table 3.3.

A tonnage may be available for the total use of a biocide. Howwever, for the specific use it may be absent. If the tonnage of biocides is not supplied by the notifier at present a second scenario can be used. This scenario uses post-consumer release prediction and consumption data as presented in the emission scenario document for soaps and detergents used in industrial categories 5 (Personal/domestic) and 6 (Public domain) (EC 2003a). Often no average consumption data per (generic) inhabitant per day will be available for human hygiene biocidal products. Therefore the emission scenario has been extended in such way that average amounts of product per application can be used together with a factor for the fraction of inhabitants using a specific product. The used material is discharged to the sewer going to the standard STP (10,000 inhabitant equivalents). The extended consumption scenario is presented in Table 3.4.

Table 3.3 Emission scenario for calculating the release of disinfectants used in human hygiene biocidal products (for private use) based on the annual tonnage applied (as in IC5&6 in the EU-TGD, EC 2003a)

Variable/parameter	Unit	Symbol	Default	S/D/O/P
Input				
A) Relevant tonnage in the region for this application	[tonnes.yr^{-1}]	TONNAGEreg		S
B) Relevant tonnage in EU for this application	[tonnes.yr^{-1}]	TONNAGE		S

Variable/parameter	Unit	Symbol	Default	S/D/O/P
Fraction for the region	[-]	$Fprodvol_{reg}$	0.1	D
A + B)	[-]	Fmainsource	0.002	D
Fraction of the main source (STP)				
Fraction released to wastewater	[-]	F_{water}	1	D
Number of emission days (private use)	[$d.yr^{-1}$]	Temission	365	D
Output				
Emission rate to wastewater (standard STP)	[$kg.d^{-1}$]	$Elocal_{water}$		
Intermediate calculations				
B)				
$TONNAGE_{reg} = Fprodvol_{reg} * TONNAGE$				
End calculations				
A + B)				
$Elocal_{water} = TONNAGE_{reg} * 10^3 * Fmainsource_{water} * F_{water} / Temission$				

Table 3.4 Emission scenario for calculating the release of disinfectants used in human hygiene biocidal products (private use) based on an average consumption for products containing the biocide

Variable/parameter	Unit	Symbol	Default	S/D/O/P
Input				
Number of inhabitants feeding one STP	[-]	Nlocal	10000	D
Fraction released to wastewater	[-]	F_{water}	1	D
Active substance in product:				S
				S
A)	[$g.l^{-1}$]	$Cform_{volume}$		
B)	[$g.kg^{-1}$]	$Cform_{weight}$		
C) Consumption per inhabitant per day				
C1)	[$ml.d^{-1}$]	$Vform_{inh}$		P
C2)	[$g.d^{-1}$]	$Qform_{inh}$		P
D) Consumption per application				
D1)	[ml]	$Vform_{appl}$		P
D2)	[g]	$Qform_{appl}$		P
Number of applications	[d^{-1}]	Nappl		P
Fraction of inhabitants using product N	[-]	Finh		P
Market share of disinfectant [1)]	[-]	Fpenetr	0.5	D
Specific density of product	[$kg.m^{-3}$]	RHOform	1000	D

Output		
Emission rate to wastewater	[kg.d^{-1}])	$Elocal_{,water}$

Model calculations

C1 and A)

$Elocal_{water} = Nlocal * F_{water} * Vform_{inh} * Cform_{volume} * Fpenetr * 10^{-6}$

C1 and B)

$Elocal_{water} = Nlocal * F_{water} * Vform_{inh} * RHOform * Cform_{weight} * Fpenetr * 10^{-9}$

C2 and A)

$Elocal_{water} = Nlocal * F_{water} * Qform_{inh} / RHOform * Cform_{volume} * Fpenetr * 10^{-3}$

C2 and B)

$Elocal_{water} = Nlocal * F_{water} * Qform_{inh} * Cform_{weight} * Fpenetr * 10^{-6}$

D1 and A)

$Elocal_{water} = Nlocal * Nappl * Finh * F_{water} * Vform_{appl} * 10^{-6} * Cform_{volume} * Fpenetr$

D1 and B)

$Elocal_{water} = Nlocal * Nappl * Finh * F_{water} * Vform_{appl} * 10^{-9} * RHOform * Cform_{weight} * Fpenetr$

D2 and A)

$Elocal_{water} = Nlocal * Nappl * Finh * F_{water} * Qform_{appl} / RHOform * Cform_{volume} * Fpenetr * 10^{-3}$

D2 and B)

$Elocal_{water} = Nlocal * Nappl * Finh * F_{water} * Qform_{appl} * Cform_{weight} * Fpenetr * 10^{-6}$

1) As no market shares for disinfectants applied for this purpose are known, a "best guess" of 0.5 is used. If better data for the specific products become available the default values can be overruled.

The default values for average consumption, number of applications and fractions are available in the pick-list presented in Table 3.5.

Table 3.5 Pick-list for average consumption per inhabitant per day

Product	Vforminh Qforminh	Vformappl Qformappl	Nappl	Finh
Anti-dandruff shampoo	.	12 [1)]	0.71 [2)]	0.1
Antipersprants/Deodorant:				
- aerosol	.	3 [1)]	2 [3)]	0.2
- stick, roll-on	.	0.5 [1)]	1 [1)]	0.8
Creams (e.g. anti-acne)	.	0.8 [4)]	2 [4)]	0.1
Mouth wash	.	10	3	0.05

1) TGD (EC 2003a)

2) TGD: 2-7 times per week; default 5 times per week = 0.71 times per day

3) TGD: 1-3 times per day

4) Data from the TGD for facial cream: 1-2 times per day

As can be seen in Table 3.5 no defaults for average consumption have been given at all. This means that part "C)" of the emission scenario presented in Table 3.4 is not

applicable at all. It should be noted, however, that such an average might be used if an accurate value is known for a country or region and when it is known that a disinfectant is always present.

3.4.2 Professional use

Table 3.6 presents the scenario for disinfectants in human hygiene biocidal products for professional use based on the tonnage. The fraction of the main source, Fmainsource, concerns hospitals. As the average Dutch hospital size is used the fraction of the main source is 0.007. This is basically the same emission scenario as for private use (and as such as IC5&6 in the TGD).

Table 3.6 Emission scenario for calculating the releases of disinfectants used for skin and hand application in hospitals based on the annual tonnage applied

Variable/parameter	Unit	Symbol	Default	S/D/O/P
Input				
A) Relevant tonnage in the region for this application	[tonnes.yr^{-1}]	TONNAGEreg		O
B) Relevant tonnage in EU for this application	[tonnes.yr^{-1}]	TONNAGE		
Fraction for the region A + B)		$Fprodvol_{reg}$	0.1	D
Fraction of the main source (STP)	[-]	Fmainsource	0.007	D
Fraction released to wastewater	[-]	F_{water}	1	D
Number of emission days for application	[d.yr^{-1}]	Temission	365	D
Output				
Emission rate to wastewater	[kg.d^{-1}]	$Elocal_{water}$		
Intermediate calculations				
B) Relevant tonnage in the region for this application (tonnes.yr^{-1}) TONNAGEreg = $Fprodvol_{reg}$ * TONNAGE				
End calculations				
A + B) $Elocal_{water}$ = TONNAGEreg * 10^3 * Fmainsource * F_{water} / Temission				

Table 3.7 presents the scenario for disinfectants in human hygiene biocidal products based on the average consumption per bed. These values came from six hospitals in Germany and were given for several chemical groups and concern the beds present. The defaults are averages from these data if 5 or more hospitals used chemicals from a group or otherwise the maximum. The average may be known as an average per bed present in the hospital or per bed occupied over the year. Therefore, an occupancy rate (Foccup) averaged over the year has been introduced.

Table 3.7 Emission scenario for calculating the releases of disinfectants used for skin and hand application in hospitals based on an average consumption

Variable/parameter	Unit	Symbol	Default	S/D/O/P
Input				
A)				
Number of beds in model hospital	[-]	$Nbeds_{pres}$	400	D
Occupancy rate	[-]	Foccup	0.75	D
B)				
Number of occupied beds in model hospital	[-]	$Nbeds_{occup}$	300	D
Fraction released to wastewater	[-]	F_{water}	1	D
C)				
Consumption of active ingredient per bed	[$g.d^{-1}$]	$Qsubst_{pres\_bed}$		P
D)				
Consumption of active ingredient per occupied bed	[$g.d^{-1}$]	$Qsubst_{occup\_bed}$		P
Output				
Emission rate to wastewater	[$kg.d^{-1}$]	$Elocal_{water}$		
Model calculations				
A + C) $Elocal_{water} = Nbeds_{pres} * Qsubst_{pres\_bed} * 10^{-3} * F_{water}$				
A + D) $Elocal_{water} = Nbeds_{pres} * Foccup * Qsubst_{occup\_bed} * 10^{-3} * F_{water}$				
B + C) $Elocal_{water} = Nbeds_{occup} * Qsubst_{pres\_bed} * Foccup * 10^{-3} * F_{water}$				
B + D) $Elocal_{water} = Nbeds_{occup} * Qsubst_{occup\_bed} * 10^{-3} * F_{water}$				

Table 3.8 presents the pick-list for disinfectants of some chemical groups expressed in $g.d^{-1}$ for beds present and for occupied beds assuming an occupancy rate of 75% (Foccup = 0.75).

Table 3.8 Picklist for the average use of disinfectant for professional use for $Qsubst_{pres\text{-}bed}$ and for $Qsubst_{occup\text{-}bed}$ (TGD, EC 2003a). If better data are available the default values can be overruled.

Chemical type	I	II
Alcohols	15	20
Quaternary ammonium compounds	0.004	0.005
Guanidines	0.015	0.02
Compounds generating oxygen	0.038	0.05
Compounds generating halogen	0.10	0.13

Others	0.038	0.05

4 RECOMMENDED SCENARIO

The IC5&6 emission scenario document in itself is not sufficient to estimate the emission of disinfectants in human hygiene products. However, the more elaborated scenarios presented by Van der Poel and Bakker (2002) that are based on the IC5&6 scenarios are suitable for this purpose. They present an option to use either the tonnage of disinfects supplied to the market or the estimated consumption rate per inhabitant or per application.

A modification of these scenarios could be made by addition of the 'Fraction released to wastewater' as in the scenario in Baumann et al. (2000). In this way the distinction between 'leave-on' and 'rinse-off' products could be made as well as a recognition of the fraction to air for volatile products.

Although the local scenario is always connected to an STP, the EU-TGD (EC 2003a) recommends to include calculations for a worst case situation where no sewage treatment is included.

For the exceptional cases where products may, after application, reach the fresh and marine surface water or the indoor air, no emission scenario is available. For the emission due to the disposal of the packaging material together with remnants of the product, a generic section is now included in the TGD (EC 2003a) on 'Waste disposal including waste treatment and recovery'.

The recommended scenarios are presented in the following tables:

Table 4.1 Emission scenario for calculating the release of disinfectants used in human hygiene biocidal products (for private use) based on the annual tonnage applied (as in IC5&6 in the EU-TGD, EC 2003a)

Variable/parameter	Unit	Symbol	Default	S/D/O/P
Input				
A) Relevant tonnage in the region for this application	[tonnes.yr^{-1}]	TONNAGEreg		S
B) Relevant tonnage in EU for this application	[tonnes.yr^{-1}]	TONNAGE		S
Fraction for the region	[-]	$Fprodvol_{reg}$	0.1	D
A + B) Fraction of the main source (STP)	[-]	Fmainsource	0.002	D
Fraction released to wastewater	[-]	F_{water}	1	D/S[1)]
Number of emission days (private use)	[d.yr^{-1}]	Temission	365	D

Variable/parameter	Unit	Symbol	Default	S/D/O/P
Output				
Emission rate to wastewater (standard STP)	[kg.d^{-1}]	Elocal$_{water}$		
Intermediate calculations				
B)				
TONNAGE$_{reg}$ = Fprodvol$_{reg}$ * TONNAGE				
End calculations				
A + B)				
Elocal$_{water}$ = TONNAGE$_{reg}$ * 10^3 * Fmainsource$_{water}$ * F$_{water}$ / Temission				

1) F$_{water}$ = 1 by default, but the user may alter this value in case of 'non-rinse-off' products (in that case this fraction may be below 1)

Table 4.2 Emission scenario for calculating the release of disinfectants used in human hygiene biocidal products (private use) based on an average consumption for products containing the biocide

Variable/parameter	Unit	Symbol	Default	S/D/O/P
Input				
Number of inhabitants feeding one STP	[-]	Nlocal	10000	D
Fraction released to wastewater	[-]	F$_{water}$	1	D
Active substance in product:				S S
A)	[g.l^{-1}]	Cform$_{volume}$		
B)	[g.kg^{-1}]	Cform$_{weight}$		
C) Consumption per inhabitant per day				
C1)	[ml.d^{-1}]	Vform$_{inh}$		P
C2)	[g.d^{-1}]	Qform$_{inh}$		P
D) Consumption per application				
D1)	[ml]	Vform$_{appl}$		P
D2)	[g]	Qform$_{appl}$		P
Number of applications	[d^{-1}]	Nappl		P
Fraction of inhabitants using product N	[-]	Finh		P
Market share of disinfectant [1)]	[-]	Fpenetr	0.5	D
Specific density of product	[kg.m^{-3}]	RHOform	1000	D
Output				
Emission rate to wastewater	[kg.d^{-1}])	Elocal,$_{water}$		

Model calculations

C1 and A)

$Elocal_{water}$ = Nlocal * F_{water} * $Vform_{inh}$ * $Cform_{volume}$ * Fpenetr * 10^{-6}

C1 and B)

$Elocal_{water}$ = Nlocal * F_{water} * $Vform_{inh}$ * RHOform * $Cform_{weight}$ * Fpenetr *10^{-9}

C2 and A)

$Elocal_{water}$ = Nlocal * F_{water} * $Qform_{inh}$ / RHOform * $Cform_{volume}$ * Fpenetr * 10^{-3}

C2 and B)

$Elocal_{water}$ = Nlocal * F_{water} * $Qform_{inh}$ * $Cform_{weight}$ * Fpenetr * 10^{-6}

D1 and A)

$Elocal_{water}$ = Nlocal * Nappl * Finh * F_{water} * $Vform_{appl}$ * 10^{-6} * $Cform_{volume}$ * Fpenetr

D1 and B)

$Elocal_{water}$ = Nlocal * Nappl * Finh * F_{water} * $Vform_{appl}$ *10^{-9} * RHOform * $Cform_{weight}$ * Fpenetr

D2 and A)

$Elocal_{water}$ = Nlocal * Nappl * Finh * F_{water} * $Qform_{appl}$ / RHOform * $Cform_{volume}$ * Fpenetr * 10^{-3}

D2 and B)

$Elocal_{water}$ = Nlocal * Nappl * Finh * F_{water} * $Qform_{appl}$ * $Cform_{weight}$ * Fpenetr * 10^{-6}

1) As no market shares for disinfectants applied for this purpose are known, a "best guess" of 0.5 is used. If better data for the specific products become available the default values can be overruled.

Table 4.3 Pick-list for average consumption per inhabitant per day

Product	Vforminh Qforminh	Vformappl Qformappl	Nappl	Finh
Anti-dandruff shampoo	.	12 [1]	0.71 [2]	0.1
Antipersprants/Deodorant:				
- aerosol	.	3 [1]	2 [3]	0.2
- stick, roll-on	.	0.5 [1]	1 [1]	0.8
Creams (e.g. anti-acne)	.	0.8 [4]	2 [4]	0.1
Mouth wash	.	10	3	0.05

Table 4.4 Emission scenario for calculating the releases of disinfectants used for skin and hand application in hospitals based on the annual tonnage applied

Variable/parameter	Unit	Symbol	Default	S/D/O/P
Input				
A)				O
Relevant tonnage in the region for this application	[tonnes.yr^{-1}]	TONNAGEreg		
B)				
Relevant tonnage in EU for this application	[tonnes.yr^{-1}]	TONNAGE		
Fraction for the region A + B)		$Fprodvol_{reg}$	0.1	D
Fraction of the main	[-]	Fmainsource	0.007	D

source (STP)				
Fraction released to wastewater	[-]	F_{water}	1	D/S[1)]
Number of emission days for application	[$d.yr^{-1}$]	Temission	365	D
Output				
Emission rate to wastewater	[$kg.d^{-1}$]	$Elocal_{water}$		
Intermediate calculations				
B)				
Relevant tonnage in the region for this application ($tonnes.yr^{-1}$)				
$TONNAGEreg = Fprodvol_{reg} * TONNAGE$				
End calculations				
A + B)				
$Elocal_{water} = TONNAGEreg * 10^3 * Fmainsource * F_{water} / Temission$				

1) F_{water} = 1 by default, but the user may alter this value in case of 'non-rinse-off' products (in that case this fraction may be below 1)

Table 4.5 Emission scenario for calculating the releases of disinfectants used for skin and hand application in hospitals based on an average consumption

Variable/parameter	Unit	Symbol	Default	S/D/O/P
Input				
A)				
Number of beds in model hospital	[-]	$Nbeds_{pres}$	400	D
Occupancy rate	[-]	Foccup	0.75	D
B)				
Number of occupied beds in model hospital	[-]	$Nbeds_{occup}$	300	D
Fraction released to wastewater	[-]	F_{water}	1	D/S[1)]
C)				
Consumption of active ingredient per bed	[$g.d^{-1}$]	$Qsubst_{pres\_bed}$		P
D)				
Consumption of active ingredient per occupied bed	[$g.d^{-1}$]	$Qsubst_{occup\_bed}$		P
Output				
Emission rate to wastewater	[$kg.d^{-1}$]	$Elocal_{water}$		

Model calculations

A + C)

$Elocal_{water} = Nbeds_{pres} * Qsubst_{pres\_bed} * 10^{-3} * F_{water}$

A + D)

$Elocal_{water} = Nbeds_{pres} * Foccup * Qsubst_{occup\_bed} * 10^{-3} * F_{water}$

B + C)

$Elocal_{water} = Nbeds_{occup} * Qsubst_{pres\_bed} * Foccup * 10^{-3} * F_{water}$

B + D)

$Elocal_{water} = Nbeds_{occup} * Qsubst_{occup\_bed} * 10^{-3} * F_{water}$

1) F_{water} = 1 by default, but the user may alter this value in case of 'non-rinse-off' products (in that case this fraction may be below 1)

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