RIJKSINSTITUUT VOOR VOLKSGEZONDHEID EN MILIEU
NATIONAL INSTITUTE FOR PUBLIC HEALTH AND THE ENVIRONMENT

RIVM report 601450 008

Supplement to the methodology for risk evaluation of biocides

Emission Scenarios Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector)

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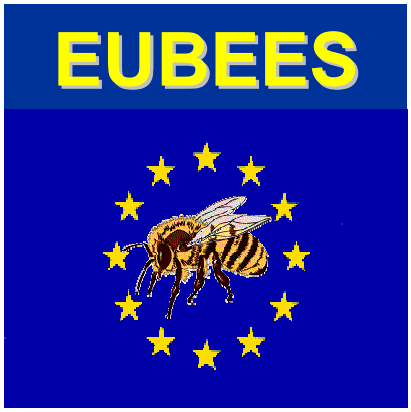
March 2001



This report has been developed in the context of the EU project entitled "Gathering, review and development of environmental emission scenarios for biocides" (EUBEES).
The contents have been discussed and agreed by the EUBEES working group, consisting of representatives of some Member States, CEFIC and Commission. The Commissions financial support of the project is gratefully acknowledged (Grant SUBV 99/134534).

This investigation has been performed by order and for the account of the Directorate-General for Environmental Protection, within the framework of project 601450, Risk assessment methodology.

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Abstract

This report is an update of the RIVM report 601450 002 which deals with emission scenarios for disinfectants used for sanitary purposes and applications in the medical sector. These biocides belong to product type 2 "Private and public health area disinfectants and other biocidal products" of the 23 product types distinguished in Appendix V of Directive 98/8/EC(EC, 1998). The scenarios have been adapted to the remarks and data supplied by the EUBEES working group in order to make them uniform and generally applicable for all EU member states.

Samenvatting

Dit rapport is een aangepaste versie van RIVM rapport 601450 002 dat emissie scenario's geeft voor biociden die toegepast worden voor ontsmetting van sanitair in woningen en openbare ruimten en voor biociden toegepast in de medische sector. Dit betreft biociden van product type 2 "Private and public health area disinfectants and other biocidal products" uit de lijst van 23 product typen die in de Europese richtlijn (Directive 98/8/EC) onderscheiden worden. Het oorspronkelijke rapport is besproken in het kader van het project "Gathering , review and development of environmental emission scenarios for biocides" (EUBEES) door de EUBEES werkgroep. Naar aanleiding hiervan zijn de scenario's zodanig aangepast dat ze voor alle lidstaten gelden.

Summary

Directive 98/8/EC (EC, 1998) distinguishes 23 product types for biocidal products, i.e. non-agricultural pesticides. This report presents emission scenarios for the two urgently needed applications of product type 2 "Private and public health area disinfectants and other biocidal products": disinfectants used for sanitary purposes and disinfectants for use in the medical sector. The application of biocides for sanitary purposes belongs to industrial category 5 (Personal/domestic) of the TGD (Technical Guidance Document). The emission module for this application is presented in Table 2.1. For applications in the medical sector they belong to industrial category 6 (Public domain). Emission modules are presented for:

1. disinfection of rooms, furniture and objects (Tables 3.5 and 3.6);
2. disinfection of instruments (scopes Table 3.7 and other instruments Table 3.8);
3. laundry disinfection (washing streets Table 3.9 and tumbler washing machines Table 3.10).

Contents

1. Introduction

The government of the Netherlands developed the first version of the Uniform System for the Evaluation of Substances (USES 1.0) in the framework of their first National Environmental Policy Plan. USES 1.0, available since 1994, harmonised the risk assessment of new and existing substances, biocides and plant protection products. USES 1.0 was tailored to the corresponding EC and national legislation. USES 1.0 was subsequently used as one of the basic documents for the development of the EU Technical Guidance Document to assess risks of new and existing substances in support of the corresponding EC legislation and its computer implementation, the European Union System for Evaluation of Substances (EUSES 1.00).

Simultaneous with the development of EUSES 1.0 next versions of USES were developed by VROM (Ministry of Housing, Spatial Planning and the Environmentr), mainly for use in the Netherlands. USES 2.0 and 3.0 comprise risk assessment methods for biocides and plant protection products, in addition to methods for new and existing substances. The risk assessment methods for biocides and plant protection products are in accordance with the corresponding national legislation and as much as possible with the corresponding EC legislation. In USES 2.0 and 3.0, the risk assessment methods for new and existing substances are fully equivalent to EUSES 1.00.

As part of USES 1.0 and USES 2.0 several emission scenarios for biocides (non-agricultural pesticides) have been developed at the RIVM within a period of approximately 10 years (Luttik *et al*., 1993 and 1995; Montfoort *et al*., 1996).
Product type 2 "Private and public health area disinfectants and other biocidal products" concerns a heterogeneous group of products used for disinfection, for example bathrooms, toilets, chemical closets, walls and floors in private homes and institutions such as offices, workshops, schools, hospitals and sport facilities (Van Dokkum *et al.*, 1998). All disinfectants not included in one of the other product types belong here. The CTB (National Board of the Authorisation of Pesticides) in The Netherlands applies the following division for the fields of application:

- Swimming pools
- Sanitary sector
- Horticulture
- Tiles and surfaces
- Medical sector

The application in the fields sanitary sector and medical sector belong to some of the most urgently needed items for which emission scenario documents are required. Therefore the original report, which was the basis for this report, was produced for the Dutch situation (Van der Poel, 1999a). Discussions in the working group for the EU project "Gathering , review

and development of environmental emission scenarios for biocides" and data supplied by some member states enabled the update presented in this report. The emission scenarios are applicable in all European Union member states.

The scenarios in this report are presented in the following way:

Input

[Variable/parameter (unit)] [Symbol] [Unit] S/D/O/P

These parameters are the input to the scenario. The S, D, O or P classification of a parameter indicates the status:

S Parameter must be present in the input data set for the calculation to be executed (there has been no method implemented in the system to estimate this parameter; no default value is set).

D Parameter has a standard value (most defaults can be changed by the user)

O Parameter is the output from another calculation (most output parameters can be overwritten by the user with alternative data).

P Parameter value can be chosen from a 'pick-list' of values.

[c] Default or output parameter is closed and cannot be changed by the user.

Output

[Symbol] [Description]

Intermediate calculations

Parameter description (Unit)

[Parameter = equation] (Equation no.)

End calculations

[Parameter = equation] (Equation no.)

In this report two main types of scenarios are presented, viz one based on the tonnage applied for a specific application and one based on the consumption (average consumption per capita or the consumption of a model source). Though it is desirable to have only one scenario, there may be circumstances for which two may be necessary or advisable. Appendix 3 gives a general explanation on the differences between the two types of emission scenarios and the advantages/disadvantages.

2. Disinfectants used in the sanitary sector

2.1 Scenario description

The application of disinfectants for sanitary purposes refers to nearly the same areas as the scenario "Disinfection in accommodations", described in Luttik *et al.* (1993) and incorporated in USES 2.0 (RIVM, VROM, VWS, 1998). The emission scenario for accommodations was designed for disinfectants used in accommodations for humans and for preparing food and drinks. It is based on the Dutch situation and uses the tonnage of the active substance applied per year in the region considered. The first sceanrio presented here uses also the regional tonnage and follows the sceanrio 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 (sewage treatment plant) of EUSES is considered as a point source where a fraction of 0.002 ($Fmainsource_2$) of the disinfectant ends up[1)]. The release to wastewater is 100% by default. As the tonnage of biocides has not to be supplied by the notifier at present a second scenario is presented here. This scenario uses the post-consumer release prediction and consumption data of the emission scenario document for soaps and detergents used in industrial categories 5 (Personal/domestic) and 6 (Public domain) (EC, 1996). That emission scenario document gives an estimate of a 100% release to waste water, and applies a consumption of detergents for surface cleaning at the level of 5 and 2 grams per capita per day for general purpose and lavatory cleaners respectively. The density of the detergents is assumed to be 1000 $kg.m^{-3}$. The scenario has been adapted in such a way that the market share is taken into account; this means the fraction of the cleaning product containing the same disinfectant. The market share is called penetration factor in the scenario. As no market shares for disinfectants applied for this purpose are known, a "best guess" of 0.5 is used.

2.2 Emission scenario

Table 2.1 presents the emission scenario applying the tonnage of the disinfectant and Table 2.2 the scenario for the average consumption. It should be noted that the standard STP of EUSES and USES is used, with 10,000 inhabitants feeding the system and an amount of 0.2 m^3 wastewater per inhabitant per day.

1) In the case of diffuse releases to wastewater, for example emissions from households, the emissions from these small sources are collected at the STP. The receiving STP may be considered as a point source then. If the use of a substance would be evenly distributed over the population (consumers) and STPs in a region and over the week, the fraction of this substance reaching the standard STP of EUSES would be *number of inhabitants connected to the STP (Nlocal) / number of inhabitants in the region (N)*. This means a fraction of $10{,}000 / 20.0.10^6 = 0.0005$ with the defaults of EUSES. As the use of (formualtion containing) substances never will be distrubuted evenly over the population and the week, a safety factor of four was assumed at the time. This means that the fraction of the main source $Fmainsource_2 = 0.002$.

Table 2.1 Emission scenario for calculating the releases of disinfectants used for sanitary purposes 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 [1)]		
B)			
Relevant tonnage in EU for this application (tonnes.yr^{-1})	TONNAGE [1)]		
Fraction for the region	F_{reg}	0.1	D
A + B)			
Fraction of the main source (STP) (-)	$Fmainsource_{water}$	0.002	D
Fraction released to waste water (-) [1)]	$F_{4, water}$	1	D
Number of emission days for life cycle stage 4 (private use) (d)	$Temission_4$	365	D
Output:			
$Elocal_{4,water}$ = Emission rate to waste water (kg.d^{-1}) [2)]			

[1)] In principle this should be $TONNAGE_k$ to identify usage in product *k* but this is not shown just as in the EUSES documentation

[2)] The subscript "4" refers to the stage of private use in conformity with EUSES 1.0 and USES 2.0.

Intermediate calculations:

B)

Relevant tonnage in the region for this application (tonnes.yr^{-1})

$TONNAGEREG = F_{reg} * TONNAGE$

End calculations:

A + B)

$$Elocal_{4,water} = TONNAGEreg * 10^3 * Fmainsource_{water} * F_{4,water} / Temission_4$$

Table 2.2 Emission scenario for calculating the releases of disinfectants used for sanitary purposes based on an average consumption

Variable/parameter (unit)	Symbol	Default	S/D/O/P
Input:			
Number of inhabitants feeding one STP (-)	Nlocal	10000	D [1]
Fraction released to waste water (-) [2]	$F_{4, water}$	1	D
Active substance in product ($kg.l^{-1}$)	$C_{product}$		S
Consumption per capita ($l.cap^{-1}.d^{-1}$)	$Q_{product}$		
General purpose (tiles, floors, sinks)		0.005	D
Lavatory		0.002	D
Penetration factor of disinfectant	F_{penetr}	0.5	D
Output:			
$Elocal_{4,water}$ = Emission rate to waste water ($kg.d^{-1}$) [1]			

[1] Default number as used in EUSES for the standard STP

[2] The subscript "4" refers to the stage of private use in conformity with EUSES 1.0 and USES 2.0.

Model calculations:

$Elocal_{4,water} = Nlocal * Q_{product} * C_{product} * F_{penetr} * F_{4, water}$

Above a certain tonnage (at the break-even point), as explained in Apendix 3, the scenario based on the tonnage should be applied preferably. For the number of emission days $Temission_4$, = 365 and the fraction for the model STP of 0.002 the break-even point can be written in the form:

$$TONNAGEREG = 1.825 \cdot 10^6 * Q_{product} * C_{product} * F_{penetr} .$$

With the default values for the consumption per capita and the penetration factor this becomes:

$$TONNAGEREG = 4.56 \cdot 10^3 * C_{product} \text{ (sanitary purposes)}$$
$$TONNAGEREG = 1.83 \cdot 10^3 * C_{product} \text{ (lavatory).}$$

If, for example, the concentration of the disinfectant $C_{product}$ = 10 $g.l^{-1}$ (0.01 $kg.l^{-1}$) the break-even point will be reached at a regional tonnage of 45.6 $t.y^{-1}$ for saniatry purposes and 18.3 $t.y^{-1}$ for lavatory purposes. As $C_{product}$ has to be supplied by the notifier the tonnage at the break-even point can be estimated.

3. Medical sector

Annex V of Directive 98/8/EC (EC, 1998) does not specify the medical sector as a separate area. Several aspects of the use of product type 2 as disinfectant are related to this sector. Table 3.1 overviews the subdivision under product type and topics relevant for the medical sector. The topics as in Van Dokkum *et al.* (1998) which belong to product type 2, are also specified in this table.

Table 3.1 Subdivision of product type 2 for topics relevant to the medical sector according to Annex V (EC, 1998) and BIOEXPO[1] (Van Dokkum et al., 1998)

Annex V		BIOEXPO
2.1	Medical equipment	Sterilisation of medical instruments in hospital
2.4	Accommodation for man	Disinfection in accommodations for man (bathrooms, toilets, chemical closets, walls and floors in institutions [amongst others hospitals])
2.7	Waste water	Sewage water from hospitals
2.8	Hospital waste	Infectious waste (including hospital waste)
2.10	Others	Laundry disinfectants (hospitals)

All topics relevant to the medical sector are described here. Section 3.1 deals with the definitions and requirements, as well as the processes and chemicals involved.

3.1 Sterilisation, disinfection and cleaning

This section deals with definitions and requirements, and processes and chemicals related to the particular topics and is derived from Dutch directives on disinfection and sterilisation to a large extent(WIP, 1991; WIP, 1998).

Sterilisation

Sterilisation is a process in which all organisms are killed or eliminated. Disinfection is a chemical or physical process aimed at eliminating the risk of passing micro-organisms. Which method is chosen depends on a number of factors, such as the nature of the material, the possible organisms concerned and the risk of infection for patients and personnel.

[1] Development of a concept for the environmental risk assessment of biocidal products for authorization purposes (BIOEXPO)

Sterilisation, conducted by heating in most cases, is required for:

- medical aids and instruments for direct contact with sterile body tissue, the bloodstream, or the circulatory system,
- accessories for endoscopes (biopsy tongs, cutting instruments, etc.),
- scopes to be inserted in sterile body tissue or cavities.

Sterilisation methods that may be applied are:

1. dry heating,
2. moist heating with saturated steam (e.g. at a temperature of 120 degrees Celsius and a pressure of 200 kPa),
3. subatmospheric steam in combination with a disinfectant,
4. ethylene oxide (ETO),
5. gamma radiation,
6. plasma sterilisation,
7. sterilisation with fluids,
8. ultraviolet (UV) radiation.

With reference to the sterilisation methods above, for methods 1, 2, 5, and 8 emission scenarios for none of these sterilisation methods have been developed, since no biocides are involved. The third method (3) is no longer applied in the Netherlands since the use of the disinfectant, formaldehyde, is prohibited for medical purposes in conformance with the Netherlands Pesticide Act. Since the General Administrative Order on Medical Aids took effect (Stb., 1995) formaldehyde sterilisers may be marketed in The Netherlands. A European standard is being drawn up at the moment. As only one specific substance, in this case formaldehyde, is involved and European standards are applicable, no emission scenario has been developed. The fourth method (4), sterilisation with ETO, is only applied to a limited number of objects, such as electronics and instruments containing thermolabile plastics (providing they are not sensitive to ETO). Sterilisation with ETO is only applied with extreme care and is bound to strict statutory regulations. Therefore this process is not covered by an emission scenario in this report. Plasma sterilisation (6) is a fairly new method. A plasma is a gas in which so much energy is introduced by means of radiation of a radio frequency that molecules are split into atoms and electrons are released from the atoms. Therefore a plasma is very reactive, reacting within a short time with essential substances in the cells of micro-organisms. An advantage is that no hazardous residues will be formed. So far, most of the experience has been acquired using a hydrogen peroxide gas plasma; this method is not allowed on the Dutch market and no emission scenario document has been developed (the substance used is unlikely to be released as it decomposes completely). Besides plasma sterilisation, small-scale experiments are carried out at using sterilisation with fluids (7): peracetic acid with or without hydrogen peroxide. Since the status of the method is unclear, no emission scenario is presented. Furthermore, the substances involved are used as disinfectants and will be covered as such in this report. It should be noted that such

equipment is designed specifically for the use of a certain chemical with unique containers and other provisions. The equipment put on the market meets the requirements of the European Union Medical Device Directive (MDD) (EEC, 1993). This means that the equipment can be placed anywhere within the EU market. It is not necessary, to ask for admission of disinfectants used in the equipment.
The practical applications of UV radiation depend on the killing action of the radiation on agents such as for example yeast, bacteria and viruses (Shechmeister, 1991). UV radiation may be considered as a surface steriliser only (Russell, 1991).

Disinfection
Disinfection has been replaced by cleaning in many cases nowadays, as disinfection is not always considered necessary. Thermal disinfection is, if possible, always and in all places preferred. Disinfection is required for:

- medical aids coming into contact with mucous membranes (e.g. "scopes", respirators, hose systems for anaesthesia),
- medical aids usually cleaned after use but which have been used incidentally on an infected patient,
- medical aids used for large amounts of excretionary products (bedpans, urinals, sputum basins); cleaning and thermal disinfection are often carried out in one operation,
- surfaces with blood or blood-containing material, pus or infected secretions.

The way disinfectants affect micro-organisms can vary. Table 3.2 presents an overview of the action mechanisms, representative groups of chemicals and their antimicrobial activity. On the list of disinfectants of the German Society for Hygiene and Microbology (DGHM, 2001) are 78 active substances according to Gartiser und Stiene (1999). Amongst these active substances were 14 quartenairy ammonium compounds, 12 aldehydes/aldehyde releasing compounds and 9 phenols/phenol derivatives (Gartiser und Stiene, 1999). These active substances include those used for disinfection of hands and skin; it is not yet clear whether they are considered as biocides within the scope of Directive 98/8/EC.

Table 3.2 Mechanisms of action on micro-organisms, representative categories of chemicals and antimicrobial activity (WIP, 1991)

Effect	Category	Antimicrobial activity *)						
		veg	myco	spor	fung	LF	HF	H/H
Dehydration and denaturation	**alcohols**							
	ethanol 70%	++	++	-	++	++	++	++
Oxidation, inactivation nucleic acids	**halogens**							
	chlorine **) 1000 ppm	++	++	++	++	++	++	++
	iodine(+alc) 1%/70%	++	++	±	++	++	++	++
	iodophore 10% aq.	++	+	±	±	+	+	++
Denaturation of cell proteins, destruction of cell walls	**phenols**							
	o-phenyl-phenol	++	++	-	+	+	-	-
Alkylation	**aldehydes**							
	glutaraldehyde 2%	++	++	+	++	++	+	++
	succinaldehyde 10%	++	++	-	++	++	-	++
Coagulation	**biguanides**							
	chlorhexidine 0.05-4%	++	-	-	-	+	-	+
	ditto (+alc) 0.5%/70%	++	++	-	++	++	++	++
Destruction of nucleic acid	**peroxides**							
	hydrogen peroxide	++	++	++	+	++	++	?

*) ++ very effective; + effective; ± effectiveness doubtful; - not effective; ? effectiveness unknown

veg = vegetative bacteria
myco = mycobacteria
spor = spores of bacteria
fung = fungi and yeasts
LF = lipophylic viruses
HF = hydrophylic viruses
H/H = (HBV) hepatitis B virus / (HIV) human immunodeficiency virus

**) sodium hypochlorite or sodium dichloroisocyanurate; ppm refers to free chlorine

This report only considers disinfectants from the Biocidal Products Directive (e.g. substances used for disinfection of the skin are therefore excluded). Indications from the Dutch directive on disinfection and sterilisation (WIP, 1991) of the substances for disinfection are presented in Table 3.3.

Table 3.3 Indications of substances for disinfection (WIP, 1991)

Category	Example	Choice
Objects resistant to chemicals	objects where risk for transfer after contamination with pathogenic micro-organisms is considerable:	
	- not containing blood	o-phenyl-phenol 2% chlorine 250 ppm
	- possibly containing blood	chlorine 1000 ppm alcohol 70%
Surfaces resistant to chemicals	operation room floor (as far as visibly contaminated)	chlorine 1000 ppm
	nursing patients in isolation quarters	chlorine 1000 ppm o-phenyl-phenol 2%
	kitchens (surfaces and equipment coming in contact with food)	chlorine 250 ppm thermal by preference
Objects and surfaces coming in direct contact with patient	thermometers, parts of anaesthesia equipment, transducers, etc.	alcohol 70% iodine 1% in alcohol 70%
Water-resistant instruments	after use and before sterilisation	sodium perborate 2%
Vulnerable temperature-sensitive, water-resistant instruments	endoscopes	glutaraldehyde 2%
Vulnerable temperature-sensitive, not water-resistant instruments	(purpose: sterilisation)	ethylene oxide

Furthermore, disinfectants are used as preservatives in the medical sector for media where development of micro-organisms may lead to infection of patients and personnel. Usually these are fluids which are not replaced frequently enough. Often disinfectants are used, however, at a low concentration. Table 3.4 - derived from the Dutch directive on disinfection and sterilisation (WIP, 1991) - gives some indications for the use of disinfectants as preservatives.

Table 3.4 Indications of the use of disinfectants as preservatives (WIP, 1991)

Type of fluid	Substance
Bath water for physiotherapy	tosylchloramide 20 $mg.m^{-3}$
Water mattresses	aldehydes *)
Water in flower vases	sodium dichloroisocyanurate 10 ppm free chlorine
Humidifier fluid for incubators	chlorhexidine 1:2000 in water
Water seal suction equipment	chlorhexidine 1:2000 in water

*) troublesome in practice, alternatives being investigated

Cleaning

Cleaning is the process of removing visible dirt and invisible organic material to prevent micro-organisms maintaining themselves, multiplying and spreading (WIP, 1993). The aim is to use cleaning as much as possible instead of disinfection. Hospitals use disinfectant-free normal household detergents and cleaning agents for cleaning.

3.2 General assumptions

Hospitals may be considered as rather small emission sources where emissions are diffuse as they may occur at various places in the buildings. Releases with wastewater are directed to the STP of the municipalities where they reside. So, again the STP is to be considered as a point source for the local situation. In order to develop an emission scenario for hospitals it was investigated which size of hospital could be expected to discharge its wastewater to the standard STP of EUSES. Therefore, data from Germany (Gartiser and Stiene, 1999) and the Netherlands (CBS, 1997; CUWVO, 1986; RIVM, 1996) were used. Appendix 2 presents some of the data used and calculations made. There are many differences between the two countries, for example:

Germany

- non-random sample of 8 hospitals including 4 (large) university hospitals
- correction for use during weekends
- calculation for beds regardless of the occupancy rate
- data on classes of chemicals
- distinction between application areas “surfaces” and “instruments”
- water consumption including - for example – kitchens

the Netherlands

- random sample for use of active ingredients (RIVM, 1996)
- no correction for use during weekends
- calculation for beds regarding the occupancy rate (CBS, 1997)
- data for several individual chemicals
- specific application known for the individual chemicals (RIVM, 1996)
- water consumption strictly per person for 6 hospitals (CUWVO, 1986)

Despite the differences it was concluded that for the scenario a medium sized hospital with about 400 beds of which some 300 are occupied (occupancy rate about 70%) may be considered. If the EU average for the hospital size should be much larger it does not seem necessary to take that into account as the amount of wastewater will be too large for the standard STP of EUSES. Then a proportionally larger STP should be considered impelling to overwriting default values without leading to different PEC calculations. It should be noted that the attention is focussed on application of biocides in aqueous solutions. Products like alcohols used as such will evaporate completely (diffuse air emissions) and not reach the sewer.

So, recapitulating the various applications of biocides in a hospital the following situations are considered:

Sterilisation of medical instruments (product subtype 2.1)	- [1)]
Disinfection of rooms, furniture and objects (product subtype 2.4 of Table 3.2 'accomodation for man')	Section 3.3
Disinfection of medical instruments	Section 3.4
Disinfection of laundry (product subtype 2.10 of Table 3.2 'others')	Section 3.5
Disinfection of hospital waste	Section 3.6

[1)] not considered here as this is covered in the Medical Device Directive 93/42/EC)

In those cases that a disinfectant has been notified for more than one application, the results for the emission rates to wastewater ($Elocal_{3,water}$) have to be summed.

3.3 Disinfection of rooms, furniture and objects

Before disinfection, normal domestic cleaning is always carried out. Furniture and objects are cleaned with disposable cloths and soap or synthetic detergents. The cleaning of floors can be carried out wet or dry. Sanitary fittings are divided into "clean" and "dirty". Clean sanitary fittings are e.g. sinks and tiles; dirty sanitary fittings are e.g. the inside of toilet bowls, toilet seats and the low tiles next to the toilet bowls.
The cleaned surfaces and objects are then treated with a disinfecting solution so that everything will remain wet for at least five minutes, i.e. the minimum exposure time required. The disinfected surfaces are allowed to air-dry. The dosage must be exact and the prescribed operating instructions must appear on the label of the disinfectant containers.

The only place where obligatory disinfection is carried out is in isolation wards. Only in the case of strict isolation disinfection has to be carried out daily, otherwise wards can be disinfected just after termination of the isolation. The disinfection applies to floors, furniture and objects in the room itself, the sanitary facilities and the sluice. Other rooms are only disinfected in situations where contamination occurs due to spilling of possible infectious material. If the disinfectant concerned is the same as for the disinfection of lavatories and surfaces in accommodations for humans (households, offices, public places, etc.), the scenarios of Chapter 2 are used. Otherwise the scenario described in this subsection has to be used.

In order to prevent spreading of contamination it is necessary that cleaning equipment is cleaned, disinfected and dried daily. Objects disinfected are buckets and (plastic) brushes. Buckets are disinfected in the bedpan-washer machines, where thermal disinfection is applied. Brushes are immersed in a disinfecting solution (e.g. 1000 ppm free chlorine or 2%

o-phenyl-phenol), rinsed and dried. Cloths are of the disposable type. Mops are preferably disposable, otherwise will to be washed in the laundry. The text above is derived from the Dutch directive on disinfection and cleaning of rooms, furniture and objects (WIP, 1993).

3.3.1 Scenario description

As for disinfectants used for sanitary purposes two scenarios are presented, viz one with the basis of the tonnage and one applying an amount of aqueous solution. In both scenarios it is difficult to establish a representative emission factor. All disinfectant present in the fraction of the solution that remains on the surfaces will be remain there until it is degraded, transported via contact or evaporate. It may theoretically be assumed that some of the remaining disinfectant will be removed at the next cleaning operation and still transferred to the wastewater. The disinfectant applied in sinks and toilet bowls and present in the remaining solution after disinfection is discharged into the sewer. Because of the lack of data a best guess for the fraction released to waste water of 0.75 has been made.
In the scenario where that the tonnage is used a fraction of the tonnage has to be estimated for the model hospital. This is not the fraction of the main source as here the relation is used between a realistic worst case size hospital connected to the standard STP of EUSES. For this fraction the ratio of the average number of beds : number of beds in the region is used. The values for the Dutch (CBS, 1997) situation has been used (because the area of the Netherlands is approximately the same as the regional area of EUSES, i.e. 200 x 200 km^2 and the fact that the data for the number of beds and the number of patient days were available). If data for the whole EU become available and differ much from the Dutch situation another default should be introduced. The fraction for the model hospital, $F_{hospital}$ = 0.007.
For the second scenario it is assumed that 25 litres of water are used for surfaces and 25 litres for objects (brushes). If the average amount in wastewater due to use on surfaces is considered for all disinfectants (excluding alohols) (derived from UBA, 1999; see also Appendix I) together with the number of beds in the model hospital (409, see aslo Appendix I), a daily application of 409 * 3.08 = 1260 g active ingredient can be estimated. With subscribed concentrations of 2 to 4 % by weight of active ingredients (e.g. 2 % for o-phenyl-phenol and 4 % for chlorhexidin) this would be 500 – 1000 g for a single used disinfectant with the 25 l defaults each for surfaces and objects. Because of the fact that most hospitals use more than one active ingredient for disinfection of rooms, furniture and objects the approach of 25 litres seems acceptable.
The emission factor will be different for the respective applications. It is assumed that the solution used for brushes will be discharged into the sewer after disinfection; so, as a best guess the fraction released to wastewater is set at 0.95 as a default. Together with the emission factor of the other scenario, which concerns both applications, the fraction for sanitary purposes is calculated from 0.5 * fraction for brushes ($Fobj_{3,water}$) + 0.5 * 0.95 ($Fsan_{3,water}$) = 0.75, namely $Fobj_{3,water}$ = 0.55. This calculation is made assuming that equal amounts of disinfectant are used for both purposes.

3.3.2 Emission scenarios

Table 3.5 presents the emission scenario applying the tonnage of the disinfectant and Table 3.6 the scenario for the amount of aqueous solution used.

Table 3.5 Emission scenario for calculating the releases of disinfectants used for sanitary purposes 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 [1)]		
B)			
Relevant tonnage in EU for this application (tonnes.yr^{-1})	TONNAGE [1)]		
Fraction for the region A + B)	F_{reg}	0.1	D
Fraction for the hospital (-)	$F_{hospital}$	0.007	D
Fraction released to waste water (-) [2)]	$F_{3,\ water}$	0.75	D
Number of emission days for life cycle stage 3 (processing) (d)	$Temission_3$	260	D
Output:			
$Elocal_{3,water}$ = Emission rate to waste water (kg.d^{-1}) [2)]			

1) In principle this should be $TONNAGE_k$ to identify usage in product *k* but this is not shown just as in the EUSES documentation

2) The subscript "3" refers to the stage of processing in conformity with EUSES 1.0 and USES 2.0.

Intermediate calculations:

B)

Relevant tonnage in the region for this application (tonnes.yr^{-1})

$TONNAGEREG = F_{reg} * TONNAGE$

End calculations:

A + B)

$$Elocal_{3,water} = TONNAGEreg * 10^3 * F_{hospital} * F_{3,water} / Temission_3$$

Table 3.6 Emission scenario for calculating of the releases of disinfectants used for sanitary purposes in hospitals based on the amount of solution of disinfectant used on a day

Variable/parameter (unit)	Symbol	Default	S/D/O/P
Input:			
Fractions released to waste water [1)]			
Sanitary purposes	$Fsan_{3,\ water}$	0.55	D
Brushes	$Fobj_{3,\ water}$	0.95	D
Concentration at which active substance is used ($kg.l^{-1}$)			
Sanitary purposes	C_{san}	.	S
Brushes	C_{obj}	.	S
Amount of water with active substance ($l.d^{-1}$)			
Sanitary purposes	Q_{water_san}	25	D
Brushes	Q_{water_obj}	25	D
Output:			
$Elocal_{3,water}$ = Emission rate to waste water ($kg.d^{-1}$) [1)]			

[1)] The subscript "3" refers to the stage of processing in conformance with EUSES 1.0 and USES 2.0.

Model calculations:

$Elocal_{3,water} = Q_{water\_san} * C_{san} * Fsan_{3,\ water}$ (sanitary purposes)

$Elocal_{3,water} = Q_{water\_obj} * C_{obj} * Fobj_{3,\ water}$ (brushes)

$Elocal_{3,water} = Q_{water\_san} * C_{san} * Fsan_{3,\ water} + Q_{water\_obj} * C_{obj} * Fobj_{3,\ water}$ (sanitary purposes + brushes)

Above a certain tonnage (at the break-even point), as explained in Apendix 3, the scenario based on the tonnage should be applied preferably. If the default values are filled in in the formulas for the calculation of the local emissions to wastewater, $Elocal=_{3,water}$, the break-even point can be written in the form:

$TONNAGEREG = 956 * C_{san}$ sanitary purposes

$TONNAGEREG = 1650 * C_{obj}$ brushes

$TONNAGEREG = 956 * C_{san} + 1650 * C_{obj}$ sanitary purposes

If, for example, the prescription for the working concentration is 0.04 $kg.l^{-1}$ the break-even point- above which the scenario of Table 3.5 should be taken preferably – is reached at a regional tonnage of 38.2 $t.y^{-1}$ for sanitary purposes, 66 $t.y^{-1}$ for objects and 104 $t.y^{-1}$ for sanitary purposes + objects respectively.

3.4 Disinfection of instruments

Disinfection of instruments like endoscopes – referred to as scopes in most cases – should be done in automated washers/disinfectors (BSG, 1998). The majority of the hospitals with endoscopy units performing several thousands procedures per year use these washers nowadays (Van Gossum *et al.*, 1989). Where patient turnover is low, manual disinfection is still carried out. The washers are connected to the sewer for removal of the waste water (including the spent disinfectant). As disinfectants such as aldehydes are fairly volatile, washers/disinfectors are supplied with air-exchange equipment, e.g. exhaust hood, ventilation system, etc.) (WIP, 1998; APIC, 1994). The contents of (ultrasonic) baths used for manual disinfection will also be discarded into the sewer. For the emission scenario, use of automated washers/disinfectors is considered as these will penetrate almost completely, manual disinfection being unacceptable in the light of the working conditions. Other instruments are disinfected in solutions (or suspensions) of disinfectants to prevent adhesion of blood, pus, etc. These baths are discarded into the sewer after use.
If a biocide is notified for both disinfection of scopes and other instruments, the emission for a single point source (one hospital) should be calculated by summing the results of both emission scenarios (Tables 3.6 and 3.7).

3.4.1 Scenario description endoscopes

The most widely used disinfectant is glutaraldehyde at a concentration of 2% (WIP, 1998; RIVM, 1996; APIC, 1994). The emission scenario assumes that the model hospital has all possible units for performing endoscopy procedures as the enquiry (RIVM, 1996) shows that relatively small hospitals may have washers/disinfectors for every speciality related to endoscopy. Therefore the model takes the hospitals in the enquiry with the highest glutaraldehyde consumption as the basic institution since these hospitals can be considered to be average-sized hospitals. These hospitals use 150 kg glutaraldehyde per year in three machines.
In the original report (Van der Poel, 1999a) a scenario was presented that considers washers/disinfectors with replacement of the disinfectant solutions at regular intervals. More and more systems are brought into use nowadays where a fresh disinfectant solution is applied every disinfection operation; the substance is discarded into the sewer after disinfection (communication by B. Henry at the 2nd meeting of the EUBEES meeting, January 2001). This system is considered also in this report and denoted here as ‘once-through’ (the other system being denoted as ‘replacement’).

Replacement

Replacement of the disinfectant solution can be done at regular intervals or at a certain measured minimum concentration. Many hospitals contacted recently state that replacement

is carried out every two weeks; however, the glutaraldehyde concentration is not known at the moment of replacement. The disinfectant concentration declines during use because of:
1. dilution due to the carry-over of water (APIC, 1996; Bradley, 1994),
2. carry-over of disinfectant onto the scopes going to the rinsing phase,
3. volatilisation from the solution,
4. probable decomposition or chemical reaction.

The original report (Van der Poel, 1999a) presented a scenario for a washer with periodical replacements only. There are, however, more and more scope washers being used with a "once through" system; this means that the solution is used once and discharged after the washing operation immediately (personal communication to B. D. Henry, 2001). So, this report deals with both types.

In a guideline from the United States (APIC, 1996) results of several investigations are given on glutaraldehyde declines, e.g. from 2.4% to 1.5% after 10 days in manual and automatic baths used for endoscopes (Mbithi *et al.*, 1993). The report mentions one investigator establishing a minimum effective concentration of 1.5%. Test strips constructed to indicate concentrations above 1.5% are available. The model assumes by default that replacement is carried out at regular intervals, with those replacements carried out the same day once every two weeks in the case of more than one washer/disinfector. This is expressed in the model as a replacement frequency of 25 times per year (with 150 kg in three machines and a concentration of 2% glutaraldehyde in the fresh solution, i.e. an amount of 100 l per machine per event).
Water emissions due to rinsing treated scopes are not considered in the model as the (daily) discharges to the sewer are negligible compared to the discharges at replacement of the disinfectant solution. They are, however, taken into account for the calculation of the remaining fraction of the disinfectant at replacement of the bath.
At the time that the original report on hospital disinfectants was written (Van der Poel, 1999a) the evaporation was also considered in the model. Calculations showed that evaporation of glutaraldehyde might be responsible for the decrease in concentration. In these calculations a vapour pressure of 2.3 kPa (WHO/IPCS/ILO, 1998) was used. This vapour pressure, however, is mainly due to the partial vapour pressure of the solvent (water). (personal communication with B.D. Henry, 2001). According to the data supplied by e-mail (Henry, 2001) the partial vapour pressure of glutaraldehyde is 27 Pa at 20° C, whereas the reduction in glutaraldehyde concentration is caused by:

Evaporation	ca	0.25	%
Reaction (aldol condensation)	ca	25	%
Carry over	ca	75	%

The emission of the disinfectant into the air because of volatilisation from the solution will decrease when the concentration in the solution decreases. The maximum emission will occur

on the first day after refreshing the bath. In the original report (Van der Poel, 1999a) a scenario was presented using the method described by R.G. Thomas in Lyman *et al.* (1990) for the calculation of this volatilisation. This method follows the two-film concept for estimating the flux of volatiles across the air-water interface. For this method the following data are needed:

- Chemical properties: vapour pressure, water solubility, molecular weight,
- Environmental characteristics: wind speed, current speed and depth of water body.

Model calculations were carried out for glutaraldehyde showed that volatilisation would be able causing the drop in concentration of 2 to 1.5 % in two weeks. These calculations used the following input data. A value for the vapour pressure of 2.3 KPa (WHO/IPCS/ILO, 1998). For the solubility of glutaraldehyde the only results found in literature were "reacts with water" or "miscible". For the calculation of Henry's law constant 950,000 $mg.l^{-1}$ was used. Furthermore, in the calculations values for the depth of the bath ≥0.5 m, wind speeds of ≤0.5 $m.sec^{-1}$ and water speeds of 0.5 $m.sec^{-1}$ were applied.
According to Henry (2001) the partial vapour pressure of glutaraldehyde is 27 Pa at 20º C. This was confirmed by recently found data (SRC, 2001) stating a vapour pressure of 6 mm Hg (approx 26.7 Pa) at 25° C and an estimated Henry coefficient of 1.1E-007 $atm.m^3.mol^{-1}$ (approx 0.011 $Pa.m^3.mol^{-1}$). The calculation for air emissions is skipped in the model if the value of the Henry coefficient is less then 0.03 $Pa.m^3.mol^{-1}$ (erroniously 3 $Pa.m^3.mol^{-1}$ in the original report) as volatilisation can be considered negligible (Lyman *et al.*, 1990).This means that the evaporation of glutaraldehyde is negligible; processes such as degaradation/reaction and dilution and transfer of bath liquid are causing the decrease in disinfectant concentration. It is very likely that other substances probably used as disinfectants in scope washers will have comparable values for the Henry coefficient. Therefore, the emission to air is left out in the scenario presented in this report. Another reason for this is the fact that we are dealing here with a small point source that will give rise to very low air concentrations.

The scopes are pre-cleaned before they are transferred to the washer/disinfector. The cleaned scopes are brought over without drying thus introducing water into the disinfectant solution. After the disinfection operation the scopes are taken out of the washer/disinfector removing some of the (slightly diluted) solution. This effect is denoted here as ‘carry-over’ and a carry-over factor is introduced here for the model. The carry-over fraction (denoted here as *r*) is defined as the fraction of the bath content replaced by water introduced and removed per day. The assumptions are that (1) the the same type and scale of disinfection operation is performed every day during the period the disinfectant solution is used in the bath, and (2) the amount of water introduced is equaling the amount of water (solution) removed.
If it is assumed that the decrease in glutaraldehyde concentration of 25 % stated earlier (from 2 % down to 1.5 %) is caused by carry-over for 75 %, according to the data supplied by Henry (2001), the following calculations can be made to establish the carry-over fraction:

[1]
The concentration of glutaraldehyde in the remaining solution after 14 days (C_T) is (2 – 0.5 * 0.75) / 2 = 0.8125 times the concentration in the fresh solution after replacement (C_0):

$$C_T = 0.8125\ C_0.$$

[2]
The concentration in the bath for the days during use of the washer/disinfector for a period of T days can be written as:

concentration on day 1 $C_1 = C_0 / (1 + r)$
concentration on day 2 $C_2 = C_1 / (1 + r) = C_0 / (1 + r)^2$
⎪
concentration on day T $C_T = C_0 / (1 + r)^T$

[3]
Filling in C_T from [1] and T = 14, the fraction carry-over is calculated as r = 0.0149. This means that with a bath content of 100 l an amount of approximately 1.5 l is discharged into the sewer daily.

Apart from removal of disinfectant from the bath due to the process described above the concentration of a disinfectant may decrease over time due to chemical reactions. Aldehydes such as glutaraldehyde tend to form dimers and trimers, a reaction known as the aldol condensation. This reaction occurs especially under alkaline conditions which arise as glutaraldehyde is “activated” by an alkaline buffer (Henry, 2001). So far, no data on the order of the reaction could be found leading to the assumption of a 1st order reaction. The model has a possibilty to specify a rate constant for degradation ($kdeg_{disinf}$) due to chemical reactions such as the aldol condensation. If no value is supplied by the notifier the scenario performs calculations with a value of zero.

Once-through

This system requires less information as degradation due to chemical reactions may be neglected (the residence time is relatively short) and there is no carry-over of bath contents. As no data on annual consumption of disinfectant in once-through washers/disinfectors are known the 150 kg.y^{-1} for glutaraldehyde stated before are also used here. For the concentration of glutaraldehyde in the bath 1.5 % (15 g. 1^{-l}) is used as mentioned by Henry (communication by Henry (2001)). Assuming also three machines in the model hospital operating 365 days per year a once-through machine would have an average bath size of 150.10^3 / (15 * 3 * 365) = 9 l. Until better data become available the scenario will use a bath size of 10 l.

Table 3.7 presents the emission scenario using the assumptions stated above.

Table 3.7 Emission scenario for calculating the release of disinfectants used in hospitals for disinfection of scopes and other articles in washers/disinfectors

Variable/parameter (unit)	Symbol	Default	S/D/O/P
Input:			
A + B) Replacement + Once-through			
Working concentration (%)	C_{disinf}	.	S
Maximum number of washers / disinfectors [1)]	$N_{rep-max}$	3	D
Volume of solution in machine (m^3)	$Q_{machine}$		
A) Replacement		100	D
B) Once-through		10	D
A) Replacement	T_{repl}	14	D
Replacement interval (d)			
Fraction carry-over (-)	Fcarry-over	0.015	D
Rate constant for chemical conversion (d^{-1})	$kdeg_{disinf}$	.	S [2)]
		0	D [2)]

Output:

$Elocal_{3,water}$ = Maximum emission rate to water ($kg.d^{-1}$) [3)]

[1)] For 'replacement' assumption that replacement occurs on the same day

[2)] Zero by default if no data are supplied

[3)] The subscript "3" refers to the stage of processing in conformance with EUSES 1.0 and USES 2.0

Intermediate calculations:

A) Replacement

Concentration at day of replacement due to carry-over (mg/l)

$$C_{c-over} = \frac{C_{disinf}}{(1 + Fcarry-over)^{T_{repl}}}$$

Concentration at day of replacement including conversion (mg/l)

$$C_{repl} = C_{c-over} * e^{-kdeg_{disinf} * T_{repl}}$$

End calculations:

A) Replacement

$Elocal_{3,water} = N_{rep-max} * Q_{machine} * C_{repl} * 10^{-6}$

B) Once-through

$Elocal_{3,water} = N_{rep-max} * Q_{machine} * C_{disinf} * 10^{-6}$

3.4.2 Scenario description other instruments

In all out-patient departments instruments are disinfected locally in baths which are regularly disposed of into the sewer. From the enquiry (RIVM, 1996), it was not quite clear which amount of disinfectant was released per day when a bath is replaced. The amounts of active substance used per year varied between 5 and 125 kg for average-sized hospitals (in most cases disinfectants with two active substances are used whereas both active substances have almost the same concentration). The emission scenario applies a default of 250 kg of active substance per year and a number of 100 replacements per year. The substances applied are supposed to have negligible volatilisation losses. In contrast to the original report (Van der Poel, 1999a) where it was assumed that no concentration reduction occurs, this scenario has the possibility to correct for degradation due to chemical conversion. Table 3.8 presents the emission scenario using the assumptions stated above.

Table 3.8 Emission scenario for calculating the releases of disinfectants used in hospitals for disinfection of contaminated instruments

Variable/parameter (unit)	Symbol	Default	S/D/O/P
Input:			
Amount of active substance ($kg.y^{-1}$)	$Qyear_{disinf}$	250	D
Emission days, i.e. replacements (y^{-1})	$Temission_3$ [2]	100	D
Rate constant for chemical conversion (d^{-1})	$kdeg_{disinf}$	.	S [1]
		0	D [1]

Output:

$Elocal_{3,water}$ = Maximum emission rate at the day of a replacement ($kg.d^{-1}$) [2]

[1] Zero by default if no data are supplied

[2] The subscript "3" refers to the stage of processing in conformance with EUSES 1.0 and USES 2.0

Intermediate calculations:

Average time a disinfectant solution is in use (d)

$T_{repl} = INT\ (365 / Temission_3 + 0.5)$ [1]

End calculations:

$$Q_{repl} = \frac{Qyear_{disinf}}{Temission_3} * e^{-kdeg_{disinf} * T_{repl}}$$

[1] INT = Integer (this notation has been used to ensure that in computer calculations a whole numer for the number of days will be returned)

3.5 Laundry disinfectants

Most Dutch hospitals nowadays do not have their own laundry but send the laundry out to specialised laundries (WIP, 1993) (personal communication with A. Sprenger, Hilversum hospital, 1998). At the moment about 100 large laundries are in operation for the catering industry and health care (Rozenburg, 1998). One large company, active in 8 EU countries with 25 establishments in the Netherlands and 35 in Germany, offers so-called re-usable OR (operating room) systems to hospitals. These consist of a complete supply of patient-covers and clothing for the OR staff (Rentex, 1998). The Directive for linen (WIP, 1993) has no guidelines for hygiene in laundries but refers to the handbook of the Certex Foundation, which certifies laundries according to ISO 9002. It has 46 certified members with a market share of about 80% in The Netherlands (Certex, 1998).
In the certification the means for disinfection described is a time-temperature formula. It is possible, however, that disinfectants are used in laundries at present (personal communication with A. Sprenger, Hilversum hospital, 1998 and with P.G.M. Valk, Foundation Certex, Tilburg, 1998). The use of disinfectants in laundries is mentioned in literature (Van Dokkum *et al.*, 1998; Van Kasteren, 1998)., It turned out that at some (large) laundries approached in case of contaminated clothing disinfectants, especially hydrogen peroxide and hypochlorite, are commonly used.

Biologically contaminated laundry is packed in special (coloured) bags to distinguish it from ordinary laundry. The contaminated laundry is then not sorted but put directly into the machine where the bag is opened automatically. Some laundries treat the contaminated laundry in a separate washing machine (like hospitals with their own laundries); others put it into the 'washing street' (a series of one or more washing "tubes", i.e. continuously operating machines where the laundry enters dirty at one end and leaves clean at the other between the normal laundry). A number of certified laundries was approached by telephone; from the information gathered it turns out that in the case of the ‘washing street’ some laundries always use hydrogen peroxide or hypochlorite, while others use tumbler washing machines (10 - 25 kg laundry per batch) and rely on the temperature-time formula. In the latter method the temperature may be raised from 80-85° C to 90-95° C or a detergent-like peracetic acid may be used at a lower temperature (60° C) for temperature-sensitive fabrics.

Scenario description
The size of commercial laundries can vary considerably but large laundries may have three or more washing tubes with a capacity of 8000 $kg.day^{-1}$ per tube, producing 48 $m^3.day^{-1}$ of waste water (Van Kasteren, 1998) (personal communication with Dr.ir. P. Brasser of the Technical University of Delft, 1998). It is assumed here that a commercial laundry connected to the standard STP of EUSES/USES (2000 m^3 waste water per day) can have three washing tubes (3 * 48 = 144 m^3 waste water per day). On the other hand, the situation is considered where a

hospital is doing its own laundry or where the contaminated laundry is done at a commercial laundry using a tumbler washing machine. It is estimated that per kg of dirty laundry 6 g of detergent ("soap") is used, 4 g for soaking and 2 g for the washing cycle (Van Kasteren, 1998). In the case of disinfection, it is estimated that about 10% of the amount of soap is disinfectant.

The scenario for washing streets is presented Table 3.9 as this represents the worst case situation, using the assumptions stated above.. The scenario for tumbler washing machines is presented in Table 3.9. This scenario is of importance for the overall calculation in case a disinfectant is also notified for one or more other purposes such as disinfection of rooms, objects and instruments.

Table 3.9 Emission scenario for the calculating the release of disinfectants used for doing biologically contaminated laundry from hospitals in washing streets

Variable/parameter (unit)	Symbol	Default	S/D/O/P
Input:			
Number of washing tubes (with disinfectant) (-)	Nm	3	D
Capacity of washing tube ($kg.d^{-1}$) *(laundry)*	Cap	8000	D
Amount of disinfectant for laundry ($l.kg^{-1}$)	$V_{product}$		S
Concentration active substance in disinfectant ($kg.l^{-1}$)	$C_{disinf1}$		S
Concentration reduction in washing process	F_{red}	0	D
Output:			
$Elocal_{3,water}$ = Maximum emission rate at the day of a replacement ($kg.d^{-1}$) [1)]			

[1)] The subscript "3" refers to the stage of processing in conformance with EUSES 1.0 and USES 2.0.

Model calculations:

a) Washing street

a.1) $Elocal_{3,water} = Nm * Cap * V_{product} * C_{disinf1} * (1 - F_{red})$

Table 3.10 Emission scenario for the calculating the release of disinfectants used for doing biologically contaminated laundry from hospitals in tumler washing machines

Variable/parameter (unit)	Symbol	Default	S/D/O/P
Input:			
Capacity of machine (kg)	Cap	25	D
Number of batches (d^{-1})	Nb	3	D
Amount of disinfectant for laundry ($l.kg^{-1}$)	$V_{product}$		S
Concentration active substance in disinfectant ($kg.l^{-1}$)	$C_{disinf2}$		S
Concentration reduction in washing process	F_{red}	0	D
Output:			
$Elocal_{3,water}$ = Maximum emission rate at the day of a replacement ($kg.d^{-1}$) [1)]			

[1)] The subscript "3" refers to the stage of processing in conformance with EUSES 1.0 and USES 2.0.

Model calculations:

b) Tumbler washing machine

$Elocal_{3,water} = Nb * Cap * V_{product} * C_{disinf2} * (1 - F_{red})$

3.6 Hospital waste disinfectants

In the General Administrative Order Decree Hazardous Waste (Stb., 1993) of the Environmental Protection Act a definition is given for the waste streams which are regarded as hazardous waste (see Table 3.11). This category of potentially infectious hazardous waste is usually called ‘hospital waste’. According to the Act hospital waste may only be delivered to a competent firm for collection or processing.

Table 3.11 Waste streams originating from medical treatment in intramural and extramural health care according to the General Administrative Order, Decree Hazardous Waste (Stb., 1993)

No.	Waste stream
46.1	Human anatomical remains and parts of organs released in operative and obstetrical surgery, in obduction and in scientific research/education
46.2	Laboratory animals and parts of laboratory animals (if not presented for destruction)
46.3	Waste from accommodations for laboratory animals as far as it is contaminated with pathogens
46.4	Waste from wards/rooms where patients are nursed in isolation because of danger of infecting hospital personnel
46.5	Waste from microbiological laboratories contaminated with bacteria, viruses or yeasts
46.6	Sharp objects such as (hypodermic) needles, capillaries snipped off, scalpels, unserviceable instruments and blood tubes
46.7	Larger amounts of blood, plasma and other paste-like and liquid waste materials
46.8	Cytostatica

Hospital waste has to be incinerated at ZAVIN in Dordrecht. ZAVIN is the only competent processor for hospital waste in the Netherlands (in cases of peaks, the kiln oven of AVR at Rotterdam is allowed to function as a "catch"). The waste is packed in sealed containers immediately after creation, so no disinfectants are used. In some cases hospital waste is sterilised in an autoclave at the source. After this sterilisation the remaining waste can be treated as normal waste. However, it is known that in one case the remaining waste is still sent for incineration to ZAVIN after removal of components suitable for recycling, e.g. glass. At the moment pilot projects are planned for three places in the Netherlands in which a combined shredder / disinfection system, as mentioned in the BIOEXPO report (Van Dokkum, 1998), will be used. In France there are two routes for the disposal of waste with infectious risks according to the Minsitry of the Environment (Migné, 2001). This waste should be either incinerated or preliminary treatment. The preliminary treatment processes are carried out in disinfection equipment as mentioned earlier, which is validated by the Upper Council of Public Health of France (Conseil supérieur d'hygiène publique de France, CSHPF). Of the ca 15 machines validated at the moment (MES, 1999) two apply chemicals

for disinfection. One machine states that a disinfectant with a large antimicrobial activity and the other that acetic acid plus hydrogen peroxide is used. Preliminary treated hospital waste is assumed to be comparable to household waste; it may be incinerated or landfilled but composting has been excluded.

As no data were available at present on amounts of hospital waste treated and disinfectant used no emission scenario estimating the amount of disinfectants landfilled and incinerated. For the fate of biocides at the stage of waste treatment a report has been generated already (Van der Poel, 1999b).

3.7 Disinfectants with more than one application

If a disinfectant has been notified for more than one application, the results for the emission rates to wastewater ($Elocal_{3,water}$) of the individual scenarios that are applicable have to be summed. This concerns the scenarios of Tables 3.5, 3.6, 3.7 and 3.9.

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30		Hoofd Laboratorium voor Stoffen en Riscobeoordeling
31		Hoofd Laboratorium voor Ecotoxicologie
32		Hoofd Laboratorium voor Effectenonderzoek
33		Hoofd Laboratorium voor Luchtonderzoek
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Appendix 2 Underlying data used

For the scenarios described in this report is was assumed that the model hospital is situated near a locality that discharges its wastewater to the standard STP of EUSES, which means 2000 m^3 of wastewater per day (10,000 inhabitants, 0.2 m^3 wastewater $cap^{-1}.d^{-1}$). In order to see if this can be expected to be a reasonable assumption related to the size of the hospital expressed as the number of beds and the wastewater produced some data available for Germany and the Netherlands were investigated:

A) Germany
The data discussed here are derived from Gartiser and Stiene (1999). The amount of wastewater for 8 selected hospitals ranges from 278 – 641 $l.d^{-1}.bed^{-1}$ with an average of 500 $l.d^{-1}.bed^{-1}$.
The consumption of active ingredients – expressed as $g.bed^{-1}.d^{-1}$ - the 8 hospitals surveyed is presented in the table below; the number of observations is stated between parenthesis:

Group:	Alcohols	Aldehydes	Quats	Alkyl amines	Guana-dines
Surfaces	(6)	(8)	(8)	(5)	(3)
Average	2.13	0.94	0.78	0.46	0.06
Minimum	0.26	0.02	0.05	0.04	0.03
Maximum	4.54	2.12	1.95	1.21	0.17
Instruments	(8)	(8)	(6)	(2)	(3)
Average	1.38	0.94	0.36	0.69	0.06
Minimum:	0.09	0.07	0.06	0.33	0.00
Maximum:	4.36	1.62	1.30	1.22	0.14

Group:	Per-compounds	Halogen releasers	N-acetals	REST	TOTAL (ex alcohols)
Surfaces	(1)	(3)	(0)	(4)	
Average	0.71	0.03	-	0.10	3.08
Minimum	.	0.0002	-	0.02	
Maximum	.	0.07	-	0.22	
Instruments	(5)	(5)	(5)	(6)	
Average	0.17	0.30	0.38	0.23	
Minimum:	0.02	0.01	0.03	0.03	
Maximum:	0.29	0.74	1.33	0.98	

B) the Netherlands

Data on water consumption		*Source*
Number of hospitals	148 (-)	CBS (1997)
Number of beds	60.489 (-)	CBS (1997)
Number of patient days	15,779,000 (y^{-1})	CBS (1997)
Number of employees	137,478 (-)	CBS (1997)
Amount of wastewater	133 - 270 ($l.d^{-1}.cap^{-1}$; patients + personnel)	CUWVO (1986)

Calculations

1. Average number of patient-days per year	15,779,000 / 148	=	107,000
2. Average number of employees	137,478 / 148	=	1300
3. Estimated percentage of employees present per day			70
4. Average amount of wastewater per person ($l.d^{-1}.cap^{-}$)	(133 + 270) / 2	≅	200
5. Average amount of wastewater from one hospital ($m^{-3}.d^{-1}$)	(107,000 / 365 + 0.7 * 1300) * 0.2	=	250
6. Average number of beds in a hospital (-)	60,489 / 148	≅	409
7. Ratio average number of beds in a hospital / number of beds in the Netherlands (-) (= fraction of model hospital)	409 / 60,489	≅	0.007

Data on biocide consumption

For three individual biocides (active ingredients) data on the annual use were available from an enquiry (RIVM, 1996):

active ingredient	amount ($kg.y^{-1}$)	number of hospitals
glutaraldehyde	679	14
Sodium perborate	518	7
tetraacetylethylenediamine	389	7
4-chloro-benzylphenol and *o*-phenylphenol	80	7

Calculations

As the random sample for this enquiry was supposed to be representative for the population the average number of occupied beds of the above calculations was used to calculate the minimum, average and maximum amounts of active ingredient per occupied bed per day ($g.bed^{-1}.d^{1}$):

active ingredient	minimum	average	maximum
glutaraldehyde	0.04	0.33	0.84
Sodium perborate	0.04	0.52	0.86
tetraacetylethylenediamine	0.27	0.38	0.64
4-chloro-benzylphenol and *o*-phenylphenol	<0.01	0.08	0.41

Appendix 3 Differences between emission scenarios

In general two types of emission scenarios may be distinguished, viz one based on the regional tonnage and the other on the consumption.

1. Emission scenario based on tonnages

In general no regional tonnage will be known for an arbitrary substance. In that case the regional tonnage is derived from the EU tonnage by multiplication by 0.1 (10 % rule). This is about twice the amount that may be expected on account of the fraction of inhabitants in the region of the EU (see 4). Such a situation will not be unlikely in most cases as it may be expected that the more densely populated areas will have more industrial activities than the rural areas.

For diffuse emissions caused by e.g. households the standard STP with 10,000 inhabitants feeding the system and an amount of 0.2 m^3 wastewater per inhabitant per day is considered as a point source. If the use of a substance would be evenly distributed over the population (consumers) and STPs in a region and over the week, the fraction of this substance reaching the standard STP of EUSES would be *number of inhabitants connected to the STP (Nlocal) / number of inhabitants in the region (N)*. This means a fraction of $10{,}000 / 20.0.10^6 = 0.0005$ with the defaults of EUSES. As the use of (formualtion containing) substances never will be distrubuted evenly over the population and the week, a safety factor of four was assumed at the time. This means that the fraction of the main source = 0.002. This value is used in the emission tables of the TGD.
There may be other applications where a point source is considered such as a hospital. In this report the fraction for the model hospital has been estimated to be 0.007. This fraction was calcualted as from the average number of beds in a region per hospital and the total number of beds in that region (see Appendix 2).

2. Emission scenario based on the consumption

This type of emission scenarios apply either the average consumption per inhabitant or the – estimated – use in a process. An example of the average consumption is the use of soaps and detergents for cleaning and washing ($l.cap^{-1}.d^{-1}$ or $g.cap^{-1}.d^{-1}$). The emission scenario is simple and applies an emission factor, the concentration of the substance in the product (in this report a disinfectant for which the notifier has to specify the value) and the penetration factor (i.e. the fraction of the product on the market containing the specific substance).
For a point source like a hospital it may be also the use of this kind of products (usually known in $kg.y^{-1}$). The emission scenario is even more simple as there is no penetration factor needed. Only an emission factor and an amount of product used is needed besides the concentration of the substance in the product.

3. Tonnage versus Consumption

When a substance with diffuse emissions is assessed the scenarios based on the tonnage will produce emissions directly related to the volume of the use. This is an advantage compared to scenarios that are based on consumptions.
There are, however, also some disadvantages in using scenarios based on the tonnage; there is an uncertainty in the regional tonnage if this is not known and another uncertainty in the fraction reaching the standard STP.

The use of average consumptions has several disadvantages. First, there is no direct relation with the actual quantity of the disinfectant for the application in case of diffuse emissions. Second, the average consumptions are often not specifically for e.g.detergents with a biocide leading to an uncertainty and for many products no reliable data are known. Third, the average consumption in a region may be different from the EU average leading to an uncertainty (reason for the 'safety factor' of 4 applied in the STP calculations with tonnages). Last but not least, the factor for the market penetration has a considerable uncertainty.
For point sources the main disadvantage is the fact that calculations of the consumption may have considerable uncertainties because of lacking data impelling detours to obtain estimates.

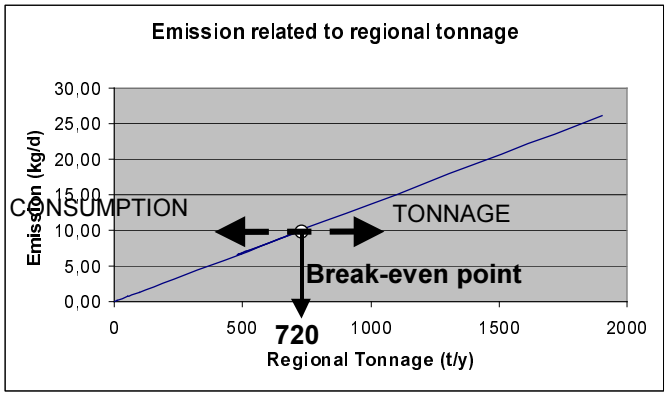
Because of the complete different character the two types of scenarios will provide outcomes which may be quite different. The emission factor and concentration of the substances in the product will be the same. For the diffuse emissions, i.e. emissions caused by use by the public at large, the scenario with the average consumption will give a fixed value whereas the scenario with the tonnage will give the emission as a linear relation to the quantity. It may be assumed that the tonnage scenario is more realistic as the consumption per habitant determines the tonnage.
For the point sources there may be a situation that the use of the tonnage scenario is underestimating the emission. This is the case where the substance is not used in the product by all sources. For example, if we consider a cleaner with a disinfectant for sanitary purposes the various manufacturers of that product may apply different active substances. So, one hospital will apply the disinfectant assessed but another applies a different substance. The tonnage scenario, however, will distribute the whole amount over all hospitals so to say by using the fraction of its relative size (0.007). So, there will be a break even point below which the consumption scenario will be better.
This is illustrated for a fictious situation with the following data (see also figure):

Emission factor (-)	1
Number of emission days (y^{-1})	365
fraction for main point source (-)	0.005
Consumption point source (kg. y^{-1})	3600

The emissions with the two scenarios are calculated as:

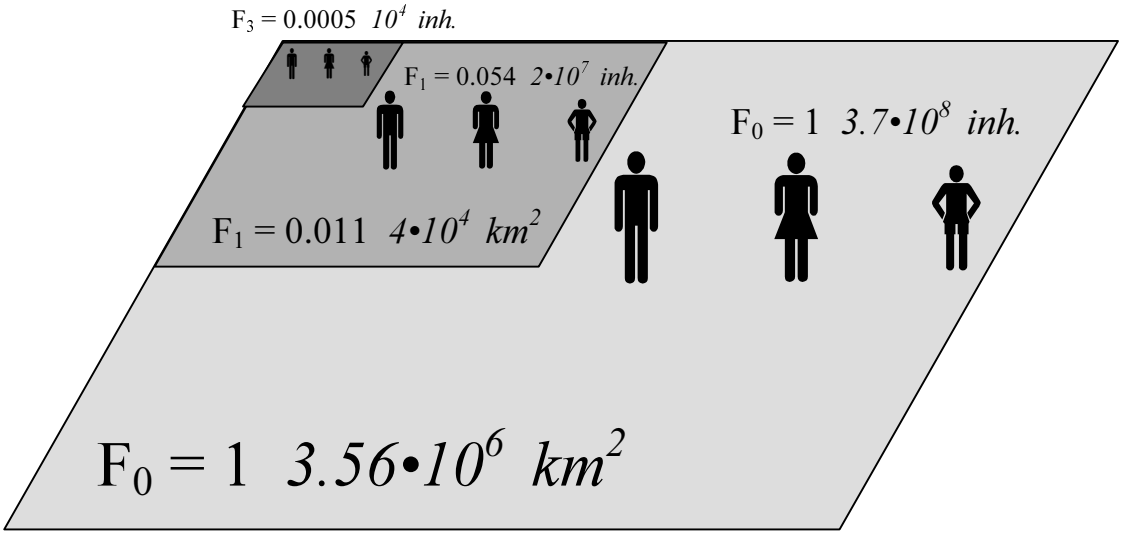
Tonnage: Emission = Tonnage * 10^3 * 0.005 * 1 / 365
Consumption: Emission = 3600 * 1 / 365 = 9.86 $kg.d^{-1}$

Break-even point: 9.86 = Tonnage * 10^3 * 0.005 * 1 / 365 ▶ Tonnage = 720 $t.y^{-1}$



4. Number of inhabitants and area sizes in the TGD

In the TGD the area of the region is 200 x 200 km^2, which is more densely populated than the average region of that size elsewhere in the EU (total area of the EU $3.56 \cdot 10^6$ km^2). The number of inhabitants considered in the TGD is $2 \cdot 10^7$ in the region and $3 \cdot 7.10^8$ in the EU. So, the number of inhabitants per km2 is 500 in the region and 104 in the EU. This means that the fraction of inhabitants in the region is $2 \cdot 10^7$ / $3 \cdot 7.10^8$ = 0.054 and the fraction of the regional area $4 \cdot 10^4$ / $3.56 \cdot 10^6$ = 0.011.



Glossary

Disinfectant

an agent that frees from infection, usually a chemical agent but sometimes a physical one, such as x rays or ultraviolet light, that destroys disease or other harmful microorganisms but may not kill bacterial spores. It refers to substances applied to inanimate objects *(Chapter 2 – Definition of terms, in: Disinfection, Sterilization and Preservation (4th edition), S.S. Block, pp. 18-25;)*

Endoscope

an instrument for visualizing the interior of a hollow organ

Sterilisation

the act or process, physical or chemical, that destroys or eliminates all forms of life, especially microorganisms *(Chapter 2 – Definition of terms, in: Disinfection, Sterilization and Preservation (4th edition), S.S. Block, pp. 18-25;)*

Acronyms

DGHM	Deutsche Gesellschaft für Hygiene und Mikrobiologie
ETO	Ethylene oxide
EUSES	European Union System for the Evaluation of Substances
ISO	International Standardization Organization
MDD	Medical Device Directive
OR	Operation room
PEC	Predicted environmental concentration
STP	Sewage Treatment Plant
TGD	Technical Guidance Document
USES	Uniform System for the Evaluation of Substances