

Recommendation no. 15

BPC Ad hoc Working Group on Human Exposure

**Harmonisation of PT2 small surface disinfection
exposure scenarios for biocidal products
containing highly volatile active substances by
RTU wipes and trigger sprayer**

Version 2

(Agreed at the Human Health Working Group IV-2023 on 5 December 2023)

Document history		
Version	Changes	Date
1	First version	04 December 2018
2	Changes: <ul style="list-style-type: none"> • General: Ventilation rate unit /h was changed to <i>ACH</i> • Chapter 1: Explanation for types of surface disinfection was updated • Chapter 2: Numerical definition of the term <i>small surfaces</i> was refined • Chapter 3: Two more scenarios were added: <ul style="list-style-type: none"> ○ <i>Hotel guest bathrooms</i> ○ <i>Private bathrooms in domestic dwellings</i> • Chapter 4: Introduction of a Reference list 	05 December 2023

1. Introduction

Whilst the assessment of wet wipes used to disinfect small surface areas in laboratories has been agreed during the assessment of biocidal active substances in PT2, a number of applications for uses beyond those considered are currently being evaluated in active substance approval and product authorisation context. These applications include trigger sprayers for small surfaces in hospital/care homes, medical practices and laboratories and ready-to-use containerised liquids for use in larger scale areas such as clean rooms.

Although previous general principles and approaches (e.g. inhalation exposure using the exposure vapour model in ConsExpo) can be followed for product assessments, further consideration of the scenarios (including secondary exposure) and parameters used (e.g. scale of use, room size, and ventilation rates) is needed as PT2 exposure guidance is limited and often does not reflect the volatile nature of substances like propan-2-ol, propan-1-ol, ethanol.

Critically, methods of application, usage areas (room type and ventilation rates), scale of use (high volume use for larger surface areas) and duration of application differ to that considered in previous assessments (e.g. use in laboratories on small surface areas of 0.5 m², with a high level of ventilation). As a result, further consideration is required, drawing on available guidance [e.g. HEAdhoc recommendation 2 - Professional Mopping and Wiping Time Used for cleaning Hard Surfaces (PT2) and HEAdhoc recommendation 9 - Hand disinfection in hospitals] to define the use patterns and scenarios for both primary and secondary exposures for these products.

The following paper includes proposals for defining relevant use scenarios (considering both primary and secondary exposure) and realistic parameters for certain scenarios (e.g. ventilation rates and room sizes).

In general, disinfection of surfaces can be separated into two groups of activities:

a) Rapid in-between disinfection or disinfection as part of a special working routine, the professional is not cleaning staff person.

Condition for choosing this activity: short duration and limited number of applications per day are expected

Examples: lab workers, doctors, surgeons, nurses, non-professionals in private premises (e.g. in case of diseases)

b) Disinfection as main job task, all sort of cleaning staff

Examples: cleaning staff at hotels, offices, fitness studios; professional disinfection of surgeon rooms, houses, hospitals

Please note: the applicant has to clarify the focus of product for the user groups and choose the scenario given in recommendation 15 accordingly. The field of use has to be detailed enough to allow choosing the appropriate exposure scenario(s).

This document focuses on the exposure assessment for disinfection of small surfaces only (e.g. work bench) using volatile active substances and application patterns with trigger sprayer, wiping after spraying with trigger sprayer and RTU wipes. It is assumed that trigger spray is applied downwards, not in direction of other people. In addition, the assessments presented in this document concentrate mainly on inhalation exposure.

2. Key issues and parameters for consideration

- **Room sizes**

Room size can be variable and dependent on use situations. Hospital rooms have indicative sizes (80 m³) provided within HEAdhoc Rec 9, whereas for laboratories 25 m³ has been considered appropriate in active substance assessment. However, for cleanrooms and medical practices no harmonised values are available. As a first tier approach, it is suggested to use the indicative values as described in the ConsExpo General Fact Sheet - RIVM report 320104002/2006 for a non-specified room (e.g. ventilation rate 0.6 ACH, room size 20 m³).

These issues are considered further in the following use scenarios and proposed risk assessment approaches. Please note that alternative room sizes and ventilation rates have been proposed by different applicants.

- **Air exchange/hour (ACH)¹**

Ventilation rates can differ significantly between usage areas e.g. hospital room is 1.5 ACH (HEAdhoc recommendation 9), laboratories is 8 ACH as considered in previous assessments (assumed to be positively ventilated, e.g. fume hood). There is limited harmonisation for ventilation rates in other common usage areas where PT2 products are used e.g. cleanrooms, care homes and medical practice. Ventilation rates impact significantly on the removal of airborne residues and the potential accumulation between treatments.

- **Surface area treated and frequency of use**

Small surfaces to be disinfected are defined to cover a surface area of 0.5 m². The assessment of volatile active substances has previously considered the use of impregnated wipes on small surfaces (0.5 m²). However, a wider range of uses including large-scale application e.g. floors and walls may need to be assessed. As a result, the amount of active substance used is variable.

- **Application rates and efficacy**

No set application rate can be recommended from an efficacy perspective, but instead surface contact times are used. Applicants should therefore provide recommended application rates which are realistic and can be used in the exposure assessment. In any case, products should be used in line with the application rates stated in the use instructions on the label. In accordance with efficacy requirements regarding contact time, such use/application rate should result in treated surfaces remaining wet for at least one minute. Applicants should be asked to confirm that contact times can be met if products are used in line with their instructions.

- **Secondary exposure scenarios**

Although primary exposure can be used to cover secondary exposure for professional/industrial environments (e.g. laboratories and cleanrooms), for use within hospitals and care homes this is not the case. In previous assessments of active substances, extrapolation from laboratory use to hospital environments have been made. However, these assessments were limited to short exposure durations (5 minutes), whereas it is considered that for hospital patients exposure would be chronic e.g. ≤ 24

¹ Air exchange/hour : The number of total air changes in the room per unit of time. Synonymous definition: ventilation rate [/h] or room ventilation [/h]

² The size of small surfaces shall be 0.5 m² in the calculations, as this allows harmonisation and comparison of products for the user. Surfaces larger than 0.5 m² should be given as "surfaces (XX m²)". Other parameters of this recommendation, e.g. application frequency, however remain the same. The size of the surface to be disinfected should be indicated in the SPC use instructions.

hours a day and the critical exposure group would be toddlers occupying these environments.

- **Formulation of the products**

Examples of in use disinfectant products assessed so far by eCAs are as follows:

- Ready to use liquid solutions
- Ready to use sprays
- Ready to use wipes

3. Use scenarios and proposed risk assessment approaches

A. Laboratories

The approach and parameters used in the previous assessments of disinfectant active substances for use in small areas in laboratories can be followed with minor refinements/adjustments to reflect each specific product. Details of this approach are presented below for completeness, and this provides the basic principles upon which most other assessment scenarios are based.

Description of Laboratory Scenario	
<p>The application liquid is either poured or sprayed from a hand-held bottle onto the surface to be treated or onto a wipe. Finally, the surface to be disinfected is wiped off. Alternatively, the application liquid is sprayed onto the surface which is then left to dry or the surface is wiped with a ready-to-use wipe already impregnated with the application solution. To get the alcoholic disinfectant effectively onto the surface, the spraying is carried out directly from a very short distance. In laboratories the rapid in-between/routine disinfection of small surfaces (0.5 m²) is commonly performed before and/or after every new task.</p> <p>As a worst case scenario, based on previous assessments it is assumed that one person disinfects the work bench every 45 minutes in a small room (25 m³) during an 8 hour work shift.</p>	
Parameters	Value
Concentration of a.s. in b.p.	% v/v or % w/w
Density of the solution	g/mL
Area disinfected (application rate):	small surface of 0.5 m ²
Event exposure duration	45 mins (harmonised with previous assessments)
Frequency of use	10 events per day (harmonised with previous assessments, equivalent to 5 m ² per day)
Application duration	1 min/0.5m ² (harmonised with previous assessments)
Product amount per application	= density x application rate x area disinfected
Temperature	25°C (harmonised with previous assessments)
Ventilation rate	8 /hr (harmonised with previous assessments)
Room volume	25 m ³ (harmonised with previous assessments)
Mass transfer rate	10 m/hr (new default value in ConsExpo Web)

ConsExpo web modelling parameters:

- Model – ‘Exposure to Vapour’
- Mode of release – ‘Evaporation’
- Release area – ‘Increasing’.

Secondary exposure to volatilised residues

The above primary exposure scenario can be considered as covering secondary exposure (worst-case scenario considering an adult bystander present in the laboratory during disinfection). Please note that primary exposure cannot cover secondary exposure if PPE are required during the disinfection task. In this case, different RMMs (e.g. a re-entry time) need to be implemented to reduce the secondary exposure.

B. Cleanrooms

For use in cleanrooms the scale of use is variable (full clean, floor and small surface disinfection) and specific product information provided by the applicant may be essential to compose realistic exposure scenarios.

As a first-tier assessment the basic approach listed for laboratories is proposed to be followed, with adjustment of the following parameters that are more specific to the Use scenario

- **User** – dependent on the scale of use and frequency of use e.g. lab worker and/or professional cleanroom cleaners.
- **Room size** - 55 m³ is suggested based on information proposed by a range of applicants.
- **Ventilation rates** – In Tier 1, a minimum of 8 ACH based on the laboratory use has been considered in previous assessments. In Tier 2, a ventilation rate of 20 ACH is considered realistic³. Higher ventilation rates could be considered based on information provided by the applicant.
- **Area treated** – Although a default value for the area to be treated cannot be established, it could be assumed that disinfection with RTU wipes or trigger spray will be performed for small surfaces. This is a critical parameter as it dictates the amount of active used and the amount of volatilised residue for inhalation exposure. For small use area, the parameters in the CAR are considered appropriate (e.g. duration of 1 min wiping an area of 0.5 m²).
- **Duration of use and number of operations/frequency per day** – These parameters depend on the proposed use (e.g. small area) and user group (lab worker or cleaner).

Secondary exposure to volatilised residues

The above primary exposure scenario can be considered as covering secondary exposure (worst-case scenario considering an adult bystander present in the cleanroom during disinfection). Please note that primary exposure cannot cover secondary exposure if PPE are required during the disinfection task. In this case, different RMMs (e.g. a re-entry time) need to be implemented to reduce the secondary exposure.

³ Guidance for Industry: Sterile drug products produced by aseptic processing – Current Good Manufacturing Practice, 2004

C. Hospitals and medical practices (including care homes)

Primary exposure

This use has not been considered fully in previous assessments and there is no agreed approach for the use of disinfectant wipes in hospital/care home situations (e.g. number and frequency of wipes used in hospitals/care homes). Although hospitals and care homes are listed as scenarios within previous assessments, the approach presented is specific to laboratory situations and critically does not reflect hospital use/work patterns.

For example, ventilation rates are proposed for hospital environments in HEAdhoc recommendation 9 - Hand disinfection in hospitals and it is proposed that these should be used in this scenario. The working patterns (e.g. duration of exposure, number of rooms treated) for the hospital/care home situation described in HEAdhoc Recommendation 9 - Hand disinfection in hospitals are relevant here. The active substances behaviour and the working patterns described for nurses (e.g. room visits, duration spent in patients' rooms, room size and ventilation rate) can be considered representative. An extract of HEAdhoc recommendation 9 is presented below for reference and to highlight the key values used in the exposure assessment.

'One nurse is responsible for 8 patients. This figure is in line with the research done for the HEAdhoc recommendation No. 1 among Europe. Two patients are in one patient room of 80 m³ size with a ventilation rate of 1.5 per hour. During her work in the patient room, 3 hand disinfections are performed. The nurse stays for 20 minutes in every room. After visiting of 4 patient rooms and 12 hand disinfections, they enters the first room again and performs again 3 hand disinfections in each room resulting in additional 12 hand rubs. One hand rub is performed e.g. at start of the shift in an 80 m³ room and staying for 10 minutes. In summary, 25 applications per shift are performed.'

Work time [hour]	0-1	1-1,5	1,5-2	2-2,5	2,5-3	3-5	5-5,5	5,5-6	6-6,5	6,5-7	7-8
Room 1		■					■				
Room 2			■					■			
Room 3				■					■		
Room 4					■					■	

■ 3 hand rubs per room (first enter the room - patient (1) care - second - patient (2) care - third - leaving the room) - duration in the room 20 minutes

Critically the above recommendation provides parameters (e.g. durations, number of tasks) that enable the estimation of both mean and residual air residues per room and the duration of exposure.

Description of hospital scenario and medical practices– primary exposure

The ready for use wipes are used on hospital and care home surfaces which require rapid and effective in-between infection control such as: door handles, cabinets, tables, non-invasive medical equipment (such as wheelchairs, walking frames) and general equipment (e.g. telephones, trolleys).

The application liquid is either poured or sprayed from a hand-held bottle onto the surface to be treated or onto a wipe. Finally, the surface to be disinfected is wiped off. Alternatively, the application liquid is sprayed onto the surface which is then left to dry, or the surface is wiped with a ready-to-use wipe already impregnated with the application solution. To get the alcoholic disinfectant effectively onto the surface, the spraying is carried out directly from a very short distance.

Based on HEAdhoc recommendation 9, during the working day a nurse/carer is expected to stay 20 minutes in every room to perform their duties. After visiting 4 rooms they are expected to repeat the process throughout the day revisiting each room in turn (therefore, 2 visits per room per day).

Parameters	Value
Concentration of a.s. in b.p.	% v/v or % w/w
Density of the solution	g/mL
Area disinfected (application rate):	small surface of 0.5m ²
Event exposure duration	20 mins (HEAdhoc recommendation 9)
Frequency of use	4 rooms visited (2 visits per room per day)
Application duration	1 min/0.5m ² (harmonised with previous assessments)
Product amount per application	= density x application rate x area disinfected
Temperature	25°C (harmonised with previous assessments)
Ventilation rate	1.5 ACH (HEAdhoc recommendation 9)
Room volume	Hospital room: 80m ³ (HEAdhoc recommendation 9) Medical practices: 20 m ³ (ConsExpo General Fact Sheet)
Mass transfer rate	10 m/hr (new default value in ConsExpo Web)

ConsExpo web modelling parameters:

- Model – ‘Exposure to Vapour’
- Mode of release – ‘Evaporation’
- Release area – ‘Increasing’.

The inhalation exposure can be estimated from the following outputs in ConsExpo – evaporation model:

- Mean air concentration from disinfection using x wipes (mg/m³): during 20 minute visit in the room, a small area 0.5 m² is disinfected for 1 minute per room.
- Remaining air concentration after 240 min: extrapolation from ConsExpo graph plot.

Inhalation exposure =

4 rooms (1st treatment) x mean air conc (xx mg/m³) x 20mins x inhalation rate (1.25m³/hr) + 4 rooms (2nd treatment) x (mean air conc xx mg/m³ + residual air conc xx mg/m³) x 20mins x inhalation rate (1.25m³/hr)

Refinements by reducing the frequency of use may be considered appropriate depending on the pattern of use and specific information on the product.

Secondary exposure to volatilised residues

The above primary exposure scenario can be adapted for secondary exposure (worst-case scenario considering a toddler in a hospital for ≤ 24 hours/day) considering a mean exposure over the 240 min period and reapplication after this period. Please note that if acceptable, secondary exposure cannot be demonstrated based on the minimum application rate e.g. 0.5 m² every 240 mins, a refinement of the exposure assessment should be performed or RMMs may be implemented to reduce secondary exposure.

D. Hotel guest bathrooms

For this scenario it is expected that a professional cleaning staff at hotels uses the product for disinfection of small surfaces in hotel guest bathrooms (e.g. toilet seat). It is mandatory that the applicant specifies the intended use range and the application method of disinfection (e.g. spraying, wiping) which is planned for the product.

- **User** – is determined to be cleaning staff of hotels, defined as professionals only.
- **Room size** - 10 m³ is suggested based on information by RIVM¹ of bathroom size in private apartments. It is assumed, that the size of bathrooms in hotels does not differ from that in domestic area at worst case conditions.
- **Ventilation rates** – A minimum of 2 ACH is suggested based on the ventilation rate of private bathrooms by RIVM for worst-case conditions.
- **Area treated** – For small use area, the parameters 0.5 m² is suggested. Surfaces larger than 0.5m² can be taken into account⁴.
- **Duration of use and number of operations/frequency per day** – It is assumed, that the hotel cleaning staff has to perform 19 applications per 8-h-working day. This number is based on the number of hotel rooms being most commonly cleaned per day following the study data from Aguilar-Escobar et al. 2021: 645-660³.

Secondary exposure to volatilised residues

The above primary exposure scenario can be considered as covering for secondary exposure (worst-case scenario considering an adult bystander present in the cleanroom during disinfection). Please note that primary exposure cannot cover for secondary exposure for general public if PPE are required during the disinfection task. In that case different RMMs (e.g. a re-entry time) need to be implemented to reduce the secondary exposure.

⁴ The size of small surfaces shall be 0.5 m² in the calculations, as this allows harmonisation and comparison of products for the user. Surfaces larger than 0.5 m² should be given as “surfaces (XX m²)”. Other parameters of this recommendation, e.g. application frequency, however remain the same. The size of the surface to be disinfected should be indicated in the SPC use instructions.

E. Private bathrooms in domestic dwellings

It is expected that a non-professional disinfects her/his bathroom in case of increased infection risk (e.g. infection by Norovirus) additionally to the common cleaning procedure. It is mandatory that the applicant specifies the intended use range (e.g. field area) and the application method of disinfection (e.g. spraying, wiping) which is planned for the product.

- **User** – is determined to be an adult non-professional at home.
- **Room size** - 10 m³ is suggested based on information by RIVM¹ of bathroom size in private apartments.
- **Ventilation rates** – A minimum of 2 ACH is suggested based on the ventilation rate of private bathrooms by RIVM for worst-case conditions.
- **Area treated** – For small use area, the parameters 0.5 m² is suggested. Surfaces larger than 0.5 m² can be taken into account⁵.
- **Duration of use and number of operations/frequency per day** –In case of acute infection a maximum of 5 applications per day can be assumed.

Secondary exposure to volatilised residues

The above primary exposure scenario can be considered as covering secondary exposure for adult non-professional bystander. However, the presence of small children (toddlers) cannot be excluded and exposure for this group should be calculated. It seems to be unlikely that the toddler will be present during each application. Therefore, one application per day is sufficient for the calculation of secondary exposure.

⁵ The size of small surfaces shall be 0.5 m² in the calculations, as this allows harmonisation and comparison of products for the user. Surfaces larger than 0.5 m² should be given as “surfaces (XX m²)”. Other parameters of this recommendation, e.g. application frequency, however remain the same. The size of the surface to be disinfected should be indicated in the SPC use instructions.

4. References

- 1) RIVM report 2014 General Fact, chapter 3.1.3., page 23
- 2) RIVM report 2014 General Fact, chapter 3.2.3., page 29
- 3) Aguilar-Escobar, V.G. et al. (2021): Hotel room cleaning: Time study and analysis of influential variables in a Spanish hotel. *Journal of Industrial Engineering and Management*, 14(3), 645-660