

Recommendation no. 1

of the BPC Ad hoc Working Group on Human Exposure

Hand disinfection – PT 1 harmonisation of exposure determinants for professional users

(Agreed at the Human Health Working Group II on 24 March 2014)



1. Introduction

Biocidal products of product type 1 (PT 1) are used for disinfection related to human body hygiene, including antiseptics in part, which are used in topical application on intact human skin surface to prevent infections.

Hand disinfection (PT 1) comprises hygienic hand disinfection and surgical hand disinfection. There are different types of products available which include hand rubs mainly based on alcohol as active substance, hand washes which contain e.g. Triclosan or quarternary ammonium chlorides as active substances, or hand wipes, which are tissues treated with disinfectant solution e.g. based on alcohol.

It is possible to differ between leave-on products such as alcohol based hand rubs and hand wipes drained with alcohol or rinse-off products such as hand washes.

Whereas the contact time and the amount of product for hand disinfection are defined based on the results of standardized efficacy tests for hand rubs, respectively hand washes, there are no defined figures for the frequency of application.

To this end a literature search was carried out to collect information on the frequency of hand disinfection especially on the application of hand rubs. The results are summarized in the tables in the annex.

2. Discussion

A working document on human exposure scenarios for disinfectants was provided by Italy (2012). The envisaged field of use of human hygiene biocidal products (PT 1) for professional users comprises hand rubs, hand washes and hand wipes. For calculation to assess exposure the duration of use and frequency, respectively, are essential parameters. Disinfection of hands using hand washes or hand wipes for professional users was assumed up to 20 applications per day according to applicant's information.

Currently in Germany the occupational exposure towards Propan-2-ol for hand disinfection purposes is assessed in the framework of approval of the active substance. According to the assumption (no data or information are provided) made by the applicant hand disinfection by a nurse is performed every 10 minutes for a reasonable worst-case scenario resulting in a frequency per day of 48 hand rubs.

The exposure in the framework of the approval of Triclosan (CAS No. 3380-34-5) for use in hand washes for hand disinfection is assessed by Denmark using an exposure frequency of 10 uses per day (Tier 1) and 7 uses per day (Tier 2), respectively

A literature research revealed that most of the publications deal with compliance to hand hygiene which means that the number of opportunities for hand hygiene e.g. before and after patient contact in a hospital is compared to the actual number of hand hygiene actions. Often there is no difference made between hand rubbing and hand washing. In addition, the patient-to-staff ratio is often not taken into account in the publications which makes it difficult to derive the actual number of hand disinfections per health-care worker per day.

Although, there are clear defined rules when a hand disinfection in a health-care setting should take place (WHO, 2009, Table I.21.4) the actual hand hygiene compliance among health-care workers is not 100%. Actual adherence to recommended hand hygiene



procedures has been reported with very variable figures, the mean baseline rates ranging from 5% to 89%, representing an overall average of 38.7% (WHO, 2009, Table I.16.2). So this factor should be considered when estimating a number for the frequency of hand disinfections per day. It is also noteworthy that there is no uniform definition of an indication for a hand hygiene opportunity such as the WHO-rules: In publications dealing with hand hygiene compliance and hygiene opportunities e.g. sometimes institutional rules are used or every direct or indirect patient contact (McArdle et al. 2006) is counted as an opportunity for hand hygiene. The publication of McArdle et al. states that a one hundred percent hand hygiene compliance by all healthcare workers would require about 230 min/patient/day. Strict adherence to recommended hand hygiene procedures is crucial to prevent the spreading of nosocomial infections but it would as well consume a substantial part of the working time of hospital staff. This makes it difficult for health-care workers to balance between hygiene requirements and the fulfilment of their workload. So in the end it may seem more reasonable to use observational data on the frequency of hand disinfections or consumption data of alcoholic hand rubs, which reflect a realistic situation, rather than data on the number of hand hygiene opportunities to obtain a valid number.

For consideration of the frequency of hand disinfections it is also important to differ between intensive-care units and non-intensive care units: In intensive-care units hand disinfections are more often required due to the specific hygiene requirements on the other hand the staff-to-patient ratio in intensive care-units in Germany is about 1:1 to 1:3 (Wikipedia, JC AINS 2010). Whereas, in non-intensive care units the staff-to-patient ratio is about 1:6 according to data from the German Federal Statistical Office (2012). There are also different procedures for hygienic hand disinfection and hand disinfection prior to surgery. A surgical hand disinfection includes both hands and forearms but due to the specific situation it is carried out less frequently than a hygienic hand disinfection e.g. four times per working day if it is assumed that a medical professional carries out four surgeries. So the exposure scenario for hygienic hand disinfection also reflects the situation for surgical hand disinfection.

Jungbauer *et al.* (2004) modelled a mean daily (wet-work) exposure during nursing work on regular wards on the basis of observation studies. Hand rubbing with an alcohol based hand rub occurs 18 times, whereas hand washing with an antimicrobial hand wash and water takes place 10 times.

In Germany information on hand disinfection activities are collected by the "Nationales Referenzzentrum (NRZ) für Surveillance von nosokomialen Infektionen am Institut für Hygiene und Umweltmedizin". A retrospective survey on the consumption data of alcohol based hand rubs in 3358 non-intensive care units in 341 German hospitals gave a number of 7 hand disinfections per patient day (SPE-KISS, 2010). According to data from the German Federal Statistical Office the average patient-to-staff ratio in German hospitals is 6:1 (German Federal Statistical Office, 2012, see above). Based on this number and assuming that hand hygiene actions mainly take place during the two day-shifts of 16 hours it is possible to state that a German health-care worker in a non-intensive care unit performs an average of 21 hand disinfections with an alcoholic hand rub per 8 hour shift.

In intensive care-units the staff-to-patient ratio is assumed as 1:1 to 1:3 (German Wikipedia, JC AINS, 2013) it is also assumed that hand hygiene actions occur during the complete day of 24 hours due to the specific hygiene requirements in intensive care. According to the study report (SPE-KISS, 2010) based on data of 543 intensive care units in 298 German hospitals 28 hand disinfections with an alcoholic hand rub per patient day are performed. Based on these assumptions above it is possible to calculate that in a German health-care worker in an intensive-care setting carries out about 9 to 28 with a mean value of 19 hand disinfections with an alcoholic hand rub per shift.



In the Guideline for Hand Hygiene in Health Care Settings (Boyce JM *et al.*, 2002) by the US Center for Disease Control and Prevention it is reported that the average number of hand disinfections with an alcoholic hand rub by health-care workers strongly varies between five and up to as many as 30 per shift.

The WHO Guidelines on Hand Hygiene in Health Care (WHO, 2009) contain a literature overview on the average number on hand hygiene actions per hour. Studies on hand washing and hand rubbing are listed. The average number of hygiene actions ranges from 1.7 per health care worker per hour up to 15.2 hand disinfections per patient room per hour (Girou *et al.* 2006). The latter number does not take into account the patient-to-staff ratio. A publication from Boyce *et al.* (2000) on this list gives an average number of 1.8 hand disinfections with an alcoholic hand rub per hour (15 per shift) in 29 health-care workers in a hospital in the US.

Voss and Widmer (1997) state that based on consumption data in an intensive care unit with 12 health-care workers in the US an average of 20 hand disinfections with an alcoholic hand rub is performed per worker per shift.

In a publication of Bessoneau *et al.* (2010) the inhalational uptake of alcohol from handrubs in French health-care professionals was assessed. The authors reported an average number of 30 hand disinfections with an alcoholic hand rub per health-care worker per shift.

The results of the literature research show a great variance in the average number of hand disinfections with an alcoholic hand rub ranging from 5 (Hübner *et al.*, 2010) up to 30 (Boyce JM *et al.*, 2002) or even 48 disinfections based on the applicant's assumption per day. Results of the research are presented in the tables in the annex.

3. Proposal for harmonisation

The frequencies per day for hand disinfection which have been used from rapporteur member states to assess occupational exposure for the different active substances are listed in the annex in table 1. Table 2 in the annex presents the results of a literature overview on the application of alcohol based hand rubs.

Soap formulations are used for surgical hand disinfection, hand washing with antimicrobial soaps and hand wipes, resp. whereas alcoholic formulations as well as liquid formulations with peracetic acid or active chlorine are used for hygienic hand disinfection.

Regarding the existing sources of information we propose to harmonise the frequency per day for exposure assessment distinguishing between the kinds of disinfection formulations.

Based on consumption data of alcoholic hand rubs and observational data a range of about 15 to 30 hand disinfections with an alcoholic hand rub per day per health-care worker was found. In the light of this result 25 applications per working day of 8 hours in the case of liquid especially alcoholic hand rubs used for hygienic hand disinfection may be a realistic default value, whereas 10 applications per day may be proposed for hand disinfection with hand washes.



Summary table:

Disinfection method	Professional use (health-care worker) Application of hand disinfectant per shift
Hand rubs (e.g. alcoholic disinfectants)	25
Hand wash (e.g. soap, liquid soap with disinfectant)	10
Use of tissues treated with disinfectant	use the information for hand rubs

4. References

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- Hübner A *et al.*,(2010). BMC Infectious Diseases, (10), 250.
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- Statistisches Bundesamt (German Federal Statistical Office). Grunddaten der Krankenhäuser 2012.
- World Health Organization (2009). WHO Guideline on Hand Hygiene in Health Care.
- Voss A and Widmer AF (1997). Control Hosp Epidemiol, (18), 205-208.
- German Wikipedia.



5. Annexes

Table 1: Hand disinfection frequencies per day used by rapporteur Member States

		form, concentration	Frequency	Duration	
EU CARs			"per day"	"minute per	
			Professionals	application"	
1-Propanol (first Draft, 2013)	DE	Liquid, 70 %	48 (32)	1	1
2-Propanol (first Draft, 2013)	DE	Liquid, 70 %	48 (32)	1	1
Ethanol (first Draft, 2013)	GR	Liquid, 70 %, 3 ml	48	1	1
Peracetic acid (first Draft, 2012)	FIN	Max. 0.2 %, 2 ml	24 (3 per h)	2	1
Active Chlor "Sterilox"	SK	0.2 %, 1.5 ml	32 (4 per h)	5	1
Sodium hypochlorite (first Draft, 2010)	IT	0.1 %, 2 ml	max. 16 (reversed)	-	1
Contact Derm. 51, 2004, p.135		Alcohol solution	18		
Jod (final Draft, 2013) "YodiCura"	S	3-6.9 g soap	8	5	3,2
Triclosan (first Draft, 2013)	DK	1 %, 3 g, soap	10	1	3
DDAC (first Draft, 2012) "QUAT"	IT	2 ml	20	2	3,4
BKC-50 (first Draft, 2012) "QUAT"	IT	0.3 %, 2 ml	20	2	3,4
DCPP (first Draft, 2013) (chlorophenol)	AT	0.2%, 3 g, soap	8	1	3
Contact Derm. 51, 2004, p.135		Soap and water	10		

1 - hygienic, sanitary hand disinfection2 - surgical hand disinfection

<u>3 -</u> hand wash, soap (antimicrobial) <u>4 -</u> hand wipes

HEEG working document	Up to 20 applications per day	Available
(15.10.2013)		
Contact Derm. 51, 2004, p.135	Soap water : 10 applications per day (duration 1 min)	Available
	Alcohol solution: 18 applications per day	
Bericht SPE-KISS August 2010,	Intensive care: 26 applications per patient day (alcohol	Available
Nationales Referenzzentrum für	solution)	on German
Surveillance von nosokomialen	Normal wards: 7 applications per patient day	
Infektionen am Institut für	Average: 8 applications per patient day	
Hygiene und Umweltmedizin		
Charité – Universitätsmedizin		
Berlin (Prof. Dr. med. Petra		
Gastmeier), Tabelle 3		

Table 2: Results of the literature review

Reference number	Reference	Conclusion	Comments
1	F.H.W. Jungbauer, J.J. van	Observation study on 33	
	der Harst, J.W. Groothoff and	nurses in a Dutch hospital,	
	P.J. Coenraads, Contact	18 hand rubs per working	
	Dermatitis 2004 (51) 135.	day	



2	Bericht SPE-KISS August 2010, Nationales Referenzzentrum für Surveillance von nosokomialen Infektionen am Institut für Hygiene und Umweltmedizin Charité – Universitätsmedizin Berlin (Prof. Dr. med. Petra Gastmeier), Tabelle 3	28 hand disinfections per patient day (3 shifts, 24 h) in intensive care units in 2009 (retrospective survey on alcoholic hand rub consumption in 298 hospitals, 543 intensive care units); 7 hand disinfections per patient day (16 h, 2 day shifts) in other hospital units (retrospective survey in 341 hospitals, 3358 non- intensive care units)	average of 21 hand rubs per working day in non-intensive care average of 19 hand rubs per working day in intensive care.
3	Grunddaten der Krankenhäuser, Statistisches Bundesamt (German Federal Statistical Office) 2012	Staff-to-patient ratio in German hospitals: 1:6	
4, 5	Wikipedia, JC AINS 2013; 2(2): 69	Staff-to-patient ratio in the intensive care units of German hospitals:1:1 to 1:3	
6	Boyce, J.M.; Pittet, D. Guideline for hand hygiene in health-care settings. Am. J. Infect. Control 2002, 30, 1- 46.	Average of five up to 30 hand rubs per working day are carried out per health care worker in the US	
7	WHO Guideline on Hand Hygiene in Health Care, WHO, 2009	Literature survey on the average number of hand hygiene actions (rubbing and washing) of health- care workers. The average number ranges from 1.7 to 15.2 hand hygiene actions per hour.	
8	Boyce JM, Kelliher S, Vallande N. Infection Control and Hospital Epidemiology, 2000, 21:442–448.	Average number of 1.8 hand disinfections per hour (15 hand rubs per working day) in 29 health-care workers in a hospital in the US	
9	Voss A, Widmer AF, Infect Control Hosp Epidemiol 1997, 18:205-208	average of 20 hand rubs are carried out per healthcare worker per working day in the US	
10	Bessonneau V, Clément M, Thomas O., Int. J. Environ. Res. Public Health 2010, 7: 3038-3050	Average of 30 hand rubs per healthcare professional per working day	
11	Hübner A, Hübner N, et. al., BMC Infectious Diseases 2010, 10:250	134 volunteers in public administrations of the German city of Greifswald. Mean frequency reported was 3 to 5 hand rubs per working day.	