

Recommendation no. 13
of the BPC Ad hoc Working Group on Human Exposure

Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3)

(Agreed at the Human Health Working Group I on 19 January 2017)

Document history		
Version	Changes	Date
1	First version	19 January 2017 at Human Health Working Group I
2	Changes in the document: <ul style="list-style-type: none">• Correction of the room size and room surface in scenario 8• Inclusion of additional reference on the Dutch Handbook	30 March 2017

1. Background

Teat disinfection products for veterinary hygiene (PT3) are applied by professional users to disinfect the teats of the udder of dairy cattle before or after milking.

The scenarios used to assess human exposure to teat disinfection products are primarily provided in the Biocides Human Health Exposure Methodology (October 2015) and the HEAdhoc Recommendation 6 – Version 2 (2016).

During the HEAdhoc-1-2016 meeting, in light of the variability of the models and parameters used by Member States Competent Authorities to assess professional exposure to teat disinfection products, it was proposed to develop an HEAdhoc recommendation on the tasks associated to teat disinfection. The availability of such a recommendation will provide a level playing field for Industry and ease the undertaking of exposure assessments. Furthermore, such a document will contribute to any discussions on harmonisation of exposure assessment within the EU. This will be especially relevant for the evaluation and peer-review of applications for Union authorisation of biocidal products, for which consistency in assessing exposure may help solving policy disagreements in advance.

2. Aim of the recommendation

This recommendation is based on a concept paper prepared by the Netherlands and aims at proposing exposure models for a harmonised exposure assessment of professional users (i.e. farmers) to biocidal products used for teat disinfection for veterinary hygiene (PT3).

The tasks of mixing and loading, application by dipping cups, manual or electronic spraying and spraying by robot, as well as using a wiping towel and cleaning of teats and equipment are considered.

3. Discussion

Table 1 gives an overview of the exposure scenarios, relevant for the assessment of teat disinfection products. The proposed exposure models are also indicated. The column "Remarks on the proposed model" includes the rationale behind the choice of the exposure models.

In general, teat disinfection is performed either pre- or post-milking. However, as a worst-case, it is considered that teat disinfection takes place pre- and post-milking. Taking into account 2 milking events per day per cow per farmer, a farmer is exposed to a total number of 4 teat disinfection events per day (disinfection pre-milking + disinfection post-milking x 2 milking events).

The Emission Scenario Document (ESD) for PT3 (2011) and various HEEG opinions or HEAdhoc recommendations were taken into consideration, where applicable, to propose the exposure models. Furthermore, the positions of Member States on specific exposure models were reflected, based on the discussions which took place during both Human Health Working Groups and Biocides Technical Meetings.

Table 1: Proposed exposure models for assessing exposure of professional users to teat disinfection products

No	Exposure scenario	Proposed exposure model	Remarks on the proposed model
1.	Mixing and loading of concentrated product	<p><u>Dermal exposure:</u> Mixing and loading model 4</p> <p><u>Inhalation exposure, for active substances with high vapour pressure:</u> ConsExpo Web¹, exposure to vapour – evaporation – constant release (Delmaar and Schuur, 2016)</p> <p>Please note that it is not necessary to assess inhalation exposure if the active substances are complex-bound, because no evaporation is expected. The applicant should provide evidence for this.</p>	<ul style="list-style-type: none"> • According to the HEEG Opinion 1 (<i>HEEG Opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale</i>), a recommended alternative approach for repeated loading for small quantities is Mixing and loading model 4. • Please note that re-filling of the equipment with the diluted product will be covered within this mixing and loading step and does not need to be assessed separately. This is because the model covers all relevant mixing and loading tasks performed by a worker on a 8-h working day. For smaller quantities, the HEEG Opinion 1 refers to the TNsG version 1 (part 2 p.136), User guidance (p.24) and TNsG version 2 (p.66), where it is reported that an indicative value of 0.01 ml/treatment is used for 1L and 0.2 ml/treatment for 5L. The value to be used should be in line with the total amount of required solution that is needed per day. • Cleaning Products Fact Sheet (Prud'homme de Lodder et al. (2006)), describes the inhalation exposure of a cleaner liquid during mixing and loading. A similar use of M&L is presumed, where defaults have been adjusted to represent M&L from a 10 L jerry can (instead of a half full 1 liter bottle). The ConsExpo Web model describes inhalation of volatiles into the personal breathing zone of the consumer. In case of the farmer preparing the teat disinfection, the model <i>Inhalation-exposure to vapour- evaporation constant surface area model</i> is suggested with the following settings: <ul style="list-style-type: none"> ○ room volume 1 m³ ○ exposure duration 0.75 min (from Cleaning Products Fact Sheet, 2006)

¹ ConsExpo Web, an improved web-based version of ConsExpo 4.1, was launched in October 2016. ConsExpo Web is now the official ConsExpo version and ConsExpo 4.1 is no longer offered.

No	Exposure scenario	Proposed exposure model	Remarks on the proposed model
			<ul style="list-style-type: none"> ○ application duration 0.25 min (from Cleaning Products Fact Sheet, 2006) ○ product amount 5 kg (10 L jerry can, specific for this scenario) ○ ventilation rate 4/hr (specific for this scenario) ○ release area (surface area jerry can (10L)), circular opening of 5 cm diameter and a surface area of 20 cm² ○ temperature, 20 degrees Celsius ○ mass transfer rate: Langmuir's method ○ mol weight matrix depends on formulation <p>Please note that the use of the default mass transfer rate of Langmuir gives an overestimation and can therefore be used as the worst-case. If refinement is needed, the Thibodeaux value (water based system) is more applicable.</p> <ul style="list-style-type: none"> • Please note that Mixing and Loading Model 4, which is proposed in this recommendation to assess dermal exposure, contains container specific (volume and aperture) exposure values. It is possible that the packaging type (size and aperture) considered for the dermal route may differ from the 10 L jerry can proposed for the inhalation route. Therefore, the proposed jerry can constitutes a realistic worst case. • Please note that product characteristics (for example, an active substance which is complex-bound to anionic surfactants) could affect the evaporation of an active.
2.	Mixing and loading of RTU	<p><u>Dermal exposure:</u> Proposed options:</p> <ul style="list-style-type: none"> • Mixing and loading model 4 (1-20 L) • ConsExpo dermal exposure model: instant application (Cleaning Products Fact Sheet, 2006 and Disinfectant Products Fact Sheet, 2006) 	<ul style="list-style-type: none"> • The same considerations under no. 1 above apply. • If drums are provided with a tap, ConsExpo direct dermal contact could be used to assess dermal exposure, using a layer thickness of 0.01 cm for the calculation of the amount of product to be used. The product amount should be therefore calculated multiplying the exposed area (e.g. palm and back of one hand, 410 cm²) by the layer thickness (0.01 cm). This approach is only suitable for containers < 20L as for larger containers a different mixing and loading process takes place.

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		<p><u>Inhalation exposure, for active substances with high vapour pressure:</u> ConsExpo Web, exposure to vapour – evaporation – constant release (Delmaar and Schuur, 2016)</p> <p>Please note that it is not necessary to assess inhalation exposure if the active substances are complex-bound, because no evaporation is expected. The applicant should provide evidence for this.</p>	
3.	Mixing and loading of robot or electronic sprayer	<p><u>Dermal exposure:</u> RISKOFDERM toolkit for connecting lines</p> <p>Inhalation exposure is not considered relevant, therefore no exposure calculations are required.</p>	<ul style="list-style-type: none"> • The indicative value of the RISKOFDERM toolkit for connecting lines is 0.92 mg/min. The duration is 1 minute. • The use of RISKOFDERM 'connecting lines' evaluation is only appropriate where automated transfer/pumping will occur, and should not be selected solely on the method of application (robotic spraying). • In the HEEG Opinion 1, it is indicated that the RISKOFDERM toolkit for connecting lines can be used when it can be justified that exposure is negligible compared to other related tasks, even though it is indicated that the RISKOFDERM toolkit is a semi-quantitative model and therefore has some limitations.
4.	Application by dipping	<p><u>Dermal exposure:</u> Covered by the mixing and loading step</p> <p><u>Inhalation exposure:</u> Covered by cleaning phase</p>	<ul style="list-style-type: none"> • Exposure during the use of dipping cups is considered covered by the dermal exposure as calculated by the scenario of mixing and loading. Furthermore, it is assumed that dipping cups are designed specifically for this task. This cup has an upper compartment for application of the dip and a lower compartment as reservoir for the dipping solution. During the application the worker holds the cup at the lower compartment, so direct hand exposure to the biocide product or a treated teat is avoided. • For inhalation exposure see no. 8 of this recommendation (the

No	Exposure scenario	Proposed exposure model	Remarks on the proposed model
			<p>calculated inhalation exposure during the cleaning phase), as this presents the exposure to inhalation from evaporation from all treated cows.</p> <ul style="list-style-type: none"> • During the HEAdhoc-1-2016 meeting, it was considered that the application of a biocidal product in the form of a foam by dipping cups is deemed covered by the application of a liquid by the same method.
5.	Application spraying by	Hand-held trigger spray model (Consumer product spraying and dusting model 2, Biocides Human Health Exposure Methodology)	<ul style="list-style-type: none"> • Please note that this model can be used for both manual trigger spraying and electronic spraying (not with robot). For this model the spray duration is needed as an input parameter. When following the Biocides Human Health Exposure Methodology document, the spraying or dipping time per cow/event is 10 seconds. The farmer milks 82 cows twice per day all year through. This would translate to 55 minutes exposure duration, if pre- and post-milking teat disinfection is performed at 2 milking events per day (82 cows x 10 seconds/cow x 4 times/day). • The Consumer product spraying and dusting model 2 only assesses the exposure to aerosol of non-volatile substances. For inhalation exposure to volatile active substances, see no. 8 of this recommendation (the calculated inhalation exposure during the cleaning phase), as this presents the exposure to inhalation from evaporation from all treated cows.
6.	Application by robot	No exposure estimate required	None
7.	Use of a wiping towel²	ConsExpo Web model for the cleaning and washing with wet tissues (RIVM report 320104003/2006, "Wet tissues")	<ul style="list-style-type: none"> • To estimate dermal exposure during wiping, the default ConsExpo Web model for the cleaning and washing with wet tissues is considered to be the most suitable. The dermal exposure due to the use of the wiping towel treated with the in-use solution is considered to be comparable with the dermal exposure due the use of wiping tissue.

² Note that the current Dutch practice is to refrain from wiping cow teats. From experience, farmers have learned that wiping cow teats is counterproductive for producing high quality milk. By refraining from wiping, the spreading of infectious bacteria between cow udders is decreased. When dirty, the modern farmer wipes udders/teats, depending on amount of dirt, with "dry" or "wet/moist" cloth. In case there are already problems with the quality of the milk, farmers will resort to disinfection methods described in this document in order to regain control over the quality of the milk.

No	Exposure scenario	Proposed exposure model	Remarks on the proposed model
			<ul style="list-style-type: none"> For dermal exposure to non volatile active substances, the scenario regards wiping the surface of 2 m² using a wiping tissue by hand once a day. Based on the total surface area of 2 m² this is considered to represent a sufficient worst-case scenario for treating 82 cows twice per day. The exposed surface of the hand is considered to be 205 cm² (default). It is presumed that by firmly squeezing one tissue, 47 mg of the liquid fraction will be transferred to the hand. As inhalation exposure was considered negligible during loading the inhalation exposure will not be calculated. This is valid for non-volatile active substances. In case of volatile active substances, ConsExpo Web, exposure to vapour – evaporation – constant release is the relevant model to be used. Please see the detailed parameters under no. 8 below.
8.	<p>Cleaning of teats, removal of freshly applied product pre-milking</p>	<p><u>Hand exposure:</u> A worst-case exposure of 0.1% of the amount of biocidal product on the surface area based on the Disinfectant Products Fact Sheet (RIVM report 320005003/2006) is assumed.</p> <p><u>Inhalation exposure:</u> ConsExpo Web, exposure to vapour – evaporation – constant release</p>	<ul style="list-style-type: none"> For the assessment of hand exposure, it is assumed that the surface area corresponds to the teats of the cow (with 44 cm²/teat and 176 cm²/cow). To calculate the amount of the biocidal product on the surface area, the layer thickness approach is considered appropriate (i.e. 44 cm²/teat x 4 teats x 0.01 cm x number of cows). Inhalation exposure can be estimated with the ConsExpo Web, exposure to vapour – evaporation – constant release. using the following input parameters: <ul style="list-style-type: none"> Room size: 168 m³, room surface 67.2 m², room height 2.5 m Ventilation rate: 4 times per hour Application and exposure duration: 180 minutes (for 2 times milking, assuming approximately 1 minute per cow and 82 cows per milking cycle) Release area: total area of 4 teats of all 82 cows (4 x 44 cm² x 82) Mass transfer rate: Thibodeaux's value. Molecular weight matrix: details to be included, depending on the formulation <p>Please note that Thibodeaux value is suggested for the mass</p>

No	Exposure scenario	Proposed exposure model	Remarks on the proposed model
			transfer rate because the experiment <i>by Thibodeaux</i> was conducted with evaporation from water and thus the surface over the water (and stagnant air layer) may approximate aqueous solutions better.
9.	Cleaning of teats, removal of dried residues post-milking	No exposure calculation, as exposure can be considered limited.	None
10.	Cleaning of teats by robot	No exposure calculation required	None
11.	Cleaning of equipment	<u>Hands:</u> RISKOFDERM 'Loading liquid, automated or semi-automated'	<ul style="list-style-type: none"> • The indicative value of the RISKOFDERM 'Loading liquid, automated or semi-automated' for the cleaning phase of different equipment (dipping cup, spaying nozzle etc.) is 0.92 mg/min. The duration is 5 minutes. • The RISKOFDERM 'Loading liquid, automated or semi-automated' provides a more realistic amount of exposure compared to the layer thickness model (> 20 L) and therefore it is proposed as the model to be applied. • After application, a small amount of diluted product will remain in the application equipment; however this will be highly diluted by the wash-water. Therefore, it is concluded that exposure during cleaning of application equipment is lower in comparison with exposure during the mixing and loading and application operations.

4. Proposal for harmonisation

For the exposure assessment of teat disinfection products for veterinary hygiene (PT3) by dipping cups, spraying and robot, it is proposed to use the information as included in Table 1.

According to the ESD for PT3, the default value for a dairy cow herd size is 100 animals. Dairy cows are regularly milked twice per day. The lactation period for dairy cows is normally 270 to 300 days, as two months before calving, dairy cows do not produce milk. Considering a lactating period of 300 days, 82 milk producing cows are milked per day, from a herd of 100 dairy cows³.

5. References

- [Biocides Human Health Exposure Methodology](#) (October 2015)
- Cleaning Products Fact Sheet to assess the risks for the consumer (RIVM report 320104003/2006), L.C.H. Prud'homme de Lodder, H.J. Bremmer, J.G.M. van Engelen
- Disinfectant Products Fact Sheet to assess the risks for the consumer (RIVM report 320005003/2006), L.C.H. Prud'homme de Lodder, H.J. Bremmer, S.M.G.J. Pelgrom, M.V.D.Z. Park, J.G.M. van Engelen
- ConsExpo Web. Consumer exposure models. Model documentation. RIVM Report 2016-0171. Delmaar JE, Schuur AG (2016).
- [Emission Scenario Document for Product Type 3](#) (2011)
- HEAdhoc-1-2016 meeting, BFR (Berlin, Germany), 28-29 April 2016
- [HEAdhoc Recommendation 6](#) - Methods and models to assess exposure to biocidal products in different product types- Version 2 (2 June 2016)
- [HEEG opinion 1](#) - HEEG Opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale
- Handboek Melkveehouderij October 2016. Melkwinning (hoofdstuk 9, Handboek 12). Wageningen UR Livestock Research, the Netherlands. (<http://www.wur.nl/nl/download/Handboek-Melkveehouderij-2016-H9.htm>)

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³ 100 (cows) * 300/365 = 82.2 = 82 milk producing cows per day.