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Helsinki, 18 April 2018

Substance name: benzyl alcohol
EC number: 202-859-9
CAS number: 100-51-6
Date of Latest submission(s) considered[1]: 15/03/2017
Decision/annotation number: Please refer to the REACH-IT message which delivered this communication (in format SEV-D-XXXXXXXXXX-XX-XX/F)
Addressees: Registrant(s)[2] of benzyl alcohol

DECISION ON SUBSTANCE EVALUATION

1. Requested information

Based on Article 46(1) of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), you are requested to submit the following information on the registered substance, benzyl alcohol:

Workers exposure related requests:

A) An exposure assessment and risk characterisation (Annex I, Sections 5 and 6) for inhalation and dermal exposure: revise exposure estimates for worker contributing scenarios 7, 8, 9, 10 and 11 in exposure scenario 15 using existing measured exposure data and/or higher tier models within their domain of applicability and revise the risk characterisation accordingly.

OR

If the modelled or measured exposure estimates lead to a risk characterisation indicating that risks are not adequately controlled, then you shall provide representative workplace measurement data taken under operational conditions and risk management measures as specified in the corresponding worker contributing scenarios, in order to perform a higher tier exposure assessment for inhalation and dermal exposure in accordance with the procedure laid down in the 'REACH Guidance on Information Requirements and Chemical Safety Assessment', Chapter R.14 and a risk assessment in accordance with the procedure laid down in Part E. With respect to worker contributing scenarios 8, 9, 10 and 11 in exposure scenario 15 you are also requested to provide further justification and information regarding the task duration as further outlined in Appendix 1. The reduction of task durations as a risk

[1] This decision is based on the registration dossier(s) at the end of the 12 month evaluation period.

[2] The terms Registrant(s), dossier(s) or registration(s) are used throughout the decision, irrespective of the number of registrants addressed by the decision.

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management measure to reduce exposure in these exposure scenarios must be appropriate for the tasks carried out.

B) A robust scientific justification why a linear concentration reduction can be used as a modifying factor for inhalation and dermal exposure estimates of the ECETOC TRA model.

You shall provide an update of the registration dossier(s) containing the requested information and an update of the Chemical Safety Report. Requirement under point 1, information shall be submitted by **25 April 2019**.

The reasons for this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Further information, observations and technical guidance as appropriate are provided in Appendix 3. Appendix 4 contains a list of registration numbers for the addressees of this decision. This appendix is confidential and not included in the public version of this decision.

2. Appeal

You can appeal this decision to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals.

Authorised[3] by Leena Ylä-Mononen, Director of Evaluation

[3] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

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Appendix 1: Reasons

Based on the evaluation of all relevant information submitted on benzyl alcohol and other relevant available information, ECHA concludes that further information is required in order to enable the evaluating Member State competent authority (evaluating MSCA) to complete the evaluation of whether the substance constitutes a risk to human health.

The evaluating MSCA will subsequently review the information submitted by you and evaluate if further information should be requested in order to clarify the concerns for exposure of workers.

Exposure-related requests - workers

The concern(s) identified

- Safe use is not proven by the exposure assessment provided by you.
- ECETOC TRA is used outside its application scope (linear approach).
- Body exposure has not been taken into account in RiskofDerm estimates.
- Measurement data from the hazardous substance information system (GISBAU) and the German Social Accident Insurance (IFA) indicate that inhalation exposure values for wide dispersive uses are higher than the ones assessed in the chemical safety report (CSR) and higher than the respective DNEL.

Request A)

Exposure assessment and risk characterisation (Annex I of the REACH Regulation, Sections 5 and 6) for inhalation and dermal exposure

Why new information is needed

You performed some higher tier assessments for the following wide dispersive use scenarios (ES 15 - indoors) in professional settings using the Advanced REACH Tool (ART v1.5) for inhalation exposure and in most cases RiskofDerm v2.0 (Hughson et al. 2004) for dermal exposure estimation:

- ES 15: Worker contributing scenario (WCS) 7: Roller application or brushing (PROC 10)
- ES 15: WCS 8: Non industrial spraying conc. [redacted] % (Level) (PROC 11)
- ES 15: WCS 9: Non industrial spraying conc. [redacted] % (Level) (PROC 11)
- ES 15: WCS 10: Non industrial spraying conc. [redacted] % (overhead) (PROC 11)
- ES 15: WCS 11: Non industrial spraying conc. [redacted] % (overhead) (PROC 11)

Only in the case of WCS 7 dermal exposure to hands was estimated using ECETOC TRA v3, which, however, does not predict body exposure.

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A cross check of the corresponding assessments by the evaluating MSCA revealed that you did not take into account body exposure as suggested by RiskofDerm. In this context it is important to note that according to RiskofDerm contact with contaminated surfaces during spraying and roller application/brushing respectively, can result in considerable exposure of both hands and body. However, you only considered hands. The evaluating MSCA has therefore recalculated these scenarios taking into account the exposure to the body as well and compared the results with the long-term systemic toxicity DNELs of 22 mg/m^3 and 8 mg/kg bw/day for the inhalation and dermal pathways of exposure, respectively (Table 1). The recalculation was based on the same input parameters and risk management measures as proposed by you. In addition, benzyl alcohol is considered a weak to moderate skin sensitiser. In order to allow for quantitative comparison of dermal exposure (expressed in µg/cm^2; Table 1) with the skin sensitising potential of benzyl alcohol, a DNEL of 591 µg/cm^2 was derived for workers based on several human repeated insult patch tests (HRIPT; NOAEL = 5906 µg/cm^2; Scognamiglio et al. 2012). It is noted that this DNEL was derived using only a minimal set of assessment factors (AFs), i.e. not including AFs for vehicle or matrix effects, differences in exposure conditions, the impact of repeated exposure, or additional uncertainties arising in general from the quantitative assessment of skin sensitisation based on non-standardised human data (cf. also Guidance on Information Requirements and Chemical Safety Assessment (IR&CSA), Chapter R.7a: Endpoint specific guidance, Section R.7.3.6.3).

In particular with respect to these uncertainties it needs to be underscored that the DNEL may be seen as an upper bound "best case" DNEL estimate only which does not represent an exposure level at which no sensitisation will occur in the exposed population. In line with the REACH guidance it is only used as a means to judge the remaining/residual likelihood of risks after implementation of appropriate risk management measures (RMMs) and operational conditions (OCs) ascertained on the basis of the qualitative risk assessment (IR&CSA Guidance R.8: Characterisation of dose [concentration]-response for human health, Appendix R 8-10). Since only a minimum set of AFs was used, exposure would need to be kept clearly below the DNEL in order to demonstrate safe use of the substance with respect to the risk of skin sensitisation. For the calculation of the surface dose on the hands and body (excluding hands) the surface areas used were 820 and 18720 cm^2, respectively (Hughson et al. 2004).

With respect to PROC 11 in ES 15 the CSR lists a limited task duration as one risk management measure: for WCS 8 (concentration [redacted] % benzyl alcohol) the task duration is limited to 70 min, for WCS 9 (concentration [redacted] % benzyl alcohol) the task is limited to < 60 min, for WCS 10 (concentration [redacted] % benzyl alcohol) the task is limited to 25 min and for WCS 11 (conc. [redacted] % benzyl alcohol) the task duration is limited to < 20 min. The dermal and inhalation exposure estimates have been generated assuming these exposure durations. ECHA notes that if longer task durations are assumed, the exposure estimate is significantly increased. Longer task durations are indicated by existing measurement data which can be clearly assigned to ES 15 (see below). As in addition

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these generic worker contributing scenarios, according to BG BAU (BG BAU 2015), may cover different tasks (e.g. paint stripping, wall paper removal) with possibly different patterns of use, ECHA considers that further information is required on the tasks in order to conclude on the practicality to use a limited task duration as risk management measure. In this context ECHA notes that according to data published by the German Social Accident Insurance (IFA 2016) exposure durations are often ≥ 6h per shift for wide dispersive surface treatments using benzyl alcohol.

While the ART model estimates remained unchanged on a comparatively low level, the RiskofDerm estimates increased significantly, showing that dermal exposure (hand + body) may constitute the main part of overall exposures (Table 1). For these ESs, combined RCR > 1 were calculated indicating that the health risks associated with systemic exposure to benzyl alcohol may not be sufficiently controlled. In addition, data from human repeated insult patch test (HRIPT) and results from clinical tests clearly show a skin sensitising potential of benzyl alcohol. Consequently, the CLP criteria for classification as Skin sens. Cat 1B appear to be met based on positive reactions above 500 µg/cm^2 and a low but substantial incidence of up to 0.3 % in large study populations with consecutive patients in clinical departments of dermatology. This conclusion is in line with the opinion of the Scientific Committee on Consumer Safety (SCCS) (2012). Except for WCS 10, PROC 10, surface dose estimates for hands exposure (Table 1.) already exceed the DNEL of 591 µg/cm^2 for induction of skin sensitisation to benzyl alcohol based on quantitative dose response data from HRIPT (Scognamiglio et al. 2012). Given that this DNEL value represents a "best case" upper bound estimate which was derived using only a minimum set of AF, ECHA finds that any exceedance of this value clearly indicates a risk of dermal allergy.

Table 1. Recalculated higher tier exposure estimates for wide dispersive use WCS and comparison with the long-term systemic DNELs of 22 mg/m^3 and 8 mg/kg bw/day for the inhalation and dermal pathways of exposure, respectively. The surface dose expressed in µg/cm^2 is given in brackets.

Exposure scenario	Contributing scenario (WCS)	Process category	Long term modelled exposure estimates (90th percentile)					RCR combined considering total dermal exposure
			Inhalation ART v1.5 [mg/m^3]		Dermal RiskofDerm v2.0 [mg/kg bw/day] ([µg/cm^2])			
			With RPE[4]	Without RPE	hands	body	Total	
ES 15 (prof)	7	PROC 10	-	6.6	5.5[5] (469.5)	-	5.5	1.0

[4] RPE: respiratory protective equipment
[5] Model estimate of ECETOC TRA v3.

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ES 15 (prof)	8	PROC 11 [redacted] % BA (level)	0.48	4.8	7.6 (648.8)	29.3 (109.6)	36.9	4.6
ES 15 (prof)	9	PROC 11 [redacted] % BA (level)	0.8	8	7.7 (657.3)	34.0 (127.1)	41.7	5.2
ES 15 (prof)	10	PROC 11 [redacted] % BA (overhead)	0.51	5.1	7.6 (648.8)	29.3 (109.6)	36.9	4.6
ES 15 (prof)	11	PROC 11 [redacted] % BA (overhead)	0.66	6.6	7.2 (614.6)	31.7 (118.5)	38.9	4.9

It has to be noted that monitoring data on inhalation exposure for the use of benzyl alcohol in professional settings are available from two institutions. The German Social Accident Insurance (IFA 2016) has published exposure data for a number of sectors where benzyl alcohol is used. The data reveals that inhalation exposure at workplaces is in general quite low or even below the limit of quantification if the underlying uses are non-dispersive in character (transfer, filling etc.). However, exposure can be rather high if benzyl alcohol is used in wide dispersive applications such as painting and spraying. For instance Table 2. indicates that the 90th percentile of 25 data points measured during surface treatments is about 25.5 mg/m^3 (exposure duration ≥ 6h). There is also monitoring data from the hazardous substance information system (GISBAU) of the German legal accident insurance for the construction industry (BG BAU), which show high exposure levels for the surface application of paint strippers and cleaning agents (BG BAU 2015, GISBAU 2011) (Table 2). ECHA has no further information on the background of the measured data as disclosed in the publications of IFA, BG BAU and GISBAU. The corresponding contextual information on for example room sizes, ventilation efficacy, used amount and concentration of benzyl alcohol is either not or only fragmentary documented. Therefore, a more specific assignment to the described WCSs by you was not possible. However, the measured data reflect real situations and can be clearly assigned to ES 15 (widespread use by professional workers – professional use – indoor) which allows meaningful analogies on the pattern of use between measured and modelled scenarios. Since the data is also specific for benzyl alcohol there is no uncertainty regarding volatility as this is the case with models (e.g. ART) which are based on exposure data from a variety of substances and exposure situations. Such an analogy approach is also advocated in guidance R.14 (R.14.6.3.2) where the use of measurement data from analogous situations is described.

Since the ART model is fitted to a set of measured exposure values, the result will not reflect all possible workplaces within one scenario equally well. Even within one scenario (e.g. painting operations in professional settings) there is still a range of possible exposure values reflecting differences that are not captured by respective model parameters. Thus, the result of ART exposure estimation for a specific workplace will

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have a component of uncertainty that is caused by the variability of the underlying measurements on which it is based. In addition, ART has never been validated on the basis of independent measurement data from wide spread use scenarios in professional settings.

Finally, a comparison of the ART estimates (without RPE) with the monitoring data indicates that ART may significantly underestimate inhalation exposure for such wide dispersive use scenarios making the rather low exposure estimates provided by you questionable.

Table 2. Measured data on inhalation exposure in professional settings from GISBAU and BG BAU.

Use (Reference No.)	Duration of exposure [h]	Number of data points	Number of facilities	Air concentration without RPE [mg/m³]	
				90th Percentile	95th Percentile
surface treatment (IFA, 2016)	≥ 6	25	20	25.5	36.25
use of paint stripper (GISBAU, 2016)	-	16	-	31	39
wide spread stripping of wall paper (BG BAU, 2015)	-	14	-	-	38.7

Since the modelled and measured inhalation exposure, in particular in combination with dermal exposure estimates of RiskofDerm (body + hands), clearly exceeds the DNEL, ECHA is of the opinion that safe use has not been demonstrated in the CSR for the wide spread use of benzyl alcohol by professional workers. ECHA notes that inhalation exposure does not contribute to the major part of total exposure. The DNEL is exceeded in almost all cases by dermal exposure (body+hand) alone.

Consideration of available methods

You are required to revise and provide further information for the professional wide spread use exposure scenario (ES) 15 (including WCS 7, 8, 9, 10 and 11) which has been identified as critical by ECHA. This shall include an improved task description for PROC 10 and 11. According to regulatory risk assessment (see e.g. ECHA Guidance R.13) a descriptor of the effectiveness of personal protective equipment must not assume 100 %. Therefore you are required to take into account body exposure in the respective ES. This may require the change of your initial assumptions and model input parameters. For the above listed PROCs, this might lead to the derivation of updated exposure estimates, including the direction of application assumed, whether a correction factor for concentration was applied, the use rate assumed, whether a modification factor for local exhaust ventilation (LEV) was applied to the exposure estimate either within or outside the model and how a glove and protective clothing modification factor was applied to the exposure estimate where both hand and body dermal exposure estimates are generated. You are required to provide all assumptions and model input

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parameters used to derive the updated exposure estimates. For dermal exposure estimates generated using Riskofderm, the dermal exposure operator (DEO) unit selected shall be provided. With respect to WCS 8, 9, 10, 11 in exposure scenarios 15, you are required to provide further justification for the task duration, taking into account the task description and the practicality of limiting task duration as a risk management measure in these scenarios.

ECHA considers that the following information and questions respectively would help in deriving exposure estimates:

- A detailed description of the real tasks that fall under the WCS 7, 8, 9, 10, 11 of ES 15. Such a description should provide details on the temporal pattern of the different activities (e.g. periods of spraying, roller application and brushing, removal of wall paper, non-exposed period etc.) and information to what extent the same worker or different workers are involved in these activities.
- What are the typical sizes of the area (application area) to be treated with benzyl alcohol or preparations containing benzyl alcohol and how long does it take? How much benzyl alcohol is needed per treated surface unit [m^2]?
- Does the worker leave the room after spraying immediately or is he involved in further activities that take place in the room (e.g. brushing, roller application, removal of wall paper etc.)? If yes, this has to be considered in the exposure scenario (leading to longer exposure durations and shorter non-exposure periods).
- Does the same worker do level and overhead spraying? If yes, this has to be considered in the exposure scenario (leading to longer exposure durations and shorter non-exposure periods).

The exposure assessment using model estimates and measured data for inhalation and dermal exposure should be performed in accordance with the procedure laid down in the 'REACH Guidance on Information Requirements and Chemical Safety Assessment', Chapter R.14; the risk assessment shall follow the procedure laid down in Part E.

Alternative approaches and proportionality of the request

The request to either revise exposure estimates and/or to use the existing data in combination with higher tier models within their domain of applicability for improved characterisation of the tasks/processes covered by ES 15 (WCS 7, 8, 9, 10, 11) is suitable and necessary to obtain information that will clarify whether there is a risk to workers. If the exposure estimates of this approach do lead to a risk characterisation showing that the risks are not adequately controlled, the optional request to provide representative workplace measurements (described above) is equally suited and necessary to obtain information that will clarify whether there is a risk to workers. ECHA has insufficient information on room sizes, ventilation efficacy, used amount and concentration of benzyl alcohol to clearly decide whether the available measurement data reflect workplace conditions as described by you in the worker contributing scenarios of ES 15. Workplace measurements might be used by you to define exposure determinants as well as the corresponding contextual information that cannot be

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disclosed by the measured data in the publications of IFA, BG BAU and GISBAU by ECHA. This may equally lead to a demonstration that risks are adequately controlled. There is no equally suitable alternative way available of obtaining this information. If the information, once obtained, confirms that there is a risk to workers, it will allow authorities to consider further regulatory risk management.

Consideration of Registrants' comments

You are of the opinion that application of the criteria defined in Regulation (EU) 1272/2008 does not justify classification of benzyl alcohol as skin sensitizer. In your view a sensitization rate of up to 0.3 % in very large collectives of dermatitis patients over decades seems not to meet the criteria of Regulation (EU) 1272/2008 of a "substantial" number of persons. According to your opinion, your conclusion is in line with current scientific evaluations (MAK 2017). You state that regarding animal data a recent LLNA indicated no sensitizing potential and that the other available animal studies from 1977 and 1978 with limited documentation and inconclusive results should be overruled by that newer test result.

ECHA considers that according to REACH Guidance R.7a, all data sources have to be considered in a weight-of-evidence approach. Thus, even though animal data of a recently conducted LLNA indicated no sensitizing potential of benzyl alcohol, the other available animal studies - even if documentation is sometimes limited - and especially data regarding the sensitising potential of benzyl alcohol in humans cannot be overruled by that newer LLNA test result; this is even more striking in view of recent study results, which suggest that LLNA results frequently yield false-negative outcomes (Urbisch et al. 2015).

The Guidance states that a percentage of ≥ 0.2 % of skin sensitising incidences in general population studies reflects a high frequency of occurrence of skin sensitisation. In dermatitis patients, a percentage of < 1 % of skin sensitising incidences is still considered to reflect a low to moderate frequency of occurrence. Criteria for sub-categorisation 1B with respect to human evidence listed in the CLP Regulation (Annex I, section 3.4.2.2.2.2) include "diagnostic patch test data where there is a relatively low but substantial incidence of reactions in a defined population in relation to relatively high exposure;" and "other epidemiological evidence where there is a relatively low but substantial incidence of allergic contact dermatitis in relation to relatively high exposure". Thus, there are grounds to consider the classification of benzyl alcohol as Skin Sens. Cat. 1B, according to CLP criteria.

You are of the opinion that body exposure counts as zero when appropriate chemical protective equipment is worn. Based on this assumption you refer to the CSR where all modelled values yield in a risk characterisation ratio (RCR) below 1. Hence you concluded that there is no need to revise the exposure assessment for ES 15 in the CSR. ECHA does not accept 100 % efficiency of personal protective clothing (PPE). Since body exposure leads to considerably higher RiskofDerm exposure estimates, a comparison of the total exposure with the DNELs reveals that safe use has not been demonstrated for the corresponding scenarios. Since it is commonly accepted in regulatory risk assessment (see e.g. ECHA Guidance R.13) that a reasonable descriptor of the effectiveness of personal protective equipment must not assume 100 %, it is ECHA's

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position that you need to consider body exposure and needs to take into account the efficiency of personal protective clothing in the exposure assessment of ES 15.

You also argue that the measured values provided by IFA, BG BAU and GISBAU are not useful for risk assessment purposes due to their low level of documentation. As already mentioned above, ECHA agrees that the documentation of the measured data is very fragmentary and does not inform sufficiently about the OCs and RMMs. However, ECHA is not in the situation to ignore measured data which are substance specific and which can clearly be assigned to ES 15 (widespread use by professional workers – professional use – indoor). In contrast, you did not provide any new facts or arguments demonstrating that the measured data do not reflect the workplace conditions as described by you in the worker contributing scenarios of ES 15. Instead you only stated that contextual information on the measured data is missing in some respect.

Your argumentation is based on the assumption that the measured data of BG BAU and GISBAU reflect spraying operations. However, neither BG BAU nor GISBAU indicated that those workplace measurements were taken during spraying operations. Hence, as you were not able to demonstrate that the measured data do not reflect the conditions of the corresponding workplace contributing scenarios, from the ECHA point of view there is currently no evidence for this assumption and ECHA will further make reference to these measured data.

Reducing the task duration has been described by you as one RMM. You state that your task in the REACH process is to describe conditions in a CSR where the substance can be used safely. Further, according to Annex II of the REACH Regulation the conditions of use including OCs and RMMs are described in the eSDS and communicated via the supply chain. You argue that you are not in the position to control on the use at downstream users' workplaces. You criticise that ECHA did not state what kind of additional information would be required. As not foreseen by the REACH Regulation, you do not see the obligation for further information beyond the eSDS.
According to ECHA Guidance R.12 "Use description" realistic information on the conditions of use is the basis to ensure a meaningful and complete exposure assessment. Whether the durations recommended in the ES reflect real and realistic workplace conditions is still questionable since you did not provide any information or arguments that invalidate the difference between recommended duration and the durations reported by downstream user associations. Furthermore it is still not clear which real tasks are covered by the generic worker contributing scenarios (WCS 7, 8, 9, 10, 11). Considering the information given by BG BAU paint stripping and wall paper removal may be covered by the WCS. However, it is not clear if spray application for paint stripping in closed rooms and for wall paper removal. You neither confirmed this nor did you provide any information on the temporal pattern of spray application for those or other tasks at real workplaces. Since extended spraying times may lead to RCRs above 1 ECHA is of the opinion that the uncertainties described above should be diminished considerably.

In order to clarify whether the spraying durations as they are recommended by you are practicable and realistic you should ask the downstream users to provide corresponding

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information. Information on how to diminish these uncertainties is provided under "Consideration of available methods" above.

You furthermore state that performance of measurements at the sites of downstream users is beyond your capacity and the responsibility. According to REACH Regulation Art. 125, 126 and 127, enforcement is performed by national member states authorities.

ECHA would like to note that the information on workplace measurements is required according to Article 46(1) of the REACH Regulation. According to this provision the competent authority may require you to provide further information. If the information submitted by you is not appropriate to meet the data requirement, the original data request shall continue to exist.

Therefore, the issue at hand is not a matter of enforcement, which is, indeed, a governmental task imposed on the Member States by Title IV, Art. 125-127 of the REACH Regulation, but a mere request for further information according to Article 46.

Conclusion

Therefore, based on the substance evaluation and pursuant to Article 46(1) of the REACH Regulation, ECHA concludes that you are required either to revise inhalation and dermal exposure estimates for particular exposure scenarios 15 (WCS 7, 8, 9, 10 and 11) using already available measured exposure data and/or higher tier models within their domain of applicability;

or

If the modelled or measured exposure estimates lead to a risk characterisation indicating that risks are not adequately controlled you are required to provide representative workplace measurements generated under operational conditions using the registered substance. With respect to worker contributing scenario 8, 9 10, 11 you are also required to provide further justification for the task duration, taking into account the practicality of limiting task duration as a risk management measure in these scenarios.

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Request B)

Scientific justification why a linear concentration reduction can be used as a modifying factor for inhalation and dermal exposure estimates of the ECETOC TRA model

Why new information is needed

In some worker contributing scenarios you diverge from the tool defaults. Instead of using the banded exposure modifiers for substances in preparations, which are implemented in the model, you used a linear approach to adjust the estimates for inhalation and dermal exposure. In this context it is important to note that all tools incorporate variability and uncertainties (J. Lamb et al. 2015). For instance, generic models like ECETOC TRA v3 do not take into account the molecular interactions of the constituents in a mixture which may lead to significant deviations from ideal (linear) behaviour (Gmehling et al. 1988). According to R.14 (ECHA 2016) it is therefore generally not admissible to further refine these outputs through, for example, applying linear reductions for elements such as concentration in mixtures or duration of exposure unless robust scientific justification is provided.

The evaluating MSCA has therefore recalculated the corresponding scenarios using the default ECETOC TRA v3 modifying factors for the concentration in mixtures and compared the obtained values with the long-term systemic toxicity DNELs of 22 mg/m^3 and 8 mg/kg bw/day for the inhalation and dermal pathways of exposure, respectively. In order to allow comparison with the DNEL for the endpoint skin sensitisation Table 3. also lists dermal exposure estimates expressed in terms of surface dose for hands. As can be seen from Table 3. the recalculated exposure estimates for inhalation and dermal exposure deviate significantly from the values assessed with a linear modification approach. Consequently, combined RCRs > 1 were calculated. In contrast to the RiskofDerm estimates discussed earlier, dermal surface doses remained below the DNEL of 591 $\mu g/cm^2$ for induction of skin sensitisation to benzyl alcohol. However, since the assessment is outside the applicability domain of the model, you should provide a robust justification why this linear exposure modification is appropriate for this specific assessment case or should use an appropriate higher tier model.

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Table 3. Comparison of exposure estimates – ECETOC TRA default modifying factors vs. linear concentration reduction approach. Values obtained using ECETOC TRA default modifying factors for concentration are compared with the long-term systemic DNELs of 22 mg/m³ and 8 mg/kg bw/day for the inhalation and dermal pathways of exposure, respectively, to calculate combined RCRs. The surface dose expressed in µg/cm² is given in brackets.

Exposure scenario	Contributing Scenario (WCS)	Process category	Long term modelled exposure estimates (ECETOC TRA default modifying factors for concentration)		Long term modelled exposure estimates as calculated by you (linear concentration reduction approach)		RCR combined considering default modifying factors
			Inhalation [mg/m³]	Dermal [mg/kg·bw/day] ([µg/cm²])	Inhalation [mg/m³]	Dermal [mg/kg·bw/day] ([µg/cm²])	
ES 4	11	PROC 19	13.5	8.49 (306.3)	4.5	2.82 (99.7)	1.6
ES 7	3	PROC 7	22.5	2.14 (99.9)	13.5	1.28 (59.7)	1.2
ES 9	4	PROC 7	22.5	2.14 (99.9)	13.5	1.28 (59.7)	1.2
ES 12	4	PROC 7	22.5	2.14 (99.9)	13.5	1.28 (59.7)	1.2
ES 13	2	PROC 7	22.5	2.14 (99.9)	13.5	1.28 (59.7)	1.2

Considerations on the test method and testing strategy

You are required to provide a justification for the use of a linear approach of the ECETOC TRA model. All assumptions and model input parameters used to derive the exposure estimates shall be documented.

Alternative approaches and Proportionality of the request

The request to justify the use of a linear approach of the ECETOC TRA model will clarify whether there is a risk to workers for inhalation and dermal exposure. There is no equally suitable alternative way available of obtaining this information. If the information, once obtained, confirms that there is a risk to workers, it will allow authorities to consider further regulatory risk management.

Consideration of Registrants' comments

For inhalation exposure, you state that you will use higher Tier models as they reflect the influence of concentration and duration.

ECHA appreciates that you will use higher tier models for inhalation exposure that can reflect the influence of concentration on exposure more realistically.

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The decision requires a robust scientific justification why a linear concentration reduction can be used as a modifying factor for dermal exposure of the ECETOC TRA model. You instead give an explanation why a reduction factor can be used that takes into account the duration of the task.

ECHA notes that a justification for a using a linear concentration factor is still missing and should be submitted accordingly.

With regard to the use of dermal exposure duration modifiers ECHA notes that the statement of Hesse et al. is taken from ECETOC Technical Report No.114. There the following is stated:

> *"Unlike inhalation exposure, the effect of duration of the work activity on the dermal exposure estimation is difficult to predict as it is related to the fate of the substance once it has been deposited onto the skin, with low / very low volatiles and 'dusty' solids remaining on the skin well beyond the cessation of the activity unless intentionally removed by washing etc."*

However, washing is generally only carried out at the end of the task and therefore a dermal exposure over the whole task is possible. TRA v3 dermal exposure duration modifiers therefore do not apply to low / very low volatility liquids or moderate and high dusty solid.

A model calculation with ECETOC TRA for (low volatile) benzyl alcohol taking into account the task duration as an exposure modifier is therefore clearly outside the scope of the model which is expected to be conservative. ECHA also does not accept your argument that "*appropriate PPE in use not exceeding the break-through time will lead to exposure on the PPE but to no exposure on the worker´s skin surface*". The reason for this has been outlined in the comments above. It is therefore recommended to use higher tier models that can address the influence of the task duration. As an alternative, exposure measurements in real exposure situations can be carried out.

Conclusion

Therefore, based on the substance evaluation and pursuant to Article 46(1) of the REACH Regulation, ECHA concludes that you are required to provide a robust scientific justification why a linear approach for the concentration modifying factor, instead of the default banded approach of the ECETOC TRA model, is appropriate to adjust the estimates for inhalation and dermal exposure.

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Appendix 2: Procedural history

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to wide dispersive use, suspected sensitiser, exposure of workers, high RCRs, benzyl alcohol, CAS No 100-51-6 (EC No 202-859-9) was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2016. The updated CoRAP was published on the ECHA website on 22 March 2016. The Competent Authority of Germany (hereafter called the evaluating MSCA) was appointed to carry out the evaluation.

Pursuant to Article 45(4) of the REACH Regulation the evaluating MSCA carried out the evaluation of the above substance based on the information in your registration(s) and other relevant and available information.

In the course of the evaluation, the evaluating MSCA identified additional concerns regarding reproductive toxicity.

The evaluating MSCA considered that further information was required to clarify the concern rising from exposure of workers and the concern based on insufficient information on effects on fertility in order to draw a final conclusion regarding possible effects of benzyl alcohol on fertility of humans. Therefore, it prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted the draft decision to ECHA on 21 March 2017.

The decision making followed the procedure of Articles 50 and 52 of the REACH Regulation.

ECHA notified you of the draft decision and invited you to provide comments.

Registrant(s)' commenting phase

ECHA received comments from you and forwarded them to the evaluating MSCA without delay.

The evaluating MSCA took the comments from you, which were sent within the commenting period, into account and they are reflected in the reasons (Appendix 1). The request(s) and the deadline were amended. During the process you updated information on effects on fertility. The evaluating MSCA accepted the weight of evidence proposed by you and subsequently dropped the request for further information on effects on fertility.

Proposals for amendment by other MSCAs and ECHA and referral to the Member State Committee

The evaluating MSCA notified the draft decision to the competent authorities of the other Member States and ECHA for proposal(s) for amendment.

As no amendments were proposed, ECHA took the decision according to Articles 52(2) and 51(3) of the REACH Regulation.

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Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided by you in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on your dossier(s) at a later stage, nor does it prevent a subsequent decision under the current substance evaluation or a new substance evaluation process once the present substance evaluation has been completed.

2. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.