Helsinki, 20 November 2018

Addressee: [redacted]

Decision number: CCH-D-2114451441-58-01/F
Substance name: Butyl glycollate
EC number: 230-991-7
CAS number: 7397-62-8
Registration number: [redacted]
Submission number: [redacted]
Submission date: 08/10/2013
Registered tonnage band: Over 1000

DECISION ON A COMPLIANCE CHECK

Based on Article 41 (1)(c) and (3) of Regulation (EC) No 1907/2006 (the REACH Regulation), ECHA requests you to submit information on:

1. **Identification of DNEL(s) and risk characterisation (Annex I, Section 1.4. and 6.): revise long-term DNELs for systemic effects for workers via inhalation and dermal route and for the general population for all routes (inhalation, dermal and oral route) using the assessment factors according to ECHA Guidance R.8 for DNEL derivation and revise the risk characterisation accordingly *or* provide a detailed justification for not using the recommendations of ECHA Guidance R.8 for DNEL derivation;**

2. **Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for human health: revise worker exposure estimates for ES3, ES4, ES5 using a model within its domain of applicability *or* provide adequate measured representative exposure data and revise the risk characterisation accordingly;**

3. **Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for human health: provide a qualitative exposure assessment demonstrating the likelihood that serious eye damage is avoided in all identified uses for workers, detail the operational conditions and risk management measures and revise the risk characterisation accordingly**

4. **Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for human health: refine exposure assessment demonstrating the likelihood that serious eye damage is avoided for consumers (ES6, ES7), detail the operational conditions and risk management measures and revise the risk characterisation accordingly;**

5. **Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for environment:**

   - use default release factors from the relevant Environmental Release Categories for exposure assessment for Exposure Scenarios 1, 4-7 and revise the risk characterisation accordingly *or* provide a detailed justification for not using the relevant Environmental Release Categories for the description of the use and the default release factors for exposure assessment (for instance based on risk management measures, operational conditions or substance properties);

   - identify article service life of the substance, if the technical role of the substance in coating formulations is not a solvent and substance is included into/onto article, and generate relevant exposure assessment and the risk characterisation accordingly;

   - use the default release factors from the relevant Environmental Release Category for Exposure Scenario 3 *or* identify the Specific Environmental Release Category used for the exposure assessment for exposure assessment for this Exposure Scenario;

   - use the default number of use (release) days from ECHA Guidance on information requirements and Chemical Safety Assessment, Chapter R.16 (version 3.0, February 2016) for the exposure assessment for Exposure Scenario 3 *or* provide a justification for the use of specific non-default number of use (release) days;

   - justify efficiencies of the substance removal by Sewage Treatment Plant used for the exposure assessment of various Exposure Scenarios;

   - use default effluent discharge and receiving water flow rates from ECHA Guidance on information requirements and Chemical Safety Assessment, Chapter R.16 (version 3.0, February 2016) for the exposure assessment of Exposure Scenario 1 or provide a detailed justification for the use of specific non-default effluent discharge and receiving water flow rates;

   - provide a clear and detailed explanation of the distribution of manufactured volume of the substance through all life-cycle stages of the substance.

You have to submit the requested information in an updated registration dossier by ***21 January 2020***. You also have to update the chemical safety report, where relevant.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

The scope of this compliance check decision is limited to the standard information requirements of Annex I and VI to the REACH Regulation.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to 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[1] by Kevin Pollard, Head of Unit, Evaluation E1

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

Appendix 1: Reasons

In accordance with Articles 10(b) and 14(1) of the REACH Regulation, the registration must contain a chemical safety report (CSR) which documents the chemical safety assessment (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I to the REACH Regulation.

1. Identification of DNEL(s) and risk characterisation (Annex I, Section 1.4. and 6).

According to Article 14(4) and Annex I, Section 1.0, of the REACH Regulation, one of the objectives of human health hazard assessment is to derive levels of exposure to the substance above which human individuals should not be exposed. This level of exposure is known as the Derived No-Effect Level (DNEL).

Annex I, Section 1.4.1 of the REACH Regulation requires that the following factors shall, among others, be taken into account when deriving DNELs:

a) the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;
b) the nature and severity of the effect;
c) the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies;
d) and that the DNELs reflect the likely route(s), duration and frequency of exposure.

If it is not possible to identify a DNEL, this must be clearly stated and fully justified (Annex I, Section 1.4.2)

The ECHA Guidance on information requirements and chemical safety assessment Chapter R.8 Characterisation of dose [concentration]-response for human health (version 2.1, November 2012) provides further details and specifically provides default factors which should be applied to derive DNELs in the absence of substance specific information to fulfill the REACH obligations.

ECHA notes that you applied assessment factors (AF), which you neither derived in accordance to the default assessment factors recommended in the ECHA Guidance R.8 for DNEL derivation nor did you provide a full justification for the deviating derivation of DNELs, which would be in line with Annex I, 1.4.1.

ECHA observes that in the DNEL derivation for workers, via inhalation, for long-term systemic effects, you have modified the starting point converting an oral rat NOAEL to an inhalation NOAEL, and therefore the differences in the allometry are taken into account by differences in the respiratory rate, and the allometric scaling factor is not usually applied. However, you have not applied the additional AF of 2.5 for other interspecies differences. Additionally, you have applied an AF of [redacted] for intraspecies variations between humans, while the default AF according to ECHA Guidance R.8 is 5 for workers. ECHA notes as well that you have not applied any factor for the difference in the experimental exposure duration and the duration of exposure for the workers. The starting point for the DNEL is a sub-chronic 90-day repeated dose toxicity study, which corresponds to an extrapolation from sub-chronic to chronic and therefore the default AF of 2 should have been applied.

ECHA observes that in the DNEL derivation for workers via dermal route, for long-term systemic effects, you have modified the starting point assuming a [redacted] absorption via dermal route. Additionally, you have taken into account the following AF based on ECETOC Guidances (2010 and 2003): [redacted] for interspecies differences (allometric scaling), [redacted] for intraspecies variations and [redacted] for exposure duration (sub-chronic to chronic). Also in this case, ECHA underlines that according to ECHA Guidance R.8 an additional AF of 2.5 for other interspecies differences shall be applied, and the AF accounting for intraspecies variations between humans according to ECHA Guidance R.8 is 5 instead of [redacted] applied by you.

ECHA observes that in the DNEL derivation for the general population, for all routes (inhalation, dermal and oral) and for long-term systemic effects, you have the same deficiencies (lack of the additional AF of 2.5 for other interspecies and the lack of the AF for exposure duration for inhalation route) as for worker's DNEL derivation. However, here you have applied an AF of [redacted] for the intraspecies variations between humans for inhalation and dermal route and [redacted] for oral route, while the default AF accounting for intraspecies variations recommended in ECHA Guidance R.8 is 10 for the general population for all routes.

ECHA notes that, according to your dossier, the registered substance does not cause any observed adverse effects for skin irritation/corrosion or for skin sensitization. Hence, the DNELs for local effects are not needed. However, the registered substance is classified for serious eye damage/irritation and thus a moderate hazard conclusion for eyes, local effects, shall be included in a qualitative risk assessment for workers and the general population in the CSR.

The following table lists assessment factors (AF) you applied in your registration dossier compared to the default factors recommended in ECHA Guidance R.8.

DNEL		AFs applied	ECHA AFs
Workers, long-term, inhalation, systemic effects	interspecies allometric scaling	[redacted]	-
	interspecies remaining	[redacted]	2.5
	intraspecies	[redacted]	5
	exposure duration	[redacted]	2
	Overall AF	[redacted]	25
Workers, long-term, dermal, systemic effects	interspecies allometric scaling	[redacted]	4 (rat to human)
	interspecies remaining	[redacted]	2.5
	intraspecies	[redacted]	5
	exposure duration	[redacted]	2
	Overall AF	[redacted]	100
General population, long-term, inhalation, systemic effects	interspecies allometric scaling	[redacted]	-
	interspecies remaining	[redacted]	2.5
	intraspecies	[redacted]	10
	exposure duration	[redacted]	2
	Overall AF	[redacted]	50
General population,	interspecies allometric scaling	[redacted]	4 (rat to human)

DNEL		AFs applied	ECHA AFs
long-term, dermal, systemic effects	interspecies remaining	[redacted]	2.5
	intraspecies	[redacted]	10
	exposure duration	[redacted]	2
	Overall AF	[redacted]	200
General population, long-term, oral, systemic effects	interspecies allometric scaling	[redacted]	4 (rat to human)
	interspecies remaining	[redacted]	2.5
	intraspecies	[redacted]	10
	exposure duration	[redacted]	2
	Overall AF	[redacted]	200

ECHA notes that the reference to the ECETOC guidance cannot replace the ECHA Guidance which has been agreed between all stakeholders, including industry representatives.

As explained above, the information provided on DNEL for the registered substance in the chemical safety report does not meet the general provisions for preparing a chemical safety report as described in Annex I, 1.4.1.

Consequently, you are given two options: you shall revise the long-term DNELs for workers and for the general population for all relevant routes by applying the assessment factors recommended by ECHA that are appropriate in this case, as specified above. Subsequently, you shall re-assess related risks.

In the alternative, you shall, in accordance with Annex I, Section 1.4.1, provide a full justification for the DNELs derived for workers and for the general population provided in the chemical safety report by specifying how the following has been taken into account:

a) the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;
b) the nature and severity of the effect;
c) the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies;
d) and that the DNELs reflect the likely route(s), duration and frequency of exposure.

In your comments to the draft decision you indicate that you agree with the information requirement in the draft decision. In addition, you indicate that you have addressed the information requirement in an updated registration dossier which includes an updated Chemical Safety Report (CSR), submitted to ECHA on 9 February 2018. You outline in your comments to the draft decision how you could address the information requirement by stating that "The DNELs were revised as proposed in ECHA's draft decision CCH-D-2114381302-57-01/D ". In your dossier update, you explain what was provided as well as providing new information that has not been available earlier, to meet the information requirement addressed in this decision.

You are reminded that this decision does not take into account any updates submitted after the notification of the draft decision to you. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to revise long-term DNEL(s) for workers via inhalation and dermal route and for the general population via inhalation, dermal and oral route for systemic effects using the default assessment factors and other recommendations of ECHA Guidance R.8 for DNEL derivation and revise the risk characterisation accordingly *or* provide a detailed justification for not using the recommendations of ECHA Guidance R.8 for DNEL derivation.

2. Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for human health; worker's quantitative exposure assessment

According to Article 14(4), if the substance fulfils the criteria for hazard classes or categories of the CLP Regulation listed in that Article, the chemical safety assessment must include an exposure assessment (governed by Annex I, section 5) and a risk characterisation (governed by Annex I, section 6).

Annex I, Section 5.2.4 requires you to perform an estimation of the exposure levels for all human populations (workers, consumer and humans liable to exposure via the environment) for which exposure to the substance is known or reasonably foreseeable. Each relevant route of exposure (inhalation, oral, dermal and combined through all relevant routes and sources of exposure) shall be addressed.

Further, Annex I, Section 5.2.5. states that appropriate models can be used for the estimation of exposure levels. However, special consideration shall be given to representative exposure data where available, when conducting the exposure assessment.

ECHA notes that you have classified the registerered substance as serious eye damage, cat. 1 and reproductive toxicant, cat. 2, which are hazard classes/categories listed in Article 14(4) of the REACH Regulation. Accordingly, your chemical safety assessment must include an exposure assessment and a risk characterisation.

ECHA also observes that, according to the information provided in the technical registration dossier and in the CSR, you have used the ECETOC TRA v.3 model for estimating exposure. ECHA notes that the quantitative worker exposure assessment contains the following deficiencies:

1. You have applied ECETOC TRA model for predicting exposure for PROCs 7 (industrial spraying), 11 (non-industrial spraying) and 10 (roller application and brushing) in worker contributing scenario (WCS) 2 and 6 in the exposure scenario (ES)3, in WCS3 and 6 in the ES4 and in WCS3 and 4 in the ES5. For spraying applications (PROC 7 and PROC 11) and for rolling and brushing activities (PROC 10), inhalation exposure is mostly due to aerosol generation while the ECETOC TRA model predicts only vapour phase exposure and exposure by aerosol formation is not taken into account. As stated in ECETOC TRA technical report No. 114, section 2.2.4: "*if aerosol formation is relevant, refer to other information or model*". Additionally, the substance is in low fugacity band (vapour pressure = 1 Pa) and therefore the inhalation exposure of the registered substance may be underestimated and the estimated worker exposures may be associated with a higher level of uncertainty.

ECHA notes that the quantitative (or the semi-quantitative) assessment should be carried out according to ECHA's *Guidance on information requirements and chemical safety assessment* Part E, Risk characterisation (version 3.0, May 2016), section E.3 and Chapter R.14 Occupational exposure assessment (version 3.0, August 2016). Following REACH Regulation Annex I, Section 6.4 and ECHA's Guidance Part E and Chapter R.14, the risk to humans can be considered to be adequately controlled, if the exposure level estimates do not exceed the appropriate DNEL (derived no effect level) and RCR (risk characterisation ratio) are below 1.

ECHA notes that you are using exposure estimates in your exposure scenarios, which have been calculated by using a model in an inappropriate manner. For predicting exposure levels and assessing risk in case of potential aerosol formation, ECHA recommends using appropriate exposure models, such as ART or Stoffenmanager, and, where available, measured data. For spraying tasks, there is a need to consider adequate control of exposure to aerosol for all routes of exposure. You should provide sufficiently detailed descriptions of RMMs, which you recommend to implement for controlling inhalation, dermal and eye exposure in all relevant contributing scenarios. ECHA also notes that the quantitative exposure estimations should be consistent with the qualitative risk characterisation in the CSR.

In your comments to the draft decision you indicate that you agree with the information requirement in the draft decision. In addition, you indicate that you have addressed the information requirement in an updated registration dossier which includes an updated CSR, submitted to ECHA on 9 February 2018. You outline in your comments to the draft decision how you could address the information requirement by stating that "The use and exposure scenarios for butyl glycollate were completely revised based on the most recent internal information. The risk assessment for human health (worker's quantitative exposure assessment) was updated as proposed in draft decision CCH-D-2114381302-57-01/D.". In your dossier update, you explain what was provided as well as providing new information that has not been available earlier.

You are reminded that this decision does not take into account any updates submitted after the notification of the draft decision to you. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

Irrespective of whether the newly provided information in the dossier update may be sufficient to meet the information requirement addressed in this decision, ECHA can already point out the following:

- the ECETOC TRA model predicts only vapour phase exposure: "*if aerosol formation is relevant, refer to other information or model*" as indicated in the ECETOC TRA technical report No. 114;
- the use of a higher vapour pressure ([redacted]) than the one of the registered substance is not acceptable without specific justification and also in view of the fact that this does not change the fugacity band of the substance (please refer to the ECETOC TRA model for boundaries of the fugacity bands);
- the use of a lower vapour pressure ([redacted]) than the one of the registered substance is not acceptable without specific justification;
- all exposure estimates shall be reproducible.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to revise worker exposure estimates for ES3, ES4, and ES5, demonstrating safe use using a model within its domain of applicability and in accordance with the guidance for the model used or provide adequate measured representative exposure data and revise the risk characterisation accordingly.

3. Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for human health; worker's qualitative exposure assessment

As described in section 2 above, your chemical safety assessment must include an exposure assessment and a risk characterisation.

Annex I, Section 5. of the REACH Regulation indicates that the objective of the exposure assessment shall be to make a quantitative or qualitative estimate of the dose/concentration of the substance at which humans [...] are or may be exposed. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards.

Further, Annex I, Section 6.5. of the REACH Regulation states that "*for those human effects and those environmental spheres for which it was not possible to determine a DNEL or a PNEC, a qualitative assessment of the likelihood that effects are avoided when implementing the exposure scenario shall be carried out.*" Additionally in ECHA's *Guidance on information requirements and chemical safety assessment,* Chapter E, Risk characterisation (version 3.0, May 2016), section E.3.4., it is reported that "*The endpoints for which the available data may trigger a qualitative risk characterisation are: irritation/corrosion, sensitisation, acute toxicity, carcinogenicity and mutagenicity".* ECHA notes that the registered substance is classified for a serious eye damage (Eye Damage 1) which indicates corrosive to severe irritant effect to the eye.

You have used a quantitative approach alone within your exposure assessment and risk characterisation. The model used by you is ECETOC TRA version 3.

In section 9.0.2.3. of the CSR, you claim that the risk characterisation for workers for the local effects on eyes is not needed since "*no hazard is identified*". Additionally, ECHA observes that in section 5.11.2 of the CSR you state for eyes local effects: "[redacted] *is irritating to eyes. Therefore, the use of sufficient protective measures to eyes (goggles) can be assumed*" and "*No DNELs for acute systemic or local effects were derived. Long-term DNEL in combination with suitable safety measures for processing/packaging with regards to classification as severe eye irritant are considered sufficient to ensure that exposure will not occur at the work place*" and "*There are not acute DNEL values calculated because worker exposure is highly unlikely due to production in closed systems, low vapor pressure, suitable safety measures for processing/packaging with regards to classification as severe eye irritant and finally the acute DNELs would be covered by the long term DNELs".*

However, ECHA notes that all worker exposure scenarios described in the CSR are not occuring under closed system and there is no recommendation to use safety goggles.

Now, your substance, which has a classification as Eye damage 1, is allocated to the moderate hazard band on the basis that exposure to such an eye damaging substance is assumed to be well-controlled. As described in the ECHA's *Guidance on information requirements and chemical safety assessment,* Chapter E, Risk characterisation (version 3.0, May 2016), a qualitative assessment to define risk management measures (RMMs) and operational conditions (OCs) should have been the first step, describing how to prevent the contact with the substance.

ECHA notes that essential parts of the qualitative assessment are missing from the CSR. The exposure scenarios should include a sufficiently detailed description of the operational conditions and risk management measures that are applied to prevent eye contact from the manufacture and identified uses of the substance through the supply chain.

In your comments to the draft decision you indicate that you agree with the information requirement in the draft decision. In addition, you indicate that you have addressed the information requirement in an updated registration dossier which includes an updated CSR, submitted to ECHA on 9 February 2018. You outline in your comments to the draft decision how you could address the information requirement by stating that "The risk assessment for human health (worker's qualitative exposure assessment) was updated as proposed in draft decision CCH-D-2114381302-57-01/D". In your dossier update, you explain what was provided as well as providing new information that has not been available earlier, to meet the information requirement addressed in this decision.

You are reminded that this decision does not take into account any updates submitted after the notification of the draft decision to you. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to provide a qualitative exposure assessment demonstrating the likelihood that serious eye damage is avoided for all identified uses for workers, detail the operational conditions and risk management measures and revise the risk characterisation accordingly.

4. Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for human health; consumer exposure assessment

As described in section 2 above, your chemical safety assessment must include an exposure assessment and a risk characterisation.

According to Annex I, section 5.0, the exposure assessment shall entail the following two steps, which shall be clearly identified as such in the Chemical Safety Report:

Step 1. The generation of exposure scenario(s) or the generation of relevant use and exposure categories.
Step 2. Exposure estimation.

The generation of exposure scenarios should include, where relevant, a description of operational conditions, such as the activities of consumers and the duration and frequency of their exposure to the substance, and risk management measures to reduce or avoid direct and indirect exposure of humans, including consumers. An estimation of the exposure levels shall be performed for all human populations, including consumers.

You have provided two consumer use scenarios – consumer use of coatings, outdoor and indoor (ES6 and ES7). In both consumer uses you have two consumer contributing exposure scenarios (CCS) named as [redacted]. You have predicted the consumer exposure by using ConsExpo 4.1 and TRA Consumer v3. In your CSR, you state that the outdoor uses are covered by indoor use scenarios.

ECHA notes some deficiencies with your consumer exposure and risk assessments:

1. The relevant parameters *e.g.* product ingredient fraction by weight, exposure time and amount of the product used per application have not been provided for all contributing scenarios in a way that the exposure estimation could be reproduced.
2. It is unclear, which fact sheet you selected from the ConsExpo model.
3. Your exposure assessment and risk characterisation for consumer uses is lacking applied risk management measures. In section 9.0.2.4 of the CSR you state that the risk characterisation for consumers for the local effects on eyes is "*undefined (hazard conclusion missing)*".

ECHA notes, that the qualitative (or the semi-quantitative) assessment for consumer uses should be carried out according to ECHA's *Guidance on information requirements and chemical safety assessment*, Chapter R.15: Consumer exposure assessment (version 3.0, July 2016) and ECHA's *Guidance on information requirements and chemical safety assessment*, Chapter E, Risk characterisation (version 3.0, May 2016), section E.3.4, pages 22 to 36.

Risk management measures for consumer use are limited and product-integrated measures are often the only appropriate RMMs for consumer products. According ECHA Guidance (page 30): "*Risk management measures for corrosive or sensitising substances in consumer preparations are limited. Compliance in the implementation of technical controls and PPE is usually impossible to determine in a consumer population, therefore product-integrated measures (such as the maximum volume of the bottle, concentrations used, high viscosity of the product, child resistant fastening) are often the only appropriate RMMs that can be applied. Diluted preparations, child-resistant fastenings and product formulation, which prevent splashes (e.g. viscous or paste-like formulation) as well as labelling and correct use instructions are commonly recognized RMMs for consumer products*".

ECHA reminds that the registered substance may cause serious eye damage. The outcome of the risk characterisation should be used to decide whether safe use can be demonstrated or not through comparison with DNELs or by the likelihood of effects being avoided. ECHA notes that currently you have not demonstrated the safe use of consumer products and articles.

In your comments to the draft decision you indicate that you agree with the information requirement in the draft decision. In addition, you indicate that you have addressed the information requirement in an updated registration dossier which includes an updated CSR, submitted to ECHA on 9 February 2018. You outline in your comments to the draft decision how you could address the information requirement by stating that "The use and exposure scenarios for butyl glycollate were completely revised based on the most recent internal information. The risk assessment for human health (consumer exposure assessment) was updated as proposed in draft decision CCH-D-2114381302-57-01/D". In your dossier update, you explain what was provided as well as providing new information that has not been available earlier.

You are reminded that this decision does not take into account any updates submitted after the notification of the draft decision to you. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

Irrespective of whether the newly provided information may be sufficient to meet the information requirement addressed in this decision, ECHA can already point out that the precautionary statements which shall be included in the label of a consumer product containing a classified substance are missing.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to revise the exposure assessment demonstrating the likelihood that serious eye damage is avoided for consumers (ES6 and ES7), detail operational conditions and product integrated risk management measures and revise the risk characterisation accordingly.

5. Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for environment

As described in section 2 above, your chemical safety assessment must include an exposure assessment and a risk characterisation.

Annex I, Section 5 of the REACH Regulation requires the registrant to generate exposure scenarios and exposure estimations for the registered substance. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards. Pursuant to Annex I, Section 5.2.1 of the REACH Regulation the exposure estimation entails three elements: emission estimation, assessment of chemical fate and pathways and estimation of exposure levels. Emission estimation shall be performed under the assumption that the risk management measures (RMMs) and operational conditions (OCs) described in the exposure scenario (ES) have been implemented. These RMMs and OCs should be included in the ESs provided in a Chemical Safety Report (CSR).
ECHA observes that you reported seven ESs in the CSR provided in the registration dossier.

a) As explained in the ECHA Guidance on information requirements and Chemical Safety Assessment, Chapter R.16 (version 3.0, February 2016), "*a set of default release factors associated to each ERC has been defined during the process of REACH guidance development. Those release factors are assumed to be conservative default values, assuming no specific risk management measures are in place. [...] In a first instance, or in the absence of more specific information, assessors may use the release factors associated to the ERC to carry out their release estimation. If a specific RMM is applied in current practice (for example, according to the best available techniques) and the effectiveness of such a technique for the respective substance is known, release factors can be reduced accordingly and taken into account in the development of the ES.*"

   ECHA notes that for the exposure assessment for ESs 4-7 you have used release factors (RFs) from Environmental Release Categories (ERCs) 8c (Widespread use leading to inclusion into/onto article (indoor)) and 8f (Widespread use leading to inclusion into/onto article (outdoor)) which presumes that the substance is included into/onto an article.

However, ECHA notes that the technical function of the substance in the formulations reported in the registration dossier is [redacted] which presumes that the substance is not included into/onto an article. Thus, ECHA considers that the chosen ERCs are not relevant for the uses of the substance covered by ESs 4-7. For instance, ERCs 8a (Widespread use of non-reactive processing aid (no inclusion into or onto article; indoor)) and 8d (Widespread use of non-reactive processing aid (no inclusion into or onto article; outdoor)) might be used instead to describe widespread use of non-reactive processing aid (not included into/onto article). Furthermore, ECHA notes that according to ECHA Guidance on information requirements and Chemical Safety Assessment, Chapter R.16 (version 3.0, February 2016) ERCs 8c and 8f assume 5 percent release to water and not 1 percent as used by you in the exposure assessment for ESs 4-7. Moreover, ECHA notes that for the exposure assessment of ES 1, non-default ERC RFs are used and no justification based on risk management measures, operational conditions or substance properties which would support the use of these RFs is provided in the CSR.

In your comments to the draft decision you indicate that you agree with the information requirement in the draft decision. In addition, you indicate that you have addressed the information requirement in an updated registration dossier which includes an updated CSR, submitted to ECHA on 9 February 2018. You outline in your comments to the draft decision how you could address the information requirement by stating that "*...The exposure scenarios were removed, replaced or updated based on the most recent internal information. Justifications for the deviations from the default parameter for the environmental release categories (i.e. use of SpERCs) are stated in the chemical safety report.....Article service life of the substance:* [redacted]. *In both cases, it will evaporate after a while. An exposure via air is covered as a standard requirement in the chemical safety assessment. As butyl glycollate is not included in the final article, no article service life was described in the chemical safety assessment....*". In your dossier update, you explain what was provided as well as providing new information that has not been available earlier.

You are reminded that this decision does not take into account any updates submitted after the notification of the draft decision to you. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

Irrespective of whether the newly provided information in your dossier update may be sufficient to meet the information requirement addressed in this decision, ECHA can already point out the following that ECHA notes that a clear description of use of the substance covered by newly developed ES7 (use in mining chemicals) is missing, i.e. it is not clear how products containing the substance are used in mining industry to decide whether recommended RMMs and chosen effectiveness of these RMMs are adequate.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, you are requested to use default release factors from the relevant Environmental Release Categories for exposure assessment for Exposure Scenarios 1, 4-7 and revise the risk characterisation accordingly. Alternatively, you may provide a detailed justification for using other descriptors than the relevant Environmental Release Categories for the description of the use and the default release factors for exposure assessment (for instance based on risk management measures, operational conditions or substance properties). Furthermore, you are requested to identify all life stages of the article service life of the substance, if the technical role of the substance in coating formulations is not only a solvent and the substance is included into/onto the article, and generate relevant exposure assessment and the risk characterisation accordingly.

b) ECHA notes that for the exposure assessment for ES 3 you have used RFs from the Specific Environmental Release Category (SpERC). However, you do not identify the respective SpERC, which was used to choose RFs from, and reference to the publically available factsheet and background document of this SpERC in the CSR. Therefore, ECHA is not able to verify the relevance of the chosen SpERC to the identified use addressed by the ES 3 nor the justification of the RFs provided in the SpERC.

In your comments to the draft decision you indicate that you agree with the information requirement in the draft decision. In addition, you indicate that you have addressed the information requirement in an updated registration dossier which includes an updated CSR, submitted to ECHA on 9 February 2018. You outline in your comments to the draft decision how you could address the information requirement by stating that "*...Use of default release factors for ERCs of SpERCs in exposure scenario 3: The exposure scenarios were revised based on the most recent information. Justifications for the deviations from the default parameter for the environmental release categories (i.e. use of SpERCs) are stated in the chemical safety report and submitted in a separate background document* [redacted] *together with this update...* ". In your dossier update, you explain what was provided as well as providing new information that has not been available earlier, to meet the information requirement addressed in this decision.

You are reminded that this decision does not take into account any updates submitted after the notification of the draft decision to you. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation you are requested to identify Specific Environmental Release Category used for the exposure assessment for ES 3 *or* use default release factors from the relevant ERC for the exposure assessment for this ES.

c) ECHA notes that, for the exposure assessment for ES 3, you have used the non-default number of use (release) days at the site of application of [redacted]. The default number of use (release) days, as recommended in the ECHA Guidance on information requirements and Chemical Safety Assessment, Chapter R.16 (version 3.0, February 2016), based on the tonnage allocated to the industrial use addressed by the ES 3 would be [redacted]. However, ECHA notes that there is no justification for the choice of this non-default number of use (release) days provided in the CSR.

In your comments to the draft decision you indicate that you agree with the information requirement in the draft decision. In addition, you indicate that you have addressed the information requirement in an updated registration dossier which includes an updated CSR, submitted to ECHA on 9 February 2018. You outline in your comments to the draft decision how you could address the information requirement by stating that "...*Use of default number of use (release) days for exposure scenario 3: The exposure scenarios were removed, replaced or updated based on the most recent internal information. Justifications for the deviations from the default parameter for the environmental release categories (i.e. deviation from the default number of release days) are stated in the chemical safety report ....* ". In your dossier update, you explain what was provided as well as providing new information that has not been available earlier, to meet the information requirement addressed in this decision.

You are reminded that this decision does not take into account any updates submitted after the notification of the draft decision to you. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, you are requested to use default number of use (release) days as recommended in the ECHA Guidance on information requirements and Chemical Safety Assessment, Chapter R.16 (version 3.0, February 2016) for the exposure assessment for Exposure Scenario 3 *or* provide a justification for the use of specific non-default number of use (release) days.

d) ECHA observes that in all seven ESs reported in the CSR a need for the treatment of wastewater in the municipal sewage treatment plant (STP) is assumed. ECHA notes that the assumed efficiency of the municipal STP varies between ESs (removal efficiencies at STP of [redacted] and [redacted] are reported). ECHA considers that normally for one substance one removal efficiency value of unknown municipal STP should be used across different ESs by a registrant. Moreover, ECHA notes that according to the ECHA Guidance on information requirements and Chemical Safety Assessment, Chapter R.16 (version 3.0, February 2016) "*an interim figure of 80% connection to wastewater treatment was proposed for the regional standard environment. This value was thought to be representative for the actual situation in large urban areas.*" Thus, ECHA considers that removal efficiency value(s) reported in the CSR and used in the exposure assessment need to be justified. ECHA notes that such justification of the reported removal at municipal STP efficiency value(s) is missing in the CSR.

In your comments to the draft decision you indicate that you agree with the information requirement in the draft decision. In addition, you indicate that you have addressed the information requirement in an updated registration dossier which includes an updated CSR, submitted to ECHA on 9 February 2018. You outline in your comments to the draft decision how you could address the information requirement by stating that "*...Justify efficiencies of substance removal: The exposure scenarios were removed, replaced or updated based on the most recent internal information. Justifications for the deviations from the default parameter for the environmental release categories (i.e. STP efficiencies) are stated in the chemical safety report...* ". In your dossier update, you explain what was provided as well as providing new information that has not been available earlier, to meet the information requirement addressed in this decision.

You are reminded that this decision does not take into account any updates submitted after the notification of the draft decision to you. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation you are requested to justify efficiencies of the substance removal by sewage treatment plants used for the exposure assessment of various Exposure Scenarios.

e) ECHA notes that, in line with Annex I, section 5.1.1., one of the OCs, which should be included in the ESs provided in the CSR, is the dilution in the receiving environmental compartment, which depends on the effluent flow rate and on the receiving surface water (*e.g.* river) flow rate.

According to ECHA *Guidance on information requirements and chemical safety assessment*, Chapter R.16: Environmental Exposure Estimation (version 3.0, February 2016) the default effluent flow rate is 2000 m^3/d and the default receiving water flow rate is 18000 m^3/d (corresponding to a dilution factor of 10). The effluent flow rate or receiving water flow rate can be changed according to site specific data. ECHA notes that, according to the above mentioned Guidance, in case of site-specific assessments for the dilution, account should be taken of the fluctuating flow-rates of typical receiving waters. The low-flow rate (or 10^{th} percentile) should always be used in the assessment.

ECHA observes that for the exposure assessment for the ES 1, you have used site-specific effluent discharge and receiving water flow rates. ECHA notes that there is no justification provided for the site-specific values of the effluent discharge and receiving water flow rates.

In your comments to the draft decision you indicate that you agree with the information requirement in the draft decision. In addition, you indicate that you have addressed the information requirement in an updated registration dossier which includes an updated CSR, submitted to ECHA on 9 February 2018. You outline in your comments to the draft decision how you could address the information requirement by stating that "*...Use default effluent discharge rates and receiving water flow rates: Additional information regarding the modification of the default parameters of the effluent discharge rates and the receiving water flow rate was*

summarised in a background document which will be submitted in Section 13 in the updated dossier....". In your dossier update, you explain what was provided as well as providing new information that has not been available earlier.

You are reminded that this decision does not take into account any updates submitted after the notification of the draft decision to you. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

Irrespective of whether the newly provided information in your dossier update may be sufficient to meet the information requirement addressed in this decision, ECHA can already point out the following that in your justification document Figure 1 low discharge rate of [redacted] is reported (this would lead to dilution factor of receiving water of app. [redacted]). As noted above the low-flow rate (or 10th percentile) of the receiving water body should always be used in the assessment.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation you are requested to use default effluent discharge and receiving water flow rates from *ECHA Guidance on information requirements and Chemical Safety Assessment, Chapter R.16 (version 3.0, February 2016)* for the exposure assessment for Exposure Scenario 1 or provide a detailed justification for the use of specific non-default effluent discharge and receiving water flow rates.

f) The "tonnage per use" plays a key role in environmental assessment, as also laid down in Annex I, section 5.2.4. regarding exposure estimation. ECHA observes that in Table 40 of the CSR you have provided information on the different ESs and the related tonnages per use. ECHA understands that the manufactured tonnage of the substance is [redacted] per year and that [redacted] of this amount are used for the production of various, used by industry, professional users and consumers, formulations of coatings ([redacted]). ECHA understands that [redacted] a year are used for professional uses of the substance, *i.e.* this is the aggregated tonnage used by professional workers outdoor and indoor altogether, and that [redacted] a year are used by consumers, i.e. this is the aggregated tonnage used by consumers outdoor and indoor altogether. ECHA notes that the fate of the remaining manufactured tonnage of the substance is not clear and needs to be explained in the CSR. Furthermore, if the share of the tonnage used by professionals or consumers specifically outdoor and specifically indoor is known, it should be explained how this information has been collected.

In your comments to the draft decision you indicate that you agree with the information requirement in the draft decision. In addition, you indicate that you have addressed the information requirement in an updated registration dossier which includes an updated CSR, submitted to ECHA on 9 February 2018. You outline in your comments to the draft decision how you could address the information requirement by stating that "...*Clear and detailed explanation of the substance through all life cycles of the substance: The exposure scenarios were removed, replaced or updated based on the most recent internal information on tonnages and volumes. ...*". In your dossier update, you explain what was provided as well as providing new information that has not been available earlier, to meet the information requirement addressed in this decision.

You are reminded that this decision does not take into account any updates submitted after the notification of the draft decision to you. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation you are requested to provide a clear and detailed explanation of the distribution of manufactured tonnage of the substance through all uses and life-cycle stages of the substance.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 30 August 2017.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

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

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the request(s).

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

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

Appendix 3: Further information, observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

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