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Helsinki, 19 December 2018

Substance name: Methyl salicylate
EC number: 204-317-7
CAS number: 119-36-8
Date of Latest submission(s) considered[1]: 14 March 2016
Decision/annotation number: Please refer to the REACH-IT message which delivered this communication (in format SEV-D-XXXXXXXXXX-XX-XX/F)
Addresses: The present decision is exclusively addressed to the registrant of Methyl salicylate with registration number [redacted]

DECISION ON SUBSTANCE EVALUATION

1. Requested information

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

1.1 **Exposure related information:**

1.1.1 Exposure-related requests (worker – industrial and professional; refinement): refinement of the exposure assessment to be provided;

1.1.2 Exposure-related requests (worker – industrial and professional; improved characterisation): exposure assessment for spraying and roller/brushing to be revised;

1.1.3 Exposure-related requests (worker – industrial and professional; missing contributing scenarios; risk management measures): missing contributing scenarios to be added, inconsistency in substance concentration in product to be clarified and reduced task duration as risk management measure to be reconsidered for contributing scenarios with high risk characterisation ratio (RCR);

1.1.4 Exposure-related requests (consumer; improved characterisation): assessment of consumer exposure to washing and cleaning products and air care products to be revised;

1.1.5 Exposure-related requests (worker – industrial; risk management measures): provide documentation for the recommended personal protective equipment, i.e. the type of gloves (material, thickness, typical or minimum breakthrough times of the glove material);

1.1.6 Exposure-related requests (environment): improved justification of the refined emission scenarios.

All information requests above are further specified in Appendix 1.

You shall provide an update of the registration dossier(s) containing the requested

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

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information, including robust study summaries and, where relevant, an update of the Chemical Safety Report by **26 June 2019**.

The reasons of 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[2] by Leena Ylä-Mononen, Director of Evaluation

[2] 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 methyl salicylate and other relevant available information, ECHA concludes that further information is required in order to enable the evaluating Member State Competent Authority (MSCA) to complete the evaluation of whether the substance constitutes a risk to human health and the environment.

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 eye irritation and exposure of workers and general population.

1.1 EXPOSURE RELATED INFORMATION:

ECHA reminds you that authorities will propose risk management options based on the information available in the registration dossier if remaining risks are identified. At this stage, the evaluating MSCA doubts that the existing exposure information reflect reality. You have to carry out a proper risk characterisation in order to avoid overprotective risk management options to be implemented by the authorities at a later stage.

ENDPOINT 1.1.1: EXPOSURE-RELATED REQUESTS (WORKER – INDUSTRIAL AND PROFESSIONAL; REFINEMENT): REFINEMENT OF THE EXPOSURE ASSESSMENT TO BE PROVIDED

The Concern(s) Identified

For several exposure scenarios (ES), you have added an additional reduction factor in order to reduce the exposure estimate by inhalation and dermal route. The justification provided is not sufficiently robust and all Risk Characterisation Ratios (RCRs) are above 1 when this extra factor is not taken into account. The current registration dossier does not provide sufficient evidence that the risk is adequately controlled.

Why new information is needed

In ES 2 (formulation of end-products) contributing scenarios 3 and 5, ES 4 (industrial end-use of washing and cleaning products) contributing scenarios 5 and 6, ES 5 (professional end-use of washing and cleaning products) contributing scenarios 7, 8, 10 and 11, and ES 6 (professional end-use of polishes and wax blends) contributing scenarios 3 and 4, you added an additional reduction factor in order to reduce the exposure estimate by inhalation and dermal route. The argumentation given is that the concentration of the substance in the mixture is below 1% and that the substance is not volatile.

First of all, for ES 2 contributing scenario 3 and 5, the declared concentration of substance in the mixture is [redacted]%. Therefore this justification is inconsistent and your argumentation is not valid. Furthermore for the contributing exposure scenario 3, the value of the exposure estimate by inhalation calculated by you could not be verified with ECETOC TRA.

Secondly, for all contributing scenarios, the vapour pressure (13 Pa) and concentration of the substance in the mixture are already used as inputs in the model and need not be taken into account a second time. Therefore, it is not appropriate to modify the results

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by adding an extra 0.1 factor since a Tier 1 model was used. You should have provided other evidence to support this assumption and demonstrate that the risk is properly managed, such as exposure estimation obtained with a Tier 2 model and/or good quality measured data, or proposed more stringent risk management measures (RMM).

New information is needed to either support the assumption or to demonstrate safe use by a refinement of the exposure assessment.

What is the possible regulatory outcome

You have to carry out an adequate exposure assessment and risk characterisation to communicate relevant exposure scenarios to the supply chain and to avoid overprotective risk management actions to be implemented by the authorities at a later stage. If you fail to demonstrate that risks are adequately managed for workers, a restriction could be envisaged.

Considerations on the test method and testing strategy

You can perform an exposure assessment using a Tier 2 model, provide good quality measured data, or propose more stringent RMM. No RMM were proposed so far for these scenarios and you will need to determine which option is the most suitable (with justification).

Consideration of alternative approaches

No alternative available: the request is suitable and necessary to ensure safe use of methyl salicylate. You have to carry out adequate risk characterisation to avoid overprotective risk management options to be implemented by Authorities in a later stage.

Consideration of Registrants' comments

During the first commenting of the initial draft decision, you committed to review the exposure scenarios according to the exposure-related requests.

Conclusion

Therefore, based on the substance evaluation and pursuant to Article 46(1) of the REACH Regulation, ECHA concludes that you are required to:

- reiterate the risk assessment to demonstrate that the risk is adequately managed by providing exposure estimation obtained with a Tier 2 model and/or good quality measured data, or proposing more stringent RMM, or advise against the use, for ES 2 contributing scenarios 3 and 5, ES 4 contributing scenarios 5 and 6, ES 5 contributing scenarios 7, 8, 10 and 11, and for ES 6 contributing scenarios 3 and 4.

For ES 4 contributing scenarios 5 and 6, ES 5 contributing scenarios 7, 8, 10 and 11 and ES 6 contributing scenario 3 and 4, the request has to be fulfilled also by taking into account the requests of Endpoint 1.1.2.

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ENDPOINT 1.1.2: EXPOSURE-RELATED REQUESTS (WORKER – INDUSTRIAL AND PROFESSIONAL; IMPROVED CHARACTERISATION): EXPOSURE ASSESSMENT FOR SPRAYING AND ROLLER/BRUSHING TO BE REVISED

The Concern Identified

A concern is identified for workers (industrials and professionals) since the model used to estimate the exposure and demonstrate safe use may be inadequate for PROC 7, 10 and 11.

Why new information is needed

For industrial and professional spraying of cleaning and washing products (PROC 7, 10 and 11) and for professional end-use of polishes and wax blends (PROC 10), you used ECETOC TRA to estimates the workers' exposure. However, ECETOC TRA only predicts vapour phase exposure and is not appropriate to evaluate exposure to aerosols formed during spraying and brushing/roller. In this context, the exposure to methyl salicylate by inhalation and dermal route is likely to be underestimated. A revised estimation of exposure to aerosols during industrial spraying (PROC 7), professional spraying (PROC 11) and brushing/rolling (PROC 10) is thus required.

The information currently provided in the dossier is not sufficient to determine the exposure using another, more adequate model. Indeed, the following new information would be needed as inputs in higher tier tools but are not available:

- Distance of the worker from the source
- Primary emission source in the breathing zone of the worker (yes/no)
- Presence of secondary emission sources (other workers using the same substance simultaneously, period of evaporation, drying or curing after the activity)
- Segregation of workers from the source
- Spray direction
- Spray pressure
- Type of skin contact
- Viscosity and volatility of the product
- Application use rate
- Room volume for indoor use
- Direction of air flow
- Duration and frequency of exposure event.

What is the possible regulatory outcome

You have to carry out adequate exposure assessment and risk characterisation to communicate relevant exposure scenarios to the supply chain and to avoid overprotective risk management actions to be implemented by the authorities at a later stage. If you fail to demonstrate that risks are adequately managed for workers, a restriction could be envisaged.

Considerations on the test method and testing strategy

You are required to review the exposure estimation by using more appropriate tools for dermal and inhalation exposure.

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Consideration of alternative approaches

Alternatively, you can provide good quality measurements to demonstrate safe use.

Consideration of Registrants' comments

During the first commenting of the initial draft decision, you committed to review the exposure scenarios according to the exposure-related requests.

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 information regarding:
  - Distance of the worker from the source
  - Primary emission source in the breathing zone of the worker (yes/no)
  - Presence of secondary emission sources (other workers using the same substance simultaneously, period of evaporation, drying or curing after the activity)
  - Segregation of workers from the source
  - Spray direction
  - Spray pressure
  - Type of skin contact
  - Viscosity and volatility of the product
  - Application use rate
  - Room volume for indoor use
  - Direction of air flow
  - Duration and frequency of exposure event.
- recalculate the exposure to methyl salicylate for all scenarios for PROC 7 (ES 4), PROC 10 (ES 4, 5 and 6) and PROC 11 (ES 5 and 6) using an appropriate model and justify the choice of the model.

ENDPOINT 1.1.3: EXPOSURE-RELATED REQUESTS (WORKER – INDUSTRIAL AND PROFESSIONAL; MISSING CONTRIBUTING SCENARIOS; RISK MANAGEMENT MEASURES): MISSING CONTRIBUTING SCENARIOS TO BE ADDED, INCONSISTENCY IN SUBSTANCE CONCENTRATION IN PRODUCT TO BE CLARIFIED AND REDUCED TASK DURATION AS RISK MANAGEMENT MEASURE TO BE RECONSIDERED FOR CONTRIBUTING SCENARIOS WITH HIGH RCR

The concern identified

No assessment of combined exposure of workers for a whole work shift (combination of several tasks) is currently proposed in the registration dossier. However, during the same day, workers may perform several tasks where they can be exposed to methyl salicylate and to its degradation product salicylic acid.

It is acknowledged that it may be complicated for you to anticipate all possible combinations of tasks at workplace. It means that downstream users will have to take into account the overall exposure of workers when combining tasks, so as to ensure that the combined risk characterisation ratios (RCR) (sum of RCR for each task) is below 1.

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This highlights the need to provide sufficient information to the downstream users for all contributing scenarios, i.e. to include all contributing scenarios in the registration dossier and to provide an exposure assessment and risk characterisation for all of them.

Overall, workers safety is not demonstrated, and conditions of safe use are not communicated along the supply chain to enable downstream to manage the exposure of workers over a day.

Why new information is needed

New information from you is needed so as to ensure that the risk for workers (industrials and professionals) is adequately managed. Information is needed regarding three aspects which are detailed below: 1) missing contributing scenario which should be added, 2) inconsistencies in substance concentration in products reported in exposure scenarios to be removed, and 3) reduced duration as RMM which still lead to high RCR for some scenarios, for which where there may be a need for refinement.

- Missing contributing scenarios

Waste disposal: The "waste disposal" contributing scenario is not currently addressed for industrial and professional uses (ES 1, 2, 4, 5 and 6). Waste disposal has to be addressed in registration dossiers according to Annex I 5.1.1, last paragraph, and Annex I 5.2.2.

ES 5 (professional end-use of washing and cleaning products), contributing scenario 9 and 10: for the contributing scenario 9 (1h - spraying of a professional cleaning or maintenance product (indoor and outdoor), you did not propose any exposure assessment nor risk characterisation, with the argument that the RCR for the 8 hours spraying task is below 1 (note: ECHA does not agree with this assumption, refer to endpoint 1.1.2). Additionally, for ES 5 contributing scenario 10 (8h, RP - Spraying of a professional cleaning or maintenance product (indoor and outdoor)), no assessment was provided for outdoor use with no explanation. Even if these missing contributing scenarios were covered by other worst-case scenarios, it would still be necessary to include them in the related exposure scenario and give the corresponding RCR, so as to communicate appropriate information on the conditions of safe use of the substance along the supply chain.

Based on the information available in the current registration dossier, ECHA is not able to understand why these scenarios were not included/assessed, and is not able to conclude whether risk is adequately managed. Therefore you are requested to add the contributing scenarios 9 and 10-outdoor in ES 5 and the contributing scenario "waste disposal" to ES 1, 2, 4, 5 and 6, and provide an exposure assessment and risk characterisation.

- Inconsistencies on substance concentration in products

In ES 8 (consumer end-use of air care products), contributing scenario 2 (aircare, continuous action, solid and liquid), the concentration of the product is declared to be [redacted]%.

However, the ES 2 (formulation of end-products) takes into account a concentration in end-products of [redacted]%, which is inconsistent with ES 8. Therefore, if the concentration of substance in end-products is likely to be above 1%, the exposure assessment and risk

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characterisation presented in the dossier may not be sufficiently protective for ES 2 contributing scenarios 4 (equipment cleaning and maintenance), 6 (transfer of substance or preparation into small containers (dedicated filling line, including weighing)) and 7 (production of preparations or articles by tableting, compression, extrusion, pelletisation). Worst-case estimations were made with ECETOC TRA v3.1 for these three contributing scenarios, by taking into account a concentration band of [redacted]% and the same other input parameters. The calculated RCR are below 1. Therefore, no concern arises for each task taken individually. However, the appropriate RCR should be updated and communicated to the supply chain. Therefore you are requested to update the contributing scenarios 4, 6 and 7 in ES 2 by clarifying the maximum concentration of substance handled and indicating the appropriate RCR.

- Reduced task duration with high RCR

For individual tasks, most RCRs are below 1 and reduced task duration is required for some tasks to obtain RCR below 1. Time reduction is a complex risk management measure that may be not realistic or complicated to implement at workplace, and it is essential that the maximal task duration and RCR are communicated in the supply chain for each task.

As you did not provide any combined exposure assessment over a day, the exposure and risk assessment is not representative of the reality of a working day and exposure may be exceeded when workers perform several tasks.

ECHA notes in particular that the RCR is close to 1 for ES 1 contributing scenario 13 and above 1 for ES 2 contributing scenario 5, with maximal task duration of 1 hour. Further refinement of the exposure assessment or other RMM should be envisaged. The information currently provided in the registration dossier is not sufficient for ECHA to determine if the risks for industrial workers are properly managed, and is not sufficient either to be communicated to the supply chain.

What is the possible regulatory outcome

You have to carry out adequate exposure assessment and risk characterisation to communicate relevant exposure scenarios to the supply chain and to avoid overprotective risk management actions to be implemented by the authorities at a later stage. If workers safety is not demonstrated by you, a risk management option analysis (RMOA) can be envisaged to determine the appropriate way forward.

Considerations on the test method and testing strategy

No new test is required. Missing exposure scenarios have to be included in the chemical safety assessment. Contributing exposure scenarios where reduced task duration has been used to calculate the RCR, and where RCR is high nevertheless, should be reconsidered to ensure that this RMM is relevant for communication to the supply chain. For this purpose further refinement of the exposure assessment, other RMM or a combined exposure assessment and risk characterisation for workers (time weighted average over 8 hours for a similar exposed group) demonstrating safe use can be provided.

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Consideration of alternative approaches

You have to carry out adequate risk characterisation to avoid overprotective risk management options to be implemented by the authorities at a later stage.

Consideration of Registrants' comments

During the first commenting of the initial draft decision, you committed to review the exposure scenarios according to the exposure-related requests.

Conclusion

Therefore, based on the substance evaluation and pursuant to Article 46(1) of the REACH Regulation, ECHA concludes that you are required to:

- add the contributing scenarios 9 and 10-outdoor in ES 5 and provide an exposure assessment and risk characterisation (with OC, RMM and RCR);
- add the contributing scenarios "waste disposal" to ES 1, 2, 4, 5 and 6, and provide an exposure assessment and risk characterisation (with OC, RMM and RCR);
- update the contributing scenarios 4, 6 and 7 in ES 2 by clarifying the maximum concentration of substance handled and indicating the appropriate RCR.

Remark: for contributing scenarios with short task duration and high RCR (ES 1 contributing scenario 13, ES 2 contributing scenario 5), further refinement of the exposure assessment, other RMM or a combined exposure assessment and risk characterisation for workers (time weighted average over 8 hours for a similar exposed group) demonstrating safe use should be envisaged.

ENDPOINT 1.1.4: EXPOSURE-RELATED REQUESTS (CONSUMER; IMPROVED CHARACTERISATION): ASSESSMENT OF CONSUMER EXPOSURE TO WASHING AND CLEANING PRODUCTS AND AIR CARE PRODUCTS TO BE REVISED

The Concern(s) Identified

There are doubts about the robustness of the consumer safety assessment for ES 7 (consumer end-use of washing and cleaning products) and ES 8 (consumer end-use of air care products) where the model AISE REACT was used to estimate the exposure. Consumer exposure may be underestimated.

Why new information is needed

For three contributing scenarios (ES 7 contributing scenario 2, ES 8 contributing scenarios 1 and 2), the Registrant used AISE REACT (Reach Exposure Assessment Consumer Tool of the International Association for Soaps, Detergents and Maintenance Products) to estimate the consumer exposure. Little information is available regarding the validation status of this model and its reliability to estimate the exposure for these uses.

In particular, for the "all-purpose liquid cleaners" scenario, the model does not take into

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account any dermal and inhalation exposure during the mixing/loading task nor the exposure by inhalation during the application. When ECETOC TRA v3.1 is used, the RCR (inhalation) is above 1. Therefore, based on the information in the registration dossier, because no justification is provided to justify these choices, ECHA is not able to understand why you considered them adequate and is not confident that consumer safety is demonstrated.

For the "air care products" scenarios, the model does not take into account any dermal exposure. However, dermal exposure can occur when using an aerosol spray and when handling a solid or liquid air care product. No information about the products in the registration dossier supports the assumption that dermal exposure should not be taken into account. Furthermore, regarding inhalation exposure for instant action aerosols, since the duration of the spray event is a few seconds and exposure duration is 15 minutes once a day, the exposure during the exposure event should be used as the basis for the risk assessment, and not the diluted exposure over 24 hours, as indicated in ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.15: Consumer exposure assessment (version 3.0, July 2016). There is therefore a concern that the consumer exposure may be underestimated for this use and you should improve your justification and/or revise your assessment.

The uncertainty regarding the reliability of the exposure assessment performed with AISE REACT is high and consumer exposure can be underestimated. New information, such as characteristics of the products to justify the assumptions and the choice of the model, estimates obtained with another tool and/or comparison with measured data, would be necessary to validate the modelled exposure.

What is the possible regulatory outcome

You have to carry out adequate exposure assessment and risk characterisation to communicate relevant exposure scenarios to the supply chain and to avoid overprotective risk management actions to be implemented by Authorities in a later stage. If consumers' safety is not robustly demonstrated by you, a risk management option analysis (RMOA) can be envisaged to determine the appropriate way forward.

Considerations on the test method and testing strategy

You can provide more information on the characteristics of the products to justify the assumptions and the choice of the model, and can compare the estimates obtained with AISE REACT to estimates obtained with another tool and/or to measured data.

Considerations on alternative approaches

No alternative available. You have to carry out adequate risk characterisation to avoid overprotective risk management options to be implemented by the authorities at a later stage.

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Consideration of Registrants' comments

During the first commenting of the initial draft decision, you committed to review the exposure scenarios according to the exposure-related requests.

Conclusion

Therefore, based on the substance evaluation and pursuant to Article 46(1) of the REACH Regulation, ECHA concludes that you are required to:

- review the exposure assessment and risk characterisation for ES 7 contributing scenario 2 and ES 8 contributing scenarios 1 and 2, for inhalation and dermal route, taking into account all steps where exposure is expected (mixing/loading, application) and the actual exposure duration over the day;
- demonstrate that the exposure assessment carried out with AISE REACT is reliable and sufficiently conservative by comparing the exposure estimates to estimates obtained with another model and/or measured data.

ENDPOINT 1.1.5: EXPOSURE-RELATED REQUESTS (WORKER – INDUSTRIAL; RISK MANAGEMENT MEASURES): PROVIDE DOCUMENTATION FOR THE RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT, I.E. THE TYPE OF GLOVES (MATERIAL, THICKNESS, TYPICAL OR MINIMUM BREAKTHROUGH TIMES OF THE GLOVE MATERIAL)

The Concern(s) Identified

The concern identified is for workers safety. Indeed gloves are required as risk reduction measures for several scenarios, but no sufficient information is provided in the dossier to ensure that adequate protection is worn.

Why new information is needed

No information is given in the CSR regarding the suitable type of material(s), thickness and the typical or minimum breakthrough time of the gloves. The information provided is not sufficient to enable Authorities to assess the adequacy of the gloves recommended, nor to communicate adequate information on safe use to the supply chain. According to section 8.2.2.2. of Annex II of the REACH regulation, the type of material(s) of the gloves, the thickness and the typical or minimum breakthrough time shall be documented.

The new information is needed to ensure that appropriate information on safe use are communicated to the supply chain and that appropriate gloves are used at workplace. It is particularly important since the exposure assessment provided by you relies on the wearing of gloves to demonstrate safe use for several industrial scenarios.

What is the possible regulatory outcome

The possible regulatory outcome is enforcement.

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Considerations on the test method and testing strategy

You will need to determine the suitable type of material(s), thickness and the typical or minimum breakthrough time of the gloves. If such information is not already available, you will need to perform tests in order to provide the required information.

Consideration of alternative approaches

No alternative available: the request is suitable and necessary to ensure safe use of methyl salicylate.

Consideration of Registrants' comments

During the first commenting of the initial draft decision, you committed to review the exposure scenarios according to the exposure-related requests.

Conclusion

Therefore, based on the substance evaluation and pursuant to Article 46(1) of the REACH Regulation, ECHA concludes that you are required to:

- document the suitable type of material(s), thickness and the typical or minimum breakthrough time of the gloves.

ENDPOINT 1.1.6: EXPOSURE-RELATED REQUESTS (ENVIRONMENT): IMPROVED JUSTIFICATION OF THE REFINED EMISSION SCENARIOS.

The Concern(s) Identified

The environmental exposure assessment for methyl salicylate is performed using several specific input parameters in the emission scenarios which are actually not sufficiently described and justified. Then, it is not possible to evaluate if the refined release estimations, and then the exposure calculations and risk assessment, are adequate and representative of all sites.

Why new information is needed

Some specific data have been used to refine the release estimations (the discharge rate and effectiveness of wastewater treatment systems, the measured flow rate of specific river systems, the fractions of local main source). There is no explanation on how these data were obtained (methodology applied for measurements, data collection) or calculated and why they were considered adequate and representative of all sites for a use are not clearly described in the Registrants' dossier.

For the formulation of compounds use the exposure scenario (ES1) is divided into two contributing scenarios without explanations on the difference between them and on why a worst-case annual tonnage was used for the second one and not for the first one.

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Furthermore, when SpERC[3] tables are applied, additional justifications should be provided if SpERC default values are not used.

You are expected to clearly demonstrate that each specific emission scenario ensures the representativeness across various sites for a proposed use. All available on-site specific information has to be documented, clearly justified and referred to in the CSR (Chapter R16; Appendix A.16-7). Actual information provided in the registration dossier is not sufficient to enable ECHA to assess the adequacy and representativeness of the emission scenarios.

Consideration of Registrants' comments

During the first commenting of the initial draft decision, you committed to review the exposure scenarios according to the exposure-related requests.

Conclusion

Therefore, based on the substance evaluation and pursuant to Article 46(1) of the REACH Regulation, ECHA concludes that you are required to:

- describe extensively and properly the environmental exposure scenarios: all considered parameters or deviations from default parameters described in details in the previous paragraph must be explained and justified in accordance with the latest versions of REACH guidance documents;

- demonstrate clearly that when specific emission scenarios are used, they are representative of all sites for the use and they correspond to a worst-case covering all situations for a use.

Deadline to submit the requested Information

In the draft decision communicated to you the time indicated to provide the requested information was 24 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested a larval amphibian growth and development assay (test method OECD 241) and a Fish sexual development test (test method OECD 234). As these studies are not addressed in the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated registration is 6 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

[3] Specific Environmental Release Categories

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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 human health/suspected CMR, exposure/consumer use and aggregated tonnage, methyl salicylate CAS No 119-36-8 (EC No 204-317-7) was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2015. The updated CoRAP was published on the ECHA website on 17 March 2015. The Competent Authority of France (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 eye irritation, endocrine disrupting properties adsorption/desorption screening and exposure to worker/general population/environment.

The evaluating MSCA considered that further information was required to clarify the abovementioned concerns: eye irritation, endocrine disruption properties and toxicity to reproduction, adsorption/desorption screening and exposure to worker/general population/environment. 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 17 March 2016.

Registrant(s)' commenting phase (I)

On 26 April 2016 the initial draft decision was sent to you for comments.

ECHA received your comments on 1 June 2016 and forwarded them to the evaluating MSCA without delay.

The evaluating MSCA took into account your comments, which were sent within the commenting period. In addition, you provided additional references, including a pharmacology review and evaluation of a medical patch containing methyl salicylate (the Food and Drug Administration, FDA, 2006). This new data provides adequate information to allow removal of the initial requests related to genotoxicity (i.e. an *in vitro mammalian cell micronucleus test (test method OECD 487*) and reproductive toxicity (i.e. an *Extended one-generation reproductive toxicity study (test method: OECD 443))*.

However new concerns emerged based on the provided information: potential endocrine disruption for environmental organisms.

You also provided additional information which demonstrates that methyl salicylate is not expected to present any surface active properties. Indeed, you explained that based on its chemical structure methyl salicylate does not allow forming emulsions and/or

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microemulsions and/or micelles. Furthermore, you agree to provide additional justification to demonstrate that the Kow QSAR approach is appropriate and if necessary an adsorption/desorption test according to the OECD TG 121 method. Consequently, our initial request on the Kow QSAR approach for the Koc estimation of methyl salicylate has been withdrawn.

Consequently the evaluating Member State considered necessary to revise the requests to be made and it submitted to ECHA a revised draft decision.

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

Registrant(s)' commenting phase (II)

On 25 April 2018 the revised draft decision was sent to Registrant(s) for comments.

ECHA received your comments on 31 May 2018 and forwarded them to the evaluating MSCA without delay.

The evaluating MSCA took into account your comments, which were sent within the commenting period. Therefore the requests were amended and as explained in Appendix 1 the requests related to the endocrine disruption were removed.

Proposals for amendment by other MSCAs and ECHA and referral to 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 pursuant 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.

3. In relation to the required update of the registration dossier on exposure assessment, it is reminded to the Registrant(s) that new OECD Harmonised Templates (available in IUCLID6) shall be used for reporting exposure endpoints.