ECHA
EUROPEAN CHEMICALS AGENCY

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)
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 (consumer, general population; missing contributing scenarios): Exposure Scenario 8 "Private use of cosmetics, personal care products and fragranced products" to be revised;

1.1.2 Exposure-related requests (worker – industrial and professional, general population; missing contributing scenarios): Exposure Scenario 9 "Industrial or professional use of other fragranced products" 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 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 (worker – industrial and professional; 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); remove an incorrect statement about respiratory protection or provide a suitable justification; update the Exposure Scenario 3;

1.1.5 Exposure-related requests (worker – industrial; improved characterisation):

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

ECHA
EUROPEAN CHEMICALS AGENCY

conditions of use to be clarified or exposure assessment to be refined for risk not adequately managed;

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

1.1.7 Exposure-related requests (environment): description of uses.

All information requests above are further specified in Appendix 1.

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

ECHA
EUROPEAN CHEMICALS AGENCY

Appendix 1: Reasons

Based on the evaluation of all relevant information available for methyl salicylate and other relevant available information, ECHA concludes that further information is needed 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 reflects 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 (CONSUMER, GENERAL POPULATION; MISSING CONTRIBUTING SCENARIOS): EXPOSURE SCENARIO 8 "PRIVATE USE OF COSMETICS, PERSONAL CARE PRODUCTS AND FRAGRANCED PRODUCTS"" TO BE REVISED

The Concern(s) Identified

In accordance with Annex I, 5 and 6, exposure assessment and risk characterisation are required when hazards are identified. However, you did not provide any consumer exposure assessment and risk characterisation for consumer uses of the registered substance (Exposure Scenario (ES) 8 "Private use of cosmetics, personal care products and fragranced products").

Why new information is needed

You did not provide any consumer exposure assessment and risk characterisation for consumer uses considering that cosmetics uses are out of the scope of the REACH regulation. However, based on the consumer use description in ES 8, there are doubts whether some consumer uses may nevertheless be in the scope of the REACH regulation. In particular, the exposure to fragranced products and certain personal care products should have been assessed in this section. Chapter R12 guidance[3] states that "*PC 39 category includes products covered by the Cosmetics Regulation (EU Regulation 1223/2009) and other personal care products*" (emphasis added). In addition, you explicitly put "fragranced products" apart from cosmetics in the use description in the exposure scenario. Clarification is needed from you to determine which uses are not covered by the Cosmetics Regulation. Additionally, you refer to the sector of use (SU)

[3] Guidance on Information Requirements and Chemical Safety Assessment Chapter R.12: Use description Version 3.0 - December 2015.

ECHA
EUROPEAN CHEMICALS AGENCY

"Formulation [mixing] of preparations and/or re-packaging (excluding alloys)"[4] (SU 10) in the ES 8 description. It is unclear which use the SU 10 refers to in this context and in particular if own formulation of mixtures by consumers is expected (do-it-yourself activities). Your clarification is necessary as well.

Therefore, the current registration dossier does not provide sufficient evidence that the risk for consumers is adequately managed. You are requested to clarify the consumer uses of the registered substance and to provide adequate exposure assessment and risk characterisation if necessary.

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 consumer uses in the scope of the REACH Regulation, a restriction could be envisaged.

Considerations on the test method and testing strategy

No new test is required. ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.15: Consumer exposure assessment (version 3.0, July 2016) shall be taken into account.

Consideration of alternative approaches

If you justify and demonstrate that all consumer uses are out of the scope of the REACH regulation, no new assessment would be necessary.

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:

- clarify if SU 10 is relevant for Exposure Scenario 8. If relevant, detail the contributing exposure scenarios and provide an exposure assessment and risk characterisation for consumers;
- specify and justify in the exposure scenario if the described "personal care products" and "fragranced products" for consumers are in the scope of the REACH regulation or the Cosmetic Regulation (EU Regulation 1223/2009). If uses are in the scope of REACH, detail the contributing exposure scenarios and provide an exposure assessment and risk characterisation for consumers.

[4] LCS F ("Formulation or repacking") in the updated version of the R12 guidance (v3, Dec 2015).

ECHA
EUROPEAN CHEMICALS AGENCY

ENDPOINT 1.1.2: EXPOSURE-RELATED REQUESTS (WORKER – INDUSTRIAL AND PROFESSIONAL, GENERAL POPULATION; MISSING CONTRIBUTING SCENARIOS): EXPOSURE SCENARIO 9 "INDUSTRIAL OR PROFESSIONAL USE OF OTHER FRAGRANCED PRODUCTS" TO BE REVISED

The Concern(s) Identified

The Exposure Scenario 9 (Industrial or professional use of other fragranced products) is not sufficiently described and assessed, and the explanation provided is very limited. Safe use for end-uses of methyl salicylate by workers is not demonstrated.

First of all, you described the use with the following descriptors: product category (PC) 39 (Cosmetics, personal care products), sector of use (SU) 3 ("Industrial uses: Uses of substances as such or in mixture at industrial sites"[5]), SU 6b ("Manufacture of pulp, paper and paper products"), SU 22 ("Professional uses: Public domain (administration, education, entertainment, services, craftsmen)"[6]), and PROC 10 (roller or brushing, i.e. cleaning processes) (emphasis added). You initially also declared a use as PC 35 (Washing and cleaning products) but removed it. The declared SU and PROC are inconsistent with PC 39, and it is therefore not clear how the substance is actually used by workers.

Then, you did not provide any exposure scenario nor exposure estimation. Instead you assumed that "formulation scenarios with PROC 8a" are worst-cases for PROC 10. The "PROC 8a" scenarios referred to are "unloading of methyl salicylate" from ES 3 (Formulation (cosmetics, personal care products) and compounding of fragrance substances), ES 4 (Formulation of fragrance substance) and ES 5 (Formulation of fuels), and "packing of final product" from ES 3 and ES 5, with task duration of 15 min to 1 hour, and the wearing of gloves with 90% efficiency. This assumption is not supported by any justification and the relevance of considering these tasks as worst-case for the industrial or professional use of other fragranced products is questionable. The processes are very different (unloading or loading of substance/mixtures for PROC 8a, and roller/brushing application for PROC 10). Also, only industrial workers are considered for PROC 8a, and professional use is not covered. The declared duration of PROC 8a is 15 min to 1h, but a full work shift of 8 hours should be considered for industrial and professional end-uses of products. Although the concentration of the substance in end-products is likely to be lower than 5%, it is not stated. Finally, ECHA tested your assumption by estimating roughly the exposure for PROC 10 and PROC 8a using the same inputs in ECETOC TRA version 3.1. It shows that when the same inputs are used in the same model, calculated exposure and risk characterisation ratios (RCR) are always higher for PROC 10 (both professional and industrial uses) than for PROC 8a. Your assumption is not valid.

Furthermore, ECETOC TRA may not be appropriate to estimate the exposure for PROC 10 if there is a possibility that aerosols are formed. Indeed, in this case, the exposure calculated with ECETOC TRA is likely to be underestimated.

Finally, you did not provide any operational conditions (OC) nor risk management measures (RMM) for ES 9. It is required under REACH (Annex I, 5 and 6) to describe the contributing scenarios for ES 9, to indicate the OC and RMM, and to give the

[5] Most probably corresponding to LCS IS ("Use at industrial sites") and SL ("Service-life") in the new version of the R12 guidance.
[6] LCS PW ("Widespread use by professional workers") in the new version of the R12 guidance.

ECHA
EUROPEAN CHEMICALS AGENCY

corresponding RCR. This is necessary to communicate appropriate information on conditions of safe use of the substance along the supply chain.

Therefore, the current registration dossier does not provide sufficient evidence that the risk for industrial and professional workers is adequately managed.

Why new information is needed

You did not provide any exposure assessment and risk characterisation for workers (industrials and professionals) for the end-uses of other fragranced products. Therefore, the current registration dossier does not provide sufficient evidence that the risk for workers (industrials and professionals) is adequately managed, and since no exposure scenario is provided, ECHA is not able to conclude.

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 worker uses, a restriction could be envisaged.

Considerations on the test method and testing strategy

No new test is required. ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.14: Occupational exposure assessment (version 3.0, August 2016) shall be taken into account.

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 an adequate risk characterisation to avoid overprotective risk management actions 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:

- specify the Product Categories (PC) and Sector of Use (SU) so as to indicate what are the "other fragranced products" referred to in Exposure Scenario (ES) 9;
- specify the contributing scenarios for ES 9; for each contributing scenario, provide an exposure assessment and risk characterisation for industrial and professional workers.

ECHA
EUROPEAN CHEMICALS AGENCY

ENDPOINT 1.1.3: EXPOSURE-RELATED REQUESTS (WORKER – INDUSTRIAL AND PROFESSIONAL; MISSING CONTRIBUTING SCENARIOS; RISK MANAGEMENT MEASURES): MISSING CONTRIBUTING SCENARIOS TO BE ADDED 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 characterization ratio (RCR) (sum of RCR for each task) is below 1. 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 two aspects which are detailed below: 1) missing contributing scenarios which should be added, and 2) reduced duration as risk management measure (RMM) which still lead to high RCR for some scenarios, for which where there may be a need for refinement.

- Missing contributing scenarios

Equipment cleaning and maintenance, waste disposal: You developed exposure scenarios based on your own knowledge and a survey sent to downstream users. Overall, the contributing scenarios described in the registration dossier correspond to the typical contributing scenarios described in IFRA's guidance[7]. However, the contributing scenario "equipment cleaning and maintenance", which is listed in IFRA's guidance for the formulation scenarios, is missing in ES 3 (formulation (cosmetics, personal care products) and compounding of fragrance substances) and ES 4 (formulation of fragrance substance). Although manufacture and intermediate uses are not covered by IFRA's guidance, the "equipment cleaning and maintenance" scenario seems also relevant for ES 1 (manufacture of methyl salicylate) and ES 2 (use as an intermediate for industrial manufacturing) since they are also industrial processes.

The "waste disposal" contributing scenario is only addressed in the scenarios "industrial and professional use of fuels", but this contributing scenario should also have been addressed in the other scenarios (ES 1, 2, 3, 4 and 5 (formulation of fuels)). Indeed,

[7] International Fragrance Association (IFRA) "REACH Exposure Scenarios for Fragrance Substances" Document Version 2.1, 11 December 2012.

ECHA
EUROPEAN CHEMICALS AGENCY

waste disposal has to be addressed in registration dossiers according to Annex I 5.1.1, last paragraph, and Annex I 5.2.2.

No justification was given to explain why these contributing scenarios are missing. Even if these missing contributing scenarios were covered by other worst-case scenarios, it would still be necessary to add these contributing scenarios in the related exposure scenario and give the corresponding RCR, so as to communicate appropriate information on 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, and is not able to conclude whether risk is adequately managed. Therefore you are requested to add the contributing scenarios "equipment cleaning and maintenance" in ES 1, 2, 3 and 4 and "waste disposal" in ES 1, 2, 3, 4 and 5, and provide an exposure assessment and risk characterisation.

Exposure to products containing less than 1% of methyl salicylate: For the Exposure Scenarios 3 (formulation (cosmetics, personal care products) and compounding of fragrance substances) and 4 (formulation of fragrance substance), you considered that no assessment was necessary for the use of products containing less than 1% of methyl salicylate. The justifications given for this assumption are not appropriate. Indeed, for ES 3, no description of the use is available, only the statement: "For the production of preparation or article, the concentration is less than 1%, this task was not assessed with modelling tools and considered to be controlled". The meaning of this statement is too vague: thus, no assessment of the relevance of the assumption is possible by ECHA, and there is a concern that risks may have been overlooked. For ES 4, it should be clarified whether the tasks of the contributing scenarios 6, 7, 8 and 9 are the same as other tasks described elsewhere, and if OC and RMM are strictly the same with only a lower concentration of substance in the mixture. These contributing scenarios need to be described so that conditions of safe use (OC, RMM) and RCR can be communicated along the supply chain.

Based on the information available in the current registration dossier, ECHA is not able to conclude whether risk is adequately managed. Therefore you are requested to add the contributing scenario 9 in ES 3 and contributing scenarios 6, 7, 8 and 9 in ES 4, and to provide an exposure assessment and risk characterization for these contributing scenarios.

- Reduced task duration with high RCR

For individual tasks, all RCRs are below 1 but reduced task duration is required for many 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 RCRs 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 3 contributing scenario 2, ES 5 contributing scenario 2 and ES 7 contributing scenario 2 (maximal task duration of 1 hour), and ES 5 contributing scenario 2 (maximal task duration of 2 hours). Further

ECHA
EUROPEAN CHEMICALS AGENCY

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 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 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.

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.

If you justify and demonstrate that the "cleaning and maintenance" and "waste disposal" tasks are not relevant in the manufacturing and formulation plants, no additional exposure assessment and risk characterisation would be needed, but only a description of the OC, RMM and RCR would be needed.

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 "equipment cleaning and maintenance" in exposure scenarios (ES) 1, 2, 3 and 4 and "waste disposal" in ES 1, 2, 3, 4 and 5 to the exposure scenario, and provide an exposure assessment and risk characterisation (with OC, RMM and RCR);

ECHA
EUROPEAN CHEMICALS AGENCY

- add the contributing scenario 9 in ES 3 and contributing scenarios 6, 7, 8 and 9 in ES 4, and provide an exposure assessment and risk characterisation (with OC, RMM and RCR).

Remark: for contributing scenarios with short task duration and high RCR (ES 3 contributing scenario 2; ES 5 contributing scenario 2 and 5; ES 7 contributing scenario 2), 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 (WORKER – INDUSTRIAL AND PROFESSIONAL; 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); REMOVE AN INCORRECT STATEMENT ABOUT RESPIRATORY PROTECTION OR PROVIDE A SUITABLE JUSTIFICATION; UPDATE THE EXPOSURE SCENARIO 3

The Concern(s) Identified

The concern identified is for workers safety. Indeed gloves are required as risk reduction measures, but no sufficient information is provided in the dossier to ensure that adequate protection is worn. In addition, you state that respiratory protection can compensate for the lack of adequate ventilation or prolonged exposure, but this is not supported by any justification able to demonstrate workers safety.

Why new information is needed

The RMM are listed in a table at the beginning of section 9 of the CSR and for each contributing scenario.

Regarding gloves, the information provided is not sufficient to enable the evaluating MSCA to assess the adequacy of the gloves recommended, nor to communicate adequate information on safe use to the supply chain. The reference to the standard EN 374 is not sufficient, as highlighted in ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.14: Occupational exposure assessment (version 3.0, August 2016). 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.

Regarding respiratory protection, you state that "Respiratory protection (respiratory protective device with a particle filter) can be necessary in the following conditions outside the exposure scenarios described in chapter 9: insufficient ventilation; prolonged exposure". No assessment is provided to demonstrate that the use of a respiratory protection would compensate for insufficient ventilation and prolonged exposure. This is a concern since this declaration is likely to mislead workers, to prevent proper implementation of Article 37, and to prevent proper management of the risk for workers.

Additionally, ECHA noted that gloves with 90% efficiency must be added as RMM in the contributing scenario 2 of exposure scenario (ES) 3 (formulation (cosmetics, personal care products) and compounding of fragrance). Indeed, if no gloves are worn, RCR (dermal) is above 1. You took into account the wearing of gloves in your assessment but did not communicate it in the CSR.

ECHA
EUROPEAN CHEMICALS AGENCY

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

What is the possible regulatory outcome

The possible regulatory outcome is enforcement.

Considerations on the test method and testing strategy

You will need to determine the appropriate type of material(s), the 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. Regarding respiratory protection, no new test is required.

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) of the gloves, the thickness and the typical or minimum breakthrough time;
- remove the statement on respiratory protection;
- specify that gloves with 90% efficiency have to be worn for exposure scenario (ES) 3, contributing scenario 2.

ENDPOINT 1.1.5: EXPOSURE-RELATED REQUESTS (WORKER – INDUSTRIAL; IMPROVED CHARACTERISATION): CONDITION OF USE TO BE CLARIFIED OR EXPOSURE ASSESSMENT TO BE REFINED FOR RISK NOT ADEQUATELY MANAGED

The Concern(s) Identified

In the exposure scenario (ES) 5 (formulation of fuels), the duration of the task under contributing scenario 8 (workers exposure for maintenance activities) is not clear. In the CSR, it is indicated that the duration is above 4 hours but the calculations were made for a duration of 1-4 hours. This impacts directly the risk characterisation ratio (RCR) for

ECHA
EUROPEAN CHEMICALS AGENCY

inhalation as RCR (inhalation) is above 1 for indoor use if the task lasts more than 4 hours. Based on the current Exposure Scenario, the risk for workers is not adequately managed.

Why new information is needed

A clarification of the maximum duration of this task is necessary to confirm that the risk is adequately managed, or a reiteration of the risk assessment with additional RMM.

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.

Considerations on the test method and testing strategy

No new test is required. You are required to update the exposure scenario.

Consideration of alternative approaches

Alternatively, if the task duration is higher than 4 hours, you will have to refine the assessment for the exposure by inhalation indoor based on other RMM.

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:

- update the contributing scenario 8 of exposure scenario (ES) 5 (formulation of fuels) to specify the maximum duration of the task, and if necessary refine the assessment for inhalation indoor based on other risk management measures (RMM).

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

ECHA
EUROPEAN CHEMICALS AGENCY

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 release estimations, maximum daily releases to wastewater based on on-site specific measurements, on-site wastewater treatment systems or measured flow rate of specific river systems, the fraction of main source, the number of days of use per year). 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 your dossier.

Contrary to what you suggest, the largest customer does not necessarily correspond to the largest emission site, as the number of sites is higher than one (as specified in the table of identified uses in the CSR). Then, the fact that the emission scenario proposed for the largest customer is a worst case and covers all other sites for a use is questionable. Also, it is not possible to know how the maximum annual site tonnage values from which releases are estimated were calculated. This calculation should be detailed to better understand this value for each uses. –For the specific use formulation of fuels (ES5), an absence of release is expected by the Registrant but has not been justified. Finally, the maximum daily release to wastewater from process (prior to RMM) used in ES3 and ES6 corresponds to the limit values calculated to ensure that the risks are controlled. Nonetheless, justified measured values (otherwise default worst-case release factors) have to be used by the Registrant.

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;

ECHA
EUROPEAN CHEMICALS AGENCY

- 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.

ENDPOINT 1.1.7: EXPOSURE-RELATED REQUESTS (ENVIRONMENT): DESCRIPTION OF USES.

The Concern(s) Identified

The environmental exposure scenarios for 'Formulation of fragrance substances' (ES4) and for 'Industrial and professional uses of other fragranced products' (ES9) are considered as covered by the emission scenarios 'Formulation in cosmetics, personal care products and compounding of fragrances substances' (ES3) and "Private use of cosmetics, personal care and fragranced products" (ES8), respectively. However these uses are not sufficiently described to be sure that the risks assessed for the covered uses are fully controlled.

Why new information is needed

You assumed that the environmental exposure of the use 'Formulation of fragrance substances' (ES4) is covered by the assessment of the use 'Formulation in cosmetics, personal care products and compounding of fragrances substances' (ES3). However, the difference between these two uses is not clear to be sure that ES4 could cover ES3. Also, the volume considered for ES3 is assumed to cover the volume of ES4 to ensure that all environmental releases are taken into account. Nonetheless, you should precise to what this volume corresponds to, *i.e.* the total annual site tonnage for the two uses or if it is the annual tonnage for each uses. Then, further explanations are required to state that risk relative to ES4 is covered by ES3.
You considered that the two emission scenarios for "Industrial and professional uses of other fragranced products" (ES9) are covered by the emission scenario of "Private use of cosmetics, personal care and fragranced products" (ES8) since ERC8A gives a worst case estimation of releases. However, the other fragranced products from ES9 are not defined and should be different from cosmetics, personal care and fragranced products. Furthermore, the tonnage is not available for ES9 and is not clearly explained for ES8. This information is required to estimate the releases and the risks for both uses.

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 a clearer description of the following uses: 'Formulation of fragrance substances' (ES4), 'Industrial and professional uses of other fragranced products'

ECHA
EUROPEAN CHEMICALS AGENCY

(ES9), 'Formulation in cosmetics, personal care products and compounding of fragrances substances' (ES3) and 'Private use of cosmetics, personal care and fragranced products' (ES8) to ensure that release estimations for ES4 and ES9 are not required since covered by ES3 and ES8 respectively;

- Provide further explanations on the tonnages used for these uses to estimate the releases and to state that risks are acceptable.

ECHA
EUROPEAN CHEMICALS AGENCY

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.

ECHA
EUROPEAN CHEMICALS AGENCY

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

ECHA
EUROPEAN CHEMICALS AGENCY

microemulsions and/or micelles. Furthermore, you agreed 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 you 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. The requests were amended accordingly 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.

ECHA
EUROPEAN CHEMICALS AGENCY

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.