Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

trichloroethylene use:

Use of trichloroethylene as a solvent in a process to recover and purify resin from process water

ECHA/RAC/SEAC: AFA-O-0000005799-54-02/D

Date: 9 January 2015

Consolidated version of the

Opinion of the Committee for Risk Assessment
and
Opinion of the Committee for Socio-economic Analysis

on an Application for Authorisation

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular Chapter 2 of Title VII thereof, the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) have adopted their opinions in accordance with Article 64(4)(a) and (b) respectively of the REACH Regulation with regard to an application for authorisation for:

Chemical name(s): **Trichloroethylene**
EC No.: **201-167-4**
CAS No.: **79-01-6**

for the following use:

Use of trichloroethylene as a solvent in a process to recover and purify resin from process water

Intrinsic property referred to in Annex XIV:

Article 57 (a) of the REACH Regulation

Applicant

Vlisco Netherlands BV

Reference number

11-2120050202-76-0001

Rapporteur, appointed by the RAC: **Christine Bjørge**
Co-rapporteur, appointed by the RAC: **Normunds Kadiķis**

Rapporteur, appointed by the SEAC: **Simon Cogen**
Co-rapporteur, appointed by the SEAC: **Karmen Krajnc**

This document compiles the opinions adopted by RAC and SEAC.

PROCESS FOR ADOPTION OF THE OPINIONS

On 30 May 2014 Vlisco Netherlands BV submitted an application for authorisation including information as stipulated in Articles 62(4) and 62(5) of the REACH Regulation. On **23 July 2014** ECHA received the required fee in accordance with Fee Regulation (EC) No 340/2008. The broad information on uses of the application was made publicly available at http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation on **13 August 2014**. Interested parties were invited to submit comments and contributions by **8 October 2014**.

No comments were received from interested parties during the public consultation in accordance with Article 64(2)).

The draft opinions of RAC and SEAC take into account the responses of the applicant to the requests that the SEAC made according to Article 64(3) on additional information on possible alternative substances or technologies.

The draft opinions of RAC and SEAC were sent to the applicant on **18 December 2014.**

On **8 January 2015** the applicants informed ECHA that they did not wish to comment on the opinions. The draft opinions of RAC and SEAC were therefore considered as final on **9 January 2015**.

ADOPTION OF THE OPINION OF RAC

The draft opinion of RAC

The draft opinion of RAC, which assesses the risk to human health and/or the environment arising from the use of the substance – including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives – was reached in accordance with Article 64(4)(a) of the REACH Regulation on **4 December 2014**.

The draft opinion of RAC was agreed by consensus.

The opinion of RAC

Based on the aforementioned draft opinion and in the absence of comments from the applicant, the opinion of RAC was adopted as final on **9 January 2015.**

ADOPTION OF THE OPINION OF SEAC

The draft opinion of SEAC

The draft opinion of SEAC, which assesses the socio economic factors and the availability, suitability and technical and economic feasibility of alternatives associated with the use of the substance as described in the application was reached in accordance with Article 64(4)(b) of the REACH Regulation on **28 November 2014**.

The draft opinion of SEAC was agreed by consensus.

The opinion of SEAC

Based on the aforementioned draft opinion and in the absence of comments from the applicant, the opinion of SEAC was adopted as final on **9 January 2015.**

THE OPINION OF RAC

RAC has formulated its opinion on the risks arising from the use applied for and the appropriateness and effectiveness of the described risk management measures, and on the assessment of the risks related to the alternatives as documented in the application and on information submitted by interested third parties as well as other available information.

The application included the necessary information specified in Article 62 of the REACH Regulation that is relevant to the Committee's remit.

RAC confirmed that it is not possible to determine a DNEL for the carcinogenicity properties of the substance in accordance with Annex I of the REACH Regulation.

RAC confirmed that there appear not to be any suitable alternatives that further reduce the risk.

RAC confirmed that the exposure scenario(s) in the application appear(s) to limit the risk, provided that the risk management measures and operational conditions as described in the application are adhered to.

The duration for the review period has been suggested below.

THE OPINION OF SEAC

SEAC has formulated its opinion on the socio-economic factors and the availability, suitability and technical and economic feasibility of alternatives associated with the use of the substance as documented in the application and on information submitted by interested third parties as well as other available information.

The application included the necessary information specified in Article 62 of the REACH Regulation that is relevant to the Committee's remit.

SEAC took note of RAC's confirmation that it is not possible to determine a DNEL for the carcinogenicity properties of the substance in accordance with Annex I of the REACH Regulation.

SEAC confirmed that there appear not to be suitable alternatives in terms of their technical and economic feasibility for the applicant.

SEAC considered that the applicant's assessment of (a) the potential socioeconomic benefits of the use, (b) the potential adverse effects to human health or the environment of use and (c) the assessment used to compare the two is based on acceptable socio-economic analysis. Therefore, SEAC did not raise any reservations that would change the validity of the applicant's conclusion that overall benefits of the use outweigh the risk to human health or the environment, whilst taking account of any uncertainties in the assessment.

The duration for the review period has been suggested below.

SUGGESTED CONDITIONS AND MONITORING ARRANGEMENTS

Conditions

- No additional conditions to those described in the application are proposed.

Monitoring arrangements

- No additional monitoring arrangements to those described in the application are proposed.

REVIEW

Taking into account the information provided in the analysis of alternatives prepared by the applicant the duration of the review period for the use is recommended to be 12 years.

JUSTIFICATIONS

Substance name:	Trichloroethylene
Name of applicant(s):	Vlisco Netherlands BV
Use name:	Use of trichloroethylene as a solvent in a process to recover and purify resin from process water
Reference number:	11-2120050202-76-0001

The justifications for the opinion are as follows:

1. The substance was included in Annex XIV due to the following property / properties:

- ☒ Carcinogenic (Article 57(a))
- ☐ Mutagenic (Article 57(b))
- ☐ Toxic to reproduction (Article 57(c))
- ☐ Persistent, bioaccumulative and toxic (Article 57(d))
- ☐ Very persistent and very bioaccumulative (Article 57(e))
- ☐ Other properties in accordance with Article 57(f) [please specify]:

2. Is the substance a threshold substance?

- ☐ YES
- ☒ NO

Justification:

Trichloroethylene (TCE) has a harmonised classification with Carc. 1B; H350 and Muta. 2; H341 according to CLP. Based on studies which show its genotoxic potential, the Risk Assessment Committee (RAC) has concluded that trichloroethylene should be considered as a non-threshold carcinogen with respect to risk characterisation (reference to the studies examined are included in the RAC document RAC/28/2014/07 Rev. 2 Final).

3. Hazard assessment. Are appropriate reference values used?

Justification:

RAC has established a reference dose response relationship for kidney cancer following exposure to trichloroethylene (RAC 28/2014/07 Rev. 2 Final). Based on epidemiological data (cited in the RAC document) an increased risk of kidney cancer occurring with cytotoxicity was found following relatively high occupational exposure including very high peak exposure. Thus a linear dose-response relationship would overestimate the risk at low exposure levels where no cytotoxicity would occur. Therefore a sub-linear approach with a break point at 6 ppm (33 mg/m3) was considered by RAC to be the most scientifically justified approach. RAC has not derived a DMEL value for trichloroethylene.

In the socio-economic analysis SEA the remaining human health risks are evaluated based on the dose-response relationship adopted by RAC.

4. Exposure assessment. To what extent is the exposure from the use described?

Please describe:

Introduction:
The application presents three exposure scenarios in the CSR. Exposure scenario 1 describes use 1 (Use of trichloroethylene as a solvent for the removal and recovery of resin from dyed cloth) and is evaluated in the opinion for use 1. Exposure scenario 2 describes use 2 (Use of trichloroethylene as a solvent in a process to recover and purify resin from process water) and is evaluated in this opinion. Exposure scenario 3 covers consumer exposure (which is not specific to use 1 or 2) and is evaluated in the opinion for use 1.

The exposure scenario (ES) developed for Use 2 consists of an environmental contributing scenario (ECS) and four worker contributing scenarios (WCS), of which two are identical to Use 1 (WCS1 storage, connecting/disconnecting, and WCS 3 activities inside cloth de-waxing unit during malfunction).
The applicant uses 4 tonnes TCE/year for use 1 and 2 combined; as the processes presented in ESs 1 and 2 are integrated – the tonnage cannot be separated. Workers may be exposed during recovery of resin and during maintenance work. The corresponding excess kidney cancer risk for workers is in the order 10^{-5} – 10^{-6} and for man via the environment in the order of 10^{-7} – 10^{-8}.

Exposure scenario:

Exposure scenario 2: "Use at industrial site – The use of TCE as a solvent in a process to recover and purify resin from process water"

The applicant described the following tasks for exposure scenario 2 (ES2):

ECS[1] 1: Use at industrial site – The use of TCE as a solvent for the removal and recovery of resin from dyed cloth (ERC 4)

WCS[2]1: Storage of TCE including connecting and disconnecting of containers via SAFETAINER system (PROC 1)
WCS2: Recovery of resin originating from breaking-off step (PROC 1)
WCS3: Water and air treatment (PROC 1)
WCS4: Maintenance activities (room temperature) (PROC 8a)

Information on worker exposure: The amount of substance used, duration and frequency of tasks, number of workers exposed, the measured exposure and modelled exposure and the use of RPE/PPE in the four worker contributing scenarios are included in Annex I to the opinion. The individual tasks are described in sufficient details by the applicant to allow an assessment of the worker exposure.

Additional information was submitted by the applicant upon request from RAC regarding the involvement of the same workers in multiple tasks covered by more than one WCS. see Annex II that gives an overview of the workers involved in the various WCS for Use 1 and use 2.

Methodology used by the applicant:

Worker exposure:
Data on TCE concentrations measured in the air is available for WCS 2 and 3. Personal

[1] 'ECS' denotes environmental contributing scenario in the applicant's CSR
[2] 'WCS' denotes worker contributing scenario in the applicant's CSR

measurements were carried out in an intensive personal monitoring programme performed in Q4 2013 and Q1, Q2 2014 for operators involved in resin recovery activities (closed system) (WCS2) and inside the wax-recovery unit (closed system) (WCS3) and for office workers.

Modelled data have also been submitted by the applicant. For inhalation exposure ECETOC TRA v3 was used for WCS1, WCS2 and WCS3 and the higher tier model ART 1.5 was applied for WCS4. For dermal exposure ECETOC TRA v3 was used for all four WCSs.

Monitoring results give more realistic information regarding the workplace exposure to TCE compared to modelled data that is considered to overestimate the exposure. For WCS4 the higher tier model ART 1.5 was used and modelled data from this WCS was significant higher than the measured exposure. When ECETOC TRA v3 was used as the model (WCS2 and 3) the estimation of the inhalation exposure was significantly lower than the measured exposure.
For the calculation of excess cancer risk in the CSR, measured data was used for inhalation exposure and modelled data for dermal exposure.

In the exposure assessment the use of PPE is described for WCS1 and WCS4, with protective gloves for WCS1, both gloves and overalls for WCS4. Respiratory protection equipment (RPE) is included for WCS4. The use of gloves was assumed to reduce the exposure by 95%, and RPE was assumed by the applicant to reduce the exposure by 99% (APF 100). In the dermal estimates the use of PPE is taken into consideration in the modelling.

RAC considers that the type of the RMMs specified in the ES combined with the training and appropriate maintenance of the equipment is capable to provide the protection as described by the Applicant.

Biological monitoring of employees:
In addition to the monitoring of the working atmosphere a biomonitoring campaign for the evaluation of the actual dermal and inhalation exposure to TCE was performed in April 2014. This consisted of measuring the major metabolites of TCE (i.e. trichloroacetic acid (TCA) and trichloroethanol (TCOH)) in urine from 16 operators and maintenance operators in the de-waxing unit and resin-recovery unit after 4-6 shifts. The sum of the TCA and TCOH levels were shown to be below the detection limit of 5 mg/L in all samples. However, the detection limit of the method used is considered by Vlisco to be too high since the reference value of 1.2 mg/L of TCA and TCOH in urine described in the BAUA TRGS 910 is equally to an excess risk of kidney cancer of 4:100 000. Therefore Vlisco will search for a laboratory using method with a lower detection limit and repeat the biological monitoring.

Biological monitoring data indicate that the conditions of use as described for workers at Vlisco site may be generally characterised as well controlled.

Exposure man via the environment:
The exposure of man via the environment (inhalation and oral) was modelled with EUSES. Additionally, an air dispersion model was used, Geomilieu v2.4 for inhalation exposure for the calculation of TCE concentrations in air in the area surrounding the Vlisco site. Three exposure groups were identified: Vlisco to ≤ 350m, 350m to ≤ 500 m and 500m to ≤ 1400 m from the Vlisco site.

Exposure estimated by applicant
Twenty workers are involved in the operation of the resin recovery. Their activities are divided into three categories: performed on the yearly basis, daily and weekly. For the analysis of exposure and resulting health effect assessment that can be used in the

SEA, the applicant has combined exposures resulting from daily and weekly activities. The result represents the daily exposure of a worker.

Process operators in the resin recovery unit:
The process described in the WCS3 is shared with Use 1(WCS7) – and the exposure is taken into consideration in Use 1. Maintenance (WCS4) is also performed by the same workers. Therefore, the applicant has combined the inhalation exposure for WCS2 - measured daily inhalation exposure of 1.485 mg/m^3 with the modelled (ART 1.5) weekly inhalation exposure of 1.6 mg/m^3, adjusted for the frequency of use. The dermal exposure was combined in the same manner: the value of the dermal exposures for the WCS 2, 0.034 mg/kg bw/day and adjusted for frequency of use value for WCS4, 0.137 mg/kg bw/day, were combined.

The combined inhalation and dermal exposure values were used to calculate excess cancer cases for the SEA.

Table 1: worker combined exposure for Use 2:

Worker activity	**Combined exposure inhalation mg/m^3**	**Combined exposure dermal mg/kg bw/day**
Process operators in resin recovery unit	3.085	0.171

Available exposure data for workers is summarised in Annex I of the opinion.

The exposure resulting from the activity performed on the yearly basis (WCS1) is of such a low value that it is not included in the combined daily exposure.

Indirect exposure of man via the environment:
The inhalation exposure was estimated by Geomilieu v2.4 which calculated the TCE concentrations in air in different areas surrounding the Vlisco site. The lowest and highest local TCE exposure in the various areas are shown in table 2 below. The oral exposure from diet was estimated by EUSES, se table 2 below.

Table 2: Indirect exposure of man via the environment estimated by Geomilieu and EUSES

Distance from Vlisco site	Geomilieu Inhalation Low mg/m^3	Geomilieu Inhalation High mg/m^3	EUSES Oral mg/kg bw/day	Number of people exposed
Vlisco to 350m	0.0005	0.002	0.0007297	3,676
350 to 500m	0.0003	0.0005	0.0007297	4,845
500 to 1400m	0.00005	0.0003	0.0007297	43,387
➢ 1400m	< 10% of background levels of TCE			

5. If considered a threshold substance, has adequate control been demonstrated?

☐ YES

☐ NO

☒ NOT RELEVANT, NON THRESHOLD SUBSTANCE

Justification:

RAC has concluded that trichloroethylene should be considered as a non-threshold carcinogen with respect to risk characterisation.

6. If adequate control is not demonstrated, are the risk management measures and operational conditions described in the application appropriate and effective in limiting the risk?

Justification and concluding on the remaining risk:

The calculation of the remaining human health risk is based on the dose-response relationship published by RAC (RAC 28/2014/07 Rev. 2 Final) and the estimated combined exposure levels. The overall risk is determined for two main population groups:

- Risks to workers at Vlisco resulting from exposure to TCE by inhalation and dermal contact;
- Risk to the general population near the Vlisco site due to the exposure via the environment through inhalation and oral intake.

Workers

Kidney cancer in workers due to inhalation and dermal exposure to TCE is considered to be the critical effect for risk assessment. Based on the sub-linear dose response relationship established by RAC the excess lifetime kidney cancer mortality risk for workers has a breakpoint at 33 mg/m3 (6 ppm) with an excess kidney cancer risk in EU workers at 4.0×10^{-4}.

For inhalation exposure the excess risk at 33 mg/m^3 and above is **1.3×10^{-4} per mg TCE/m^3 – 0.0039**, and below 33 mg/m3 the excess risk is **1.2×10^{-5} per mg TCE/m^3** (based on 8h exposure 5 days/week during 40 years).

For dermal exposure the breakpoint for the sub-linear dose-response curve is 4.72 mg/kg bw/day with an excess kidney cancer risk in EU workers at $4x10^{-4}$.

At 4.72 mg/kg bw/day and above the excess risk is **9.09×10^{-4} per mg TCE/kg bw/day – 0.0039** and below 4.72 mg/kg bw/day **8.4×10^{-5} per mg TCE/kg bw/day** (based on 8h exposure 5 days/week during 40 years).

Process operators in the resin recovery unit:

Based on the exposure data described above the excess kidney cancer risk for daily activities via inhalation exposure is $1.485 \times 1.2 \times 10^{-5}$ per mg TCE/m^3 = 1.78×10^{-5} and for weekly activities 1.6 mg/m^3 x 1.2×10^{-5} per mg TCE/m^3 = 1.92×10^{-5}.

Via dermal exposure the excess kidney cancer risk for daily activities is 0.034 mg/kg bw/day x 8.4×10^{-5} per mg TCE/kg bw/day = 2.86×10^{-6} and for weekly activities 0.137 mg/kg bw/day x 8.4×10^{-5} per mg TCE/kg bw/day = 1.1×10^{-5}. For weekly combined (inhalation and dermal) activities the excess risk is recalculated to be 6.1×10^{-6} to take into account that the activity only takes place 1 day/week.

The excess kidney cancer risk is also determined for the combined exposure (inhalation and dermal) for the working contributing scenarios related to resin recovery that the operators and maintenance staff perform on a daily and weekly basis.

- *Combined exposure for process operator related to resin recovery:*

  There are in total 20 process operators divided into 5 teams of 4 operators. The excess kidney cancer risk for daily combined (inhalation and dermal) exposure for these operators is 2.07×10^{-5} and is considered representative for a working day (WCS2).

  The excess kidney cancer risk for weekly combined (inhalation and dermal) activities for maintenance operators related to malfunction in the resin recovery unit is 3.07×10^{-5}. When recalculated taking into account that this activity only takes place 1/week the excess kidney cancer risk is 6.1×10^{-6} and is considered representative for a weekly and daily exposure (WCS4).

The calculated excess kidney cancer risk for daily and weekly activity and for combined exposure (inhalation and dermal) for these operators is 2.07 x 10^{-5} (daily) + 6.1 x 10^{-6} (weekly) = **2.68 x 10^{-5}**.

Values used in SEA

The estimated expected statistical number of cancer cases based on the excess risk for kidney cancer following inhalation and dermal exposure to TCE as well as for daily and weekly activities for the numbers of operators included in Use 2. For operators in the resin-recovery unit the applicant included the daily inhalation and dermal exposure from this activity in Use 1 (WCS6) and the daily and weekly activity following inhalation and dermal exposure in Use 2 (WCS2 and WCS4). As a consequence, for the assessment of combined exposure there is an overlap between Use 1 and Use 2. The expected statistical number of cancer cases is included in table 3 below.

Table 3:Calculated number of predicted statistical kidney cancer cases from a working life-time exposure of 40 years

	Process operators in resin recovery unit (20)
Calculated # of kidney cancer	**0.000536**

The yearly activity (WCS1) is not taken into account since the exposure related to this activity is minimal and is considered not to affect the combined exposure for these workers due to the limited frequency of the activity and due to the negligible exposure level.

There is a yearly biological monitoring program for employees to control the effectiveness of the RMMs, with a detection limit in urine of 5 mg/L, however, Vlisco is searching for a laboratory using a methodology with a lower detection limit for the future bio-monitoring of the operators.

In the CSR, the applicant described exposure that is controlled and minimized by the design of the installation, i.e. collective measures to avoid exposure, the procedures, i.e. collective measures to reduce exposure in specific areas (de-waxing unit), in case the alarm goes off and for cleaning the equipment, and by the use of Personal Protective Equipment's (PPE) including air stream helmet (with an Assigned Protection Factor, APF of 100), gloves and overalls. The RMMs described by the applicant are considered to be appropriate/adequate to limit the exposure (closed system where possible, general and local exhaust ventilation, training and the use of PPE).

Indirect exposure man via the environment

Kidney cancers following indirect exposure to man via the environment due to inhalation and oral exposure to TCE are considered to be the critical effect for risk assessment. Based on the sub-linear dose response relationship established by RAC the excess lifetime kidney cancer mortality risk for the general population has a breakpoint at 6.2 mg/m^3 with an excess kidney cancer risk in the general population at 4.0 x 10^{-4}. For inhalation exposure the excess risk at 6.2 mg/m^3 and above is **6.9 x 10^{-4} per mg TCE/m^3 – 0.0039**, and below 6.2 mg/m^3 the excess risk is **6.4 x 10^{-5} per mg TCE/m^3** (based on 70 years of exposure).

For oral exposure the breakpoint for the sub-linear dose-response curve is 0.92 mg/kg bw/day with an excess kidney cancer risk in the general population at 4x10^{-4}. At 0.92

mg/kg bw/day and above the excess risk is **4.66 x 10^{-3} per mg TCE/kg bw/day – 0.0039** and below 0.92 mg/kg bw/day **4.32 x 10^{-4} per mg TCE/kg bw/day** (based on 70 years of exposure).

The excess kidney cancer risk for man exposed via the environment was based on the exposure described above and calculated for combined exposure (oral and inhalation). The excess risk of kidney cancer decreased with increasing distance from the Vlisco site, see table 4 below.

It can be concluded that the calculated excess kidney cancer risk for Man exposed via the environment is far below the breakpoint determined for the general population in the RAC reference document (bearing in mind that this is not a threshold) and the measures taken within Vlisco show minimisation of emission of TCE to the general population.

Table 4: The excess kidney cancer risk indirect exposure via the environment

Distance from Vlisco site	Geomilieu inhalation	EUSES oral	Combined risk	Number of people
Vlisco to 350m	1.3 x 10^{-7}	3.2 x 10^{-7}	4.4 x 10^{-7}	3,676
350 to 500 m	3.2 x 10^{-8}	3.2 x 10^{-7}	3.5 x 10^{-7}	4,845
500 to 1400 m	1.9 x 10^{-8}	3.2 x 10^{-7}	3.3 x 10^{-7}	43,387

In conclusion, RAC considers that the risk management measures and operational conditions as described in the application are appropriate and effective in limiting the risk to workers and the general population.

7. Justification of the suitability and availability of alternatives

7.1 To what extent is the technical and economic feasibility of alternatives described and compared with the Annex XIV substance?

Please describe:

The analysis of alternatives brought before SEAC considers several “drop-in” alternatives as well as alternative technologies for trichloroethylene.

A. Several “drop-in” alternatives, i.e. different solvents, were investigated.

Non-flammable **PERC** was identified to be a direct functional replacement for TCE because of its comparable technical functionality and physical properties. Other non-flammable solvents were considered as well but found to be less similar to TCE than PERC. The effects on technical and economic feasibility described below would therefore be even more pronounced.

Several intrinsic properties make PERC technically not yet feasible according to the applicant. The chlorinated solvent is less efficient, and substantially so, at dissolving the resin and has a much higher density difference with water compared to TCE. All of this leads to an overall less efficient extraction process. Additionally, the higher boiling point leads to significantly higher concentrations of PERC in the resin – and therefore also to the lower re-usability of this shielding agent - and wastewater. Using higher process temperatures would also negatively impact the re-usability since this would

result in higher thermal degradation of the resin. As a whole, these technical differences have as a consequence that a major redesign of the plant would be necessary (investment costs). No change in operational costs is expected.

The applicant calculated the downtime costs under the assumption that PERC would be used as an alternative for use 1 (*Use of trichloroethylene as a solvent for the removal and recovery of resin from dyed cloth*). SEAC considers this justifiable because the combination of PERC as use 2 with any of the proposed alternatives for use 1, except PERC, is illogical since their implementation times – during which the plant would be closed – exceed the 4 yrs needed for PERC. The downtime costs would mostly be made up of increased raw material costs (loss of resin due to lower recovery rates) due to the change to PERC in use 2 being completed 1.5 yrs after PERC in use 1. The incurred total costs (investment+downtime) lead SEAC to conclude that PERC is not economically feasible for the applicant at the sunset date.

Toluene was also considered as a possible "drop-in" alternative for TCE but shows much of the same technical disadvantages as PERC, meanwhile also adding flammability to the mix. The applicant would therefore have to also comply with the ATEX regulation for flammable liquids. Since less research has been done with toluene compared to PERC in this use, the implementation time would be longer (6 yrs) and therefore the investment cost also slightly higher.

No change in operational costs is expected. Downtime costs, additional to those for Use 1, would not accrue since the implementation time for toluene in both uses is considered to be the same (6yrs). Based on this SEAC considers toluene to not be technically and economically feasible.

B. Rosin and solvent free extraction.

A different resist is used in order to make the use of an organic solvent redundant. These alternatives for use 1 (rosin) and 2 (solvent free extraction) are inextricably linked according to the applicant - Use 1 encompasses use 2 completely and apparently utilizing rosin entails the use of a solvent free extraction - and are therefore considered together. While SEAC questions the argument used to do this (in the past TCE was used to recover the resist), it does deem the decision to look at both uses together acceptable when put into the context of the entire application.

A theoretical concept for the use of this alternative is available, but a lot of research would still be required to find a solution to some of the major problems associated with the use of a rosin. The use of rosin was discontinued over 30 years ago leading to a technological standstill. Inefficient processes therefore need to be updated to current standards. According to the applicant this would take about 9 years (downtime costs). Most important of all, a chemically modified rosin needs to be found that meets set requirements. Chemical inertia to other process chemicals being chief among them. This is stated to be important in achieving a sufficient recovery rate of the resist. New process steps will however still be required because even chemically modified rosin will still have a tendency to react under the conditions needed to work with this alternative.

Additional process steps engender investment costs, but - compared to the other alternatives - these are reasonable. Taking a look at the operational costs – because of the low recovery rate - and especially the downtime costs (partly based on lost profit) changes this picture completely. These costs exceed the yearly sales revenue significantly.

Based on this SEAC considers this alternative not to be technically and economically feasible.

C. Solvent free extraction (in combination with resin)

This technique is based on a combination of mechanical (filtration) and thermal separation/evaporation. The different identified process steps still need to be developed. For the applicant, critical factors are getting a sufficient recovery rate and purity of the resin. This development should, as insisted upon by the applicant, be done in conjunction with development of an alternative for use 1. No justification has been given for this need and its effect on technical feasibility. Furthermore the applicant explicitly states that there isn't any integration or overlap with the installation for use 1.

SEAC however agrees with Vlisco that this alternative, looked at separately from use 1, is technically not feasible at the moment.

Vlisco's assessment of economic feasibility again focusses on investment costs (equipment and engineering), operational costs (increase in raw materials, waste management and energy costs) and downtime costs. The latter are calculated on the basis of the additional cost in raw materials (resin) and waste treatment. These arise from the fact that use 1 might be implemented earlier than use 2 and are distinct from the operational cost (no double-counting).

SEAC agrees with this assessment and the conclusion that this alternative is not economically feasible.

D (use 2)/E (use 1). Switchable Solvents

The applicant described a new and promising technique which they believe to be a future, sustainable/"green" substitute to TCE, to wit, switchable solvents. The technology is still in its infancy on an industrial level, but proofs of concept are available for several applications. In theory, this technology could be applied to both uses maintaining the "premium" quality of the finished product. A long-term development plan spanning 12 years was presented.

SEAC finds it clear that this alternative is not yet technically feasible.

In its assessment of the economic feasibility of the switchable solvent alternative investment costs (new equipment) and downtime costs (lost profits) would be incurred. However, energy savings of 75% would yield operational savings. While these do not compensate the huge downtime costs, which exceed the yearly sales revenue, they do provide an incentive for substitution.

Based on the above SEAC agrees that switchable solvents are at this time not economically feasible.

The applicant thoroughly analysed the substance function of TCE within their process and screened for a broad range of alternatives, including alternative technologies. A shortlist of alternatives was arrived at which was discussed above. Numerous references to past studies, most of which fairly recent, are made and findings of these are used to discuss the technical feasibility of the alternatives. These substantiate Vlisco's claim that they've been making considerable efforts in finding an alternative for TCE, to no avail however. Currently they're in talks with Greencentre Canada and Switchable Solutions Inc. to initiate projects which could lead to a sustainable alternative for TCE (Switchable Solvents). The arguments for not considering the presented alternatives to be technically feasible are clear and transparent.
Based on this, SEAC considers the technical feasibility to have been adequately described compared to the currently used substance.

7.2 Are the alternatives technically and economically feasible?

☐ YES

☒ NO

Justification:

According to the applicant none of the alternatives are technically and economically feasible at the sunset date. Substitution would entail, at the very least and for all of the alternatives, significant alterations to the currently used process equipment or would render it obsolete. The applicant also noted the importance of the interconnectedness of the 2 uses for which authorisation is sought. As a consequence suitable alternatives should be considered for both uses simultaneously.

Based on its scrutiny of the Analysis of Alternatives, SEAC concurs with the assessment made by the applicant which states that no technically and economically feasible alternatives will be available at the sunset date.

While the sometimes very conservative assumptions made regarding the economic feasibility and the description of the effects of using a certain alternative seem acceptable, the transparency of the calculations left a lot to be desired. Often times it was impossible to make a quick check of the numbers provided to the committees. Our requests for clarifications were however satisfactorily met with and strengthened the view on the economic infeasibility of the alternatives.

7.3 To what extent are the risks of alternatives described and compared with the Annex XIV substance?

Five potential alternatives are described, three alternative substances and two alternative techniques.

Tetrachloroethylene (PERC): PERC is classified as a cat. 2 carcinogen and is considered as a potential SVHC. PERC is included in the EU Endocrine Disrupting Chemical (EDC) database as a Cat. 2 EDC. PERC is a suspected PBT substance and is under Substance Evaluation (Corap 2013). The scientific committee on occupational exposure limits (SCOEL) identified similarities between the metabolic pathway of TCE and PERC and therefore the hazard properties of the two substances are considered to have the same concern. PERC is also self-classified as Skin Sens. 1B, one of the screening criteria for the SVHC roadmap. Therefore, it is considered that the risk would not be (significantly) reduced by replacing TCE with PERC.

Flammable solvents: A number of flammable solvents was investigated, and toluene was identified as a potential alternative for Use 2, however, the use of toluene would introduce an additional risk of explosion. The overall reduction of risk has not been investigated in detail as the technical feasibility of a flammable alternative has not been proven and the economic feasibility is less favourable compared to non-flammable solvent.

Solvent free extraction in combination with resin: This process provides a reduction in the human health risk compared to the use of TCE since no solvent is used. However, more resin will be lost into the environment with this process, and the impact on the environment has not been assessed by the applicant.

Rosin and solvent free extraction: The risk has not been evaluated since the alternative has been disregarded on grounds of technical and economic feasibility.

Switchable solvent: The overall reduction of risk is not possible to assess, since the solvent to be used is not identified, but known switchable solvents are considered to be less hazardous compared to TCE.

7.4 Would the available information on alternatives appear to suggest that substitution with alternatives would lead to overall reduction of risk?

☐ YES

☒ NO

☐ NOT APPLICABLE

Justification:
With respect to the substitutes for TCE included in the applicant's non-use scenario (PERC for use 1 and solvent-free extraction for use 2), the available information on alternatives indicates that there will be no reduction in risk achieved by substitution, owing in particular to the hazard properties of PERC (as stated in 7.3).

7.5 If alternatives are suitable (i.e. technically, economically feasible and lead to overall reduction of risk), are they available?

☐ YES

☐ NO

☒ NOT RELEVANT

Justification:
SEAC agrees with the applicant that no suitable alternatives exist at this moment in time.
The applicant does describe a new and promising technique which they believe to be a future, sustainable substitute to TCE, to wit, switchable solvents. A long-term development plan spanning 12 years was presented after which time a suitable alternative might be available to him. The timeline of 12 years is valid only in an ideal case.

8. For non-threshold substances, or if adequate control was not demonstrated, have the benefits of continued use been adequately demonstrated to exceed the risks of continued use?

☒ YES

☐ NO

☐ NOT RELEVANT, THRESHOLD SUBSTANCE

Justification:
According to the AoA, the cheapest and most readily implementable non-use scenario would have been the substitution of TCE with PERC. The applicant has however chosen to go for solvent-free extraction for use 2. Several reasons for this choice pertain to the hazard profile, which is seen as worse than TCE, and the expected higher exposure of workers to PERC. Since a minimal implementation period to continue marketing Vlisco's wax products is not as critical a factor here as it is for use 1, a reduction in risk potential could become decisive in choosing an alternative.

The loss of TCE in use 2 would predominantly impact Vlisco, therefore impacts along the supply chain were disregarded. In their SEA, the applicant identified economic impacts only if authorisation would not be granted.
Investment costs would be incurred since there are significant technical differences between TCE and the solvent-free alternative technology (see point 7.1) which necessitate a major redesign of the plant.
Increases in **operating costs** can also be expected before as well as after the alternative technology is operational. In the 3.5 yrs where use 1 is operational and

use 2 is not, all process water containing wax won't be recycled. Higher amounts of wax will therefore need to be purchased. After the process becomes operational higher wax losses (compared to the TCE process) will also necessitate increased wax purchases.

The applicant claims no significant **social** and **macro-economic impacts** at the EU level are to be expected from the non-use scenario. Resin is recovered for cost savings and compliance reasons (environmental permits) only.

For the calculation of the **health impacts** of continued use, exposure (dermal and inhalation) is quantitatively linked to the health impact of interest. In this case renal cancer has been identified as the sole important contributor to the excess risks.
RAC's dose-response relationship was used in the applicant's assessment assuming worker exposure of 8 hours per working day over a working life of 40 yrs. The applicant arrived at an estimate interval of €535 and €1 861 which was calculated using different values for the fatal cancer cases only. This estimate can also be considered a best estimate for workers' excess risk, but several sensitivities were tested. Considering these, the benefits could be as high as €2 897.
Since it is not possible to distinguish the TCE emissions and related exposure between use 1 and 2 the benefits of both uses to the general population around the Helmond site, were presented in the opinion for use 1 and should not be double counted here.

As was the case for the AoA, the transparency of the cost calculations left a lot to be desired. Uncertainty on when costs start to accrue, the use of multiple base periods and calculation windows give rise to difficulties to easily assess the costs. The SEA did make up for this by incorporating some very conservative assumptions. Our requests for clarifications were however satisfactorily met with and cleared up our reservations on the calculations. The costs of non-authorisation exceed even the upper bound, worst case human health benefits estimates by such a margin (more than ten thousandfold) that SEAC can only conclude that the benefits of continued use have been adequately demonstrated to outweigh the risk.

9. Do you propose additional conditions or monitoring arrangements

☐ YES
☒ NO

Detailed description for additional conditions and monitoring arrangements:

None proposed

Justification for additional conditions and monitoring arrangements:

Not applicable

10. Proposed review period:

☐ Normal (7 years)
☒ Long (12 years)
☐ Short (…. _years)
☐ Other:

Justification for the suggested review period:

The applicant described a new and promising technique which they believe to be a future, sustainable substitute to TCE, to wit, switchable solvents. The technology is still in its infancy on an industrial level, but proofs of concept are available for several applications. Because it is a solvent-based technology the applicant is confident that it has the potential to be an alternative for both uses of TCE within the company. A long-term development plan spanning 12 years was presented, which is therefore also the review period recommended by SEAC.

Several arguments support this proposal:

- Switching to PERC would not result in a (significant) reduction in overall risk to human health and environment. PERC is carcinogen cat. 2 and a suspected PBT and EDC. Use of this substance also means complying with the SEVESO directive.
- The remaining risk is very low (worst-case scenario €104k) and the socio-economic benefits are extremely high (more than a hundredfold higher than the risk).
- The applicant has also demonstrated that in the last 35 years considerable efforts have been made to find a suitable alternative, but none were discovered so far. New research projects are being initiated which underscore the willingness to substitute.
- The costs of using the alternatives have been demonstrated to be very high and very unlikely to change in the next decade.

In regards to the last point, SEAC asked the applicant to provide the committee with cost figures for scenarios in which different review periods (4, 7, 12 yrs) were proposed. SEAC not only requested this for what seems to be the prime candidate for substitution (switchable solvents), but also for some of the other alternatives.

Shorter review periods make the PERC option more attractive cost-wise, but the benefits of continued use still substantially outweigh the risk (more than a hundredfold). One must, however, also keep in mind that PERC can not be considered a sustainable alternative for reasons cited earlier.

Longer review periods of course favour the switchable solvents option. Costs drop dramatically at the 12 year mark for this alternative, although the benefits of continued use still substantially outweigh the risk (more than a hundredfold). A review period of 12 years would allow Vlisco to carry out their proposed development plan potentially leading to a suitable alternative without them incurring excessive costs (if authorisation is granted). Extensive R&D work still has to be conducted to prove the viability of this technique as a possible suitable alternative. It does however already provide a significant advantage to the continued use and non-use scenario: energy savings. This advantage could not only benefit the company itself, but also society and the environment as a whole. Other possible advantages (sustainability and regulatory certainty) have been presented. These are still somewhat speculative at this moment in time, but can't be summarily ignored either.

A review period longer than 12 yrs is not advisable according to the applicant since this does not impact the costs and would only lead to delayed implementation of the alternative.

Annex I (Worker exposure data)

WCS	Title	Route of exposure	Number of measurements or model applied	90th percentile	Mean / Median	Duration	Frequency	Persons / shift	PPE / RPE normally used in WCS	Exposure adjusted with RPE; APF 10 / 20 ?	Table no. in CSR
1	***Storage of TCE...*** *Identical to Use 1, see ES1 WCS 1*										
2	***Recovery of resin originating from breaking-off step PROC 1***	**Inhal mg / m³**	Ecetoc TRA v3		0.055	*1h/d <8h (with other tasks)* *The operators are present in the pressurized control room of the resin recovery installation (closed system) for 6-7h/day and perform control rounds for 1-2h/day.*	*daily*	*20 divided into 5 teams of 4 operators, 1 operator per shift*	-	-	*59*
		Inhal mg / m³	Personal measurements	1.485							
		Dermal mg / kg bw / d	Ecetoc TRA v3		0.034						

3	***Water and air treatment PROC 1*** *Identical to Use 1, see ES1 WCS 7*										
4	***Maintenance activities PROC 8a***	**Inhal mg/m³**	ART 1.5	160 adjusted to 1.6 APF 100		*<1h*	*8 – 10 times per year* *(<weekly)*	*Two operators per occasion, 20 operators in total*	RPE	100	*62*
		Dermal mg/kg bw/d	Ecetoc TRA v3		0.137				PPE	20	

Annex II (Overview of the workers involved in the WCS for Use 1 and 2)

Department	Operators/shift	# shifts	Total # operators/department	Relevant ES and WCS
Dewaxing unit	3	5*	15	ES1: -WCS2 -WCS3 -WCS4 -WCS5
Resin Recovery Unit	4	5*	20	ES1: -WCS1 -WCS6 -WCS7 ES2: -WCS1 -WCS2 -WCS3 -WCS4
Preventive Maintenance engineers for Dewaxing Units	5	Day-shift only	5	ES1: -WCS4
Maintenance Service Engineers***	3	5*	15	ES1: -WCS3
Total number of workers performing task related to TCE work			55**	

*A 5-shift system means that there are five teams consisting of several operators which work 6 shift of 8 hours, after which they have 4 days off (two shifts 06.00 – 14.00 hrs, two shifts 14.00 – 22.00 hrs, two shifts 22.00 – 06.00 hrs, then 4 days off)

**in the CSR/SEA a total of 60 operators have been reported. The difference is based on a different number of Maintenance engineers involved. This was done from a precautionary principle point of view and the fact that additional Maintenance engineers might be involved in the future (e.g. more people, but lower frequency)

***In the CSR no distinction is made between these two groups of Maintenance engineers. This was from simplicity reason.