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 for the removal and recovery of resin from dyed cloth

ECHA/RAC/SEAC: AFA-O-0000005799-54-01/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 for the removal and recovery of resin from dyed cloth

Intrinsic property referred to in Annex XIV:

Article 57 (a) of the REACH Regulation

Applicant

Vlisco Netherlands BV

Reference number

11-2120050202-76-0000

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 for the removal and recovery of resin from dyed cloth
Reference number:	11-2120050202-76-0000

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/m^3) 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 Chemical Safety Report (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 this opinion. 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 the opinion for use 2. Exposure scenario 3 covers consumer exposure (which is not specific to use 1 or 2) and is evaluated in this opinion.

The Exposure Scenario (ES) developed for Use 1 consists of an environmental contributing scenario (ECS) and seven worker contributing scenarios (WCS). 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. TCE is delivered in 14 Safetainers once per year and these are connected/disconnected to the process one at the time when needed. TCE is used as a solvent for the removal and recovery of resin from dyed batik cloth in a de-waxing process. Most of the process is closed, but some inhalation and dermal exposure occurs, with the highest values when the workers handle the cloth prior to washing and following malfunction and maintenance. The environmental release and the exposure to man via the environment is addressed. The 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}.

There is a further exposure scenario (ES 3) for the service life for consumers but resulting exposure is considered to be negligible as the content of TCE in the fabric that is produced is below the detection limit (the detection limit is 0.081 mg TCE/kg dry cloth).

Exposure scenarios

Exposure scenario 1: "Use at industrial site – The use of TCE as a solvent for the removal and recovery of resin from dyed cloth (Scenarios for workers and the environment)"

The applicant described the following steps for exposure scenario 1 (ES1):

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: Activities outside the cloth de-waxing unit (PROC 1)
WCS3: Activities inside the cloth de-waxing unit during malfunction (PROC 8a)
WCS4: Maintenance activities of the cloth de-waxing unit (PROC 8a)
WCS5: Washing of cloth (PROC 8b)
WCS6: Recovery of resin originating from de-waxing step (PROC 1)
WCS7: Water and air treatment (PROC 1)

Exposure scenario 3: "Service life (consumers) – Exposure to clothes made with Vlisco textile"

The applicant described the following steps for exposure scenario 3 (ES3):

ECS1: Service life (consumers) (ERC 10a, ERC 11a)

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

CCS[3] 1: Exposure to clothes (AC5)

Information on worker exposure (for ES 1)*:* 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 seven 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, 5, 6, and 7. Personal measurements were carried out in an intensive personal monitoring programme in Q4 2013 and Q1 and Q2 2014 outside the de-waxing unit (WCS 2 and WCS 5), inside the wax-recovery unit (WCS 6 and WCS 7) and for office workers. Hand-held (mobile) measurements of TCE in air were performed for WCS3 and WCS4 to verify the air concentration values before entering the de-waxing unit in case of malfunction or maintenance.

Modelled data have also been submitted by the applicant. For inhalation exposure ECETOC TRA v3 was used for WCS1, WCS6 and WCS7 and the higher tier model ART 1.5 was applied for WCS2, WCS3 and WCS4. For dermal exposure ECETOC TRA v3 was used for all seven 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 WCS 2, 3 and 4 the higher tier model ART 1.5 was used and modelled exposure data from these WCSs were significant higher than the measured exposure. When ECETOC TRA v3 was used as the model (WCS 6 and 7) 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 WCS 1, 3, and 4, with gloves used in WCS1 and WCS4; both gloves and overalls are used for WCS3. Respiratory protection equipment (RPE) is included for WCS3 and 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.

The effectiveness of local exhaust ventilation in reducing dermal exposure was assumed to be 90 % in WCSs 3 and 4, - a value suggested by ECETOC TRA v3. RAC considers that given the volatility of TCE and in combination with the training and appropriate maintenance of the equipment, the type of RMM specified in the ES 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

[3] 'CCS' denotes consumer contributing scenario in the applicant's CSR

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 linked to an excess risk of kidney cancer of 4:100 000. Therefore Vlisco will select 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 of man via the environment:
The exposure of man via the environment (inhalation and oral) was modelled with EUSES. Additionally, for inhalation exposure, an air dispersion model Geomilieu v2.4 was used 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.

Service life - environmental contributing scenario 1
For the ES3: Service life (consumers) - The potential for exposure to the environment is considered by the applicant to be negligible, as TCE cannot be detected in the cloth (detection limit 0.081 mg TCE/kg dry cloth). Nevertheless, environmental exposure to TCE from clothes made with Vlisco textiles was modelled by EUSES. The modelled exposure to the environment related to the service life resulted in an estimated risk for kidney cancer of 3.0E-8% (i.e. $3x10^{-10}$). Since the potential for exposure from this source is considered to be extremely low, this exposure is thus not considered further in the SEA by the applicant.

Service life - consumer contributing scenario 1
The potential for consumer exposure is considered by the applicant to be negligible since TCE in the cloth cannot be detected (detection limit 0.081 mg TCE/kg dry cloth). Still for the consumer exposure to TCE from clothes made by Vlisco textiles the exposure was modelled by the use of Ecetoc TRA Consumer v3. This resulted in a cancer risk of 5.9E-6% (i.e. 5.9×10^{-8}). Since the potential for exposure from this source is considered to be extremely low, this exposure is thus not considered further in the SEA by the applicant.

Exposure estimated by applicant

Inhalation exposure for workers:
According to information in the CSR and additional information received from the applicant, the workers are divided into three groups: Production staff de-waxing (15), the non-production staff de-waxing (maintenance) (20) and production staff resin recovery (20). The applicant combined daily and weekly exposure of the most representative tasks.

Process operators in de-waxing unit:
The applicant used the most relevant, representative and recent personal monitoring information for the daily TCE exposure of 2.66 mg/m^3 (WCS2). For the weekly maintenance activities the applicant used the measured value of 0.165 mg/m^3, adjusted for the duration and frequency of the activity (WCS4). The combined exposure would be 2.825 mg/m^3.

Maintenance staff in de-waxing unit:
The applicant combined the exposure from activities inside the cloth de-waxing unit during malfunction (WCS3) with regular maintenance activities (WCS4) measured and adjusted for use of RPE and duration and frequency of the task to be 0.125 and 0.165

mg/m^3, respectively, resulting in the combined exposure value of 0.29 mg/m^3.

Process operators in the resin recovery unit

This activity is applicable to both Use 1 and Use 2. In the CSR the applicant included the daily inhalation exposure from this activity in Use 1 (WCS6) and the daily and weekly activity following inhalation exposure in Use 2 (WCS2). As a consequence, for the assessment of combined exposure there is an overlap between Use 1 and Use 2. The applicant used measured daily inhalation exposure of 1.485 mg/m^3 for Use 1. The weekly inhalation exposure is covered in Use 2, and was 1.6 mg/m^3 estimated by ART 1.5. This results in a combined exposure value of 3.085 mg/m^3 and is used in Use 2.

Dermal exposure for workers:

As described above, in the CSR the workers are divided into three groups: Process operators in de-waxing unit (15), maintenance staff in de-waxing unit (25) and production staff resin recovery (20). The applicant combined daily and weekly exposure of the most representative tasks.

Process operators in de-waxing unit:

The applicant used the most relevant estimated dermal exposure for the daily TCE exposure of 0.034 mg/kg bw/day (WCS2). For the weekly maintenance activities the applicant used the estimated exposure of 0.041 mg/kg bw/day (WCS4). Resulting total daily exposure is 0.075 mg/kg bw/day.

Maintenance staff in de-waxing unit:

The applicant combined the modelled exposure from activities inside the cloth de-waxing unit during malfunction (WCS3) with regular maintenance activities (WCS4), 0.007 and 0.041 mg/kg bw/day, respectively. Resulting total daily exposure is 0.048 mg/kg bw/day

Process operators in the resin recovery unit:

This activity is applicable to both Use 1 and Use 2. In the CSR the applicant included the daily dermal exposure from this activity in Use 1 (WCS6) and the daily and weekly activity following dermal exposure in Use 2 (WCS2). As a consequence, for the assessment of combined exposure there is an overlap between Use 1 and Use 2. The applicant used estimated daily dermal exposure of 0.034 mg/kg bw/day. The weekly dermal exposure is covered by the applicant in Use 2 and was 0.137 mg/kg bw/day estimated by ECETOC TRA V3 resulting in a combined exposure value of 0.171 mg/kg bw/day.

In the SEA the excess kidney cancer risk was calculated for both inhalation and dermal exposure, for the shift (combined WCSs) exposure value.

Table 1: Worker combined exposure for Use 1

Worker activity	**Combined exposure inhalation mg/m^3**	**Combined exposure dermal mg/kg bw/day**
Process operators in de-waxing unit	2.825	0.075
Maintenance staff in de-waxing unit	0.29	0.048
Process operators in the resin recovery unit:	3.085* 1.485 (daily)	0.171* 0.034 (daily)

*Combined exposure included for Use 2, only daily exposure included for Use 1.

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

Indirect exposure of man via the environment:
The inhalation exposure was estimated using 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 and the number of potentially exposed persons is also presented in the 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:

- Risk to workers at Vlisco resulting from exposure to TCE by inhalation and dermal contact, and
- 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/m^3 (6 ppm) with an excess kidney cancer risk in EU workers at 4.0 x 10^{-4}.

For inhalation exposure the excess risk at 33 mg/m^3 and above is **1.3 x 10^{-4} per mg**

TCE/m^3 – 0.0039, and below 33 mg/m^3 the excess risk is **1.2 x 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 x 10^{-4} per mg TCE/kg bw/day – 0.0039** and below 4.72 mg/kg bw/day **8.4 x 10^{-5} per mg TCE/kg bw/day** (based on 8h exposure 5 days/week during 40 years).

Process operators in de-waxing unit:

Based on the exposure data described above the excess kidney cancer risk for daily activities via inhalation is 2.66 mg/m^3 x 1.2 x 10^{-5} per mg TCE/m^3 = 3.2 x 10^{-5} and for weekly activities d 0.165 mg/m^3 x 1.2 x 10^{-5} per mg TCE/m^3 = 2.0 x 10^{-6} . Via dermal exposure the excess kidney cancer risk for daily activities is 0.034 mg/kg bw/day x 8.4 x 10^{-5} per mg TCE/kg bw/day = 2.9 x 10^{-6} and for weekly activities 0.041 x 8.4 x 10^{-5} per mg TCE/kg bw/day = 3.4 x 10^{-6} . For weekly combined (inhalation and dermal) activities the excess risk is recalculated to be 1.1 x 10^{-6} to take into account that the activity only takes place 1 day/week

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

- *Combined exposure for process operator in the de-waxing unit:*

  There are in total 15 process operators divided into 5 teams of 3 operators. The calculated excess kidney cancer risk for daily and weekly activities and for combined exposure (inhalation and dermal) for these operators is 3.5 x 10^{-5} (daily) + 1.1 x 10^{-6} (weekly) = **3.6 x 10^{-5}**.

Maintenance staff in de-waxing unit:

Base on the exposure data described above the excess kidney cancer risk via inhalation for malfunctions is 0.125 mg/m^3 x 1.2 x 10^{-5} per mg TCE/m^3 = 1.5 x 10^{-6} for weekly activities. For malfunction the excess kidney cancer risk for dermal exposure is 0.007 mg/kg bw/day x 8.4 x 10^{-5} per mg TCE/kg bw/day = 5.9 x 10^{-7}.

For maintenance the excess kidney cancer risk for inhalation exposure is 0.165 mg/m^3 x 1.2 x 10^{-5} per mg TCE/m^3 = 2.0 x 10^{-6}. For maintenance the excess kidney cancer risk for dermal exposure is 0.041 mg/kg bw/day x 8.4 x 10^{-5} per mg TCE/kg bw/day = 3.4 x 10^{-6}. For weekly combined (inhalation and dermal) activities the excess risk is recalculated to be 4.2 x 10^{-7} for malfunction and 1.1 x 10^{-6} for maintenance to take into account that the activity only takes place 1day/week.

- *Combined exposure for maintenance staff in the de-waxing unit:*

  There are in total 25 maintenance staff operators that perform weekly activities related to de-waxing of cloth (during malfunctions and maintenance). The calculated excess kidney cancer risk for weekly combined (inhalation and dermal) exposure is 4.2 x 10^{-7} + 1.1 x 10^{-6} = **1.52 x 10^{-6}**.

  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 x 1.2 x 10^{-5} per mg TCE/m^3 = 1.78 x 10^{-5} and via daily dermal exposure 0.034 mg/kg bw/day x 8.4 x 10^{-5} per mg TCE/kg bw/day = 2.86 x 10^{-6}. Only the daily activities are covered in Use 1. For Use 2 both the daily and weekly activities are included. For weekly activities the excess kidney cancer risk from inhalation exposure is 1.6 mg/m^3 x 1.2 x 10^{-5} per mg TCE/m^3 = 1.92 x 10^{-5} and for dermal exposure 0.137 mg/kg bw/day x 8.4 x 10^{-5} = 1.1 x 10^{-5}.

- *Combined exposure for process operator in the resin recovery unit:*

There are in total 20 process operators divided into 5 teams of 4 operators that perform daily and/or weekly activities.

The excess kidney cancer risk for daily combined (inhalation and dermal) activities related to resin recovery is $1.78 \times 10^{-5} + 2.86 \times 10^{-6} = 2.07 \times 10^{-5}$. Only the daily activities are covered in Use 1. For Use 2 both the daily and weekly activities are included. The excess kidney cancer risk for weekly combined (inhalation and dermal) maintenance activities related to malfunction in the resin recovery unit is 3.07×10^{-5}. When recalculated to daily exposure taking into account that this takes place 1 day/week the excess kidney cancer risk is 6.1×10^{-6} and is considered representative for weekly and daily activities.

The calculated excess kidney cancer risk for daily and weekly activities and for combined exposure (inhalation and dermal) for these operators is 2.07×10^{-5} (daily) + 6.1×10^{-6} (weekly) = **2.68×10^{-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 is included in Use 1. 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). As a consequence, for the assessment of combined exposure there is an overlap between Use 1 and Use 2. For this activity the estimated excess cancer statistical cases is included for both daily and weekly activities. 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 de-waxing unit (15)	**Maintenance staff in de-waxing unit (25)**	**Process operators in the resin recovery unit (20)**
Calculated # kidney cancer	0.000538	0.0000376	0.000536

The activity presented in WCS1 is not taken into account since the task is of a very short duration and is performed only few times per year: the exposure related to this activity is minimal and is considered not to affect the combined exposure for the workers.

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)..

The use of hand held mobile devices to verify the TCE concentration in air before entering the closed de-waxing unit for maintenance and malfunction reduce the possibility for potentially high TCE exposure in the closed de-waxing unit.

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

In addition, the company as documented in the application is making efforts to minimise the exposure of workers from all sources of emissions. For example, during the measurement campaign in 2013-2014 a TCE emission was identified from the de-waxed cloth leaving the de-waxing unit. The cloth was shown to contain low concentrations of TCE which evaporated before entering the second washing step. Since this TCE emission was identified, the installation of LEV with integrated air treatment has been approved for implementation as soon as possible i.e. 2015.

Indirect exposure to 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 shows 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 removing/dissolving excess resin from cloth which leads to a reduction in overall dewaxing capacity of the Helmond site. Additionally, the higher boiling point leads to significantly higher concentrations of PERC in the cloth and wastewater – if the same process conditions as for TCE are used - and renders the separation of the resin from the solvent more difficult – which in turn leads to a lower re-usability of this shielding agent. As a whole, these technical differences have as a consequence that a major redesign of the plant would be necessary (investment costs). For example, the lower solvation efficiency of PERC would necessitate the installation of additional dewaxing equipment which would in turn force the applicant to hire extra operators (higher operation costs).

Most important for the assessment of the economic feasibility would however be the downtime costs. Implementation of PERC in Vlisco's process would necessitate 4 years. Since PERC is also part of the SEA's non-use scenario the applicant has already started with pre-engineering to minimize these costs. The plant would still need to shut down for roughly 2.5 yrs during which costs in excess of the yearly sales revenue would be incurred.
SEAC calls into question the use of sales revenue in the calculation of the downtime costs, but the SEA provides us with better estimations (lost value added). Further to this, the basic assumptions are sufficiently conservative to state with confidence that economically this alternative is not feasible.

Toluene was also considered as a possible "drop-in" alternative for TCE but shows much of the same technical disadvantages as PERC, but adding flammability to the mix. The applicant would therefore have to 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. Operational costs would be the same as for the PERC alternative.

The most important cost factor would however again be the downtime costs which have now been calculated partly based on lost profit. These costs exceed the yearly sales revenue significantly. 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. Mechanical removal of resin

If successful this would make the use of a solvent redundant for use 1. Full removal, either by mechanical force or ultrasonic waves, of the melted-in resin is impossible, however. According to the applicant, melting in the resin is a prerequisite to achieve the specific characteristics sought by Vlisco. By not doing this their product would become of an inferior quality and turn into a commodity product which is not economically sustainable. SEAC agrees that this alternative can be eliminated on grounds of technical feasibility alone and concurs with the applicant's conclusion on economic feasibility.

D. Direct printing techniques

Both Rotary Screen Printing (RSP) and Inkjet printing have been extensively investigated in the past by the applicant. Neither have been able to match or get close to the results (eg. unique patterns) arrived at with Vlisco's wax process. Less dyes (eg. no indigo) can be used, which result with a more limited colour range and less brilliant colours. Consequently, Vlisco's textiles will be reduced to a mere commodity product. Since the applicant would then be entering into direct competition with manufacturers in low-cost countries, they would need to reduce their margins significantly until production costs exceed the selling price. These losses add up to several times the yearly sales revenue of the company.

SEAC agrees that this alternative can be eliminated on grounds of technical feasibility alone and concurs with the applicant's conclusion on economic feasibility.

E (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 committee's 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?

Please describe:

Six potential alternatives are described, four 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 raise 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 will 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.

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

Mechanical removal of resin: The risk reduction has not been evaluated, but no solvent is used in these processes. However, it can be assumed that the risk in using these processes is lower compared to the use of TCE.

Alternative printing technique: These processes are largely solvent free and can be considered as presenting a reduced risk compared to the use of TCE.

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:
An important fact SEAC kept in mind during the socio-economic discussion is that the applicant operates in a niche market and sells premium textile products for the African market. It effectively has zero competition in this market segment (premium quality african prints).

Considering this, the choice of non-use scenario for use 1, switching from TCE to PERC, seems appropriate to SEAC. In this scenario they would most likely still be able to ensure that their products can be considered premium quality. As the AoA has shown, the transition to PERC would also prove less disruptive to Vlisco than if they were to use some of the other assessed alternatives.

In their SEA, the applicant identified several possible socio-economic impacts if authorisation would not be granted:

- Impacts for Vlisco
  Investment costs would be incurred since there are technical differences between TCE and PERC (see point 7.2) which necessitate a major redesign of the plant. Pre-implementation has already started 1.5 yrs before the sunset date. Investments already made before this date have been deducted from the reported costs.
  Increases in **operating costs** can also be expected because current levels of production would require extra personnel.
  The biggest cost would however be the **downtime costs** accumulated during the 2.5 yrs in which no wax products are produced. The lost value added during this period would exceed the yearly sales revenue of Vlisco. Especially noteworthy here is that these costs are conservative for several reasons. One of which is that the expected sales increase between now and the sunset date has not been taken into account. Furthermore, the applicant assumes that demand for their product will automatically return to pre-closure levels and that PERC production lines will be fully operational from

the outset.

- Impacts for upstream suppliers
  The applicant states that large suppliers within the EU would not be significantly affected by their reduced demand of raw materials. Local suppliers who are slightly more dependent on Vlisco (1-18% of total sales) would however need to reduce their production. In all cases the applicant assumes shutdowns among upstream suppliers to be unlikely given the volumes purchased.

- Other impacts
  The applicant claims no significant **social impacts** at the EU level are to be expected from the non-use scenario. Likewise, adoption of PERC would not lead to significant **macro-economic impacts** (niche player).
  Some short term unemployment at Vlisco and the local suppliers is to be expected. At Vlisco specifically, permanent staff would be retained during the 2 yrs of downtime, but underemployed. Temporary staff however, would be let go. When production using PERC is up and running extra personnel will be needed, relative to the current situation, to operate the extra machinery. These social impacts were not included as separate costs in the calculations, because the lost value added already takes this into account.
  Since there are no competitors in this market segment and hardly any customers within the EU, no effects concerning these actors were considered in the SEA.

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 €536 and €1 866 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 €7 745.
Using the same method, the excess risk was also calculated for the exposure to TCE (70 yr period) of the Helmond population. Best estimates for the benefits of non-authorisation lie somewhere between €16 602 and €57 777. Here as well, sensitivity analysis was performed and showed that benefits could be as high as €96 264.
Since it is not possible to distinguish the TCE emissions and related exposure between use 1 and 2 the benefits of both uses are presented here together.

A quantitative assessment of the risks to Vlisco workers from use of PERC could not be performed according to the applicant. They state that PERC exposure is directly linked to the de-waxing equipment of which engineering specifications are not yet available (see point 7.1). A comparison of hazard profiles has however been carried out by the applicant and sufficiently shows that PERC would probably not be a major improvement hazard- and riskwise (expected higher exposure).

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 (see earlier). 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 a 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

Remark: As stated by the applicant in the CSR, the installation of LEV (local exhaust ventilation) with integrated air treatment to further reduce the TCE exposure related to the rapid evaporation of TCE from the cloth leaving the dewaxing unit should be implemented as soon as possible, i.e. in 2015.

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)

WC n=7	Title	Route of exposure	Number of measurements or model applied	90th percentile	Mean/Median	Duration	Frequency	Persons/shift	PPE/RPE normally used in WCS	APF for applied PPE	Table no. in CSR
1	***Storage of TCE including connecting and disconnecting of containers via Safetainer system*** *(280 kg TCE/ container, 14 containers received per year)* *PROC 1*	**Inhal mg/m³**	Ecetoc TRA v3		0.005	*<15min*	*Containers received: 1/y*	*One container connected/disconnected at the time by a single worker (in all 4-8 workers within a year).*	*PPE, gloves (no RPE)*		*35*
		Dermal mg/kg bw/d	Ecetoc TRA v3. Use of gloves included in input parameters		1.74E-04 (240 cm^2)[1] 95% protection					*20*	

[1] One hand face

2	***Activities outside the cloth de-waxing unit PROC 1*** *Before the cloth enters the de-waxing unit, the operator sews two pieces of cloth together. Apart from the sewing the operator is present in the control room or performs activities related to "logistics" of uncontaminated cloth*	**Inhal mg/m³**	ART 1.5. RPE is not taken into account by ART	8		*<8h/d,*	*daily activity*	*15 process operators divided into 5 teams of 3 operators.*	*no RPE/PPE*	-	*9*
		Inhal mg/m³	20 personal monitoring	2.66	1.79						
		Dermal mg/kg bw/d	Ecetoc TRA v3		0.034 (240 cm^2) 95% protection						
3	***Activities inside the cloth de-waxing unit during malfunction PROC 8a***	**Inhal mg/m³**	ART 1.5. RPE is not taken into account by ART	500 adjusted to 5 (APF 100)		*<1h*	*16 times/ y, or worst case once/w eek*	*15 operators (1-2 per occasion) fix malfunctions, mainly cloth jamming inside the closed cloth de-waxing unit. TCE as such. In addition 15 maintenance*	*PPE incl. RPE*	100	*42*
		Inhal mg/m³	measured with hand-held device		100 adjusted to 0.125 (1h, APF 100)					100	

		Dermal mg/kg bw/d	Ecetoc TRA v3. Use of gloves included in input parameters		0.007 (960 cm^2) 95% protection			*operators (1 per occasion) perform weekly activities.*		20	
4	***Maintenance activities of the cloth de-waxing unit PROC 8b***	**Inhal mg/m^3**	ART 1.5 RPE is not taken into account by ART	53 adjusted to 0.53 APF 100		*<4h per occasion*	*weekly*	*2 operators per occasion (15 in total) perform maintenance activities within the closed de-waxing unit. In addition 15 maintenance operators that perform weekly activities.*	*RPE, gloves*	100	*45*
		Inhal mg/m^3	measured with hand-held device		33 adjusted to 0.165 (4h, APF 100)					100	
		Dermal mg/kg bw/d	Ecetoc TRA v3. Use of gloves included in input parameters		0.041 (960 cm^2) 95% protection					20	
5	***Washing of cloth PROC 8b*** ***concentration of TCE < 1 %***	**Inhal mg/m^3**	9 Personal measurements	18.43 adjusted to 2.30 (for time duration 1h) and to 0.230 with LEV	8.08	*<1h/d*	*daily*	*1 operator per shift (15 operators in total) is present near the washing machines located at the exit of the de-waxing unit.*	-	-	*49*
		Dermal	Ecetoc TRA v3		0.274 (960 cm^2)					-	

6	***Recovery of resin originating from de-waxing step PROC 1*** *The operator is present in the area of the resin recovery installation (closed system) 1h/day and the rest in the control room of the recovery installation.*	**Inhal mg/m³**	Ecetoc TRA v3		0.055	*1h/d (<8h)*	*daily*	*20 process operators divided into 5 teams of 4 operators, 1 operator per shift does the resin recovery.*	-	-	*52*
		Inhal mg/m³	8 Personal measurements	1.485	1.09					-	
		Dermal mg/kg bw/d	Ecetoc TRA v3		0.034 (240 cm^2)					-	
7	***Water and air treatment PROC 1*** *The operator (1/shift, 20 in total) is present in the air and water installation (closed system) 1 h/day and the rest in the control room. The water treatment installation*	**Inhal mg/m³**	Ecetoc TRA v3		0.055	*1h/d <8h (with other tasks)*	*daily*		-	-	*55*
		Inhal mg/m³	8 Personal measurements	1.485							

	indoor, the air installation outdoor.	**Dermal mg/kg bw/d**	Ecetoc TRA v3		0.034 (240 cm^2)						

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.