Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

bis(2-methoxyethyl) ether use: Use of bis(2-methoxyethyl) ether (diglyme) as a carrier solvent in the application of sodium naphthalide etchant for fluoropolymer surface modification whilst preserving article structural integrity (downstream user processes).

Submitting applicant

Acton Technologies Limited

ECHA/RAC/SEAC: AFA-O-0000006948-56-02/D

Consolidated version

Date: 22/04/2021

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 the following application for authorisation:

Applicant	**Acton Technologies Limited** (position in supply chain: for this use Acton is upstream)
Substance ID EC No CAS No	**bis(2-methoxyethyl) ether** 203-924-4 111-96-6
Intrinsic properties referred to in Annex XIV	☐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) - [effects to human health][and][effects to the environment]
Use title	**Use of bis(2-methoxyethyl) ether (diglyme) as a carrier solvent in the application of sodium naphthalide etchant for fluoropolymer surface modification whilst preserving article structural integrity (downstream user processes).**
	Other connected uses: Use ID 0217-01
	Same uses applied for: N/A
Use performed by	☐ Applicant ☒ Downstream Users of the applicant
Use ID (ECHA website)	0217-02
Reference number	11-2120852860-52-0002

RAC Rapporteur	SCHLÜTER Urs ROTHER Dag (advisor)
SEAC Rapporteur SEAC Co-rapporteur	LÜDEKE Andreas CASTELLI Stefano
ECHA Secretariat	LOGTMEIJER Christiaan UPHOFF Andreas KVATCHADZE Giorgi

PROCESS INFORMATION FOR ADOPTION OF THE OPINIONS

Date of submission of the application	19/06/2020
Date of payment, in accordance with Article 8 of Fee Regulation (EC) No 340/2008	10/08/2020
Application has been submitted by the Latest Application Date for the substance and applicant and their DUs can benefit from the transitional arrangements described in Article 58(1)(c)(ii).	☐Yes ☒No
Consultation on use, in accordance with Article 64(2): https://echa.europa.eu/applications-for-authorisation-previous-consultations	12/08/2020-07/10/2020
Comments received	☒Yes ☐No Link: https://echa.europa.eu/documents/10162/255c0a95-fbd2-b740-41da-d04cbafaa5cc
Request for additional information in accordance with Article 64(3)	On 16/09/2020 and on 16/11/2020 Link: https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/26011/del/200/col/synonymDynamicFieldId_302/type/asc/pre/2/view
Trialogue meeting	Not held –no need for additional information/discussion on any technical or scientific issues related to the application from the rapporteurs
Extension of the time limit set in Article 64(1) for the sending of the draft opinions to the applicant	☐Yes, by [date] ☒No

The application included all the necessary information specified in Article 62 that is relevant to the Committees' remit.	☒Yes ☐No Comment:
Date of agreement of the draft opinion in accordance with Article 64(4)(a) and (b)	RAC: 18/03/2021, agreed by consensus.
	SEAC: 17/03/2021, agreed by consensus.
Date of sending of the draft opinion to applicant	05/05/2021
Date of decision of the applicant not to comment on the draft opinion, in accordance with Article 64(5)	05/05/2021
Date of receipt of comments in accordance with Article 64(5),	Not relevant
Date of adoption of the opinion in accordance with Article 64(5)	RAC: 05/05/2021, adopted by consensus.
	SEAC: 05/05/2021, adopted by consensus.
Minority positions	RAC: ☒N/A
	SEAC: ☒N/A

THE OPINION OF RAC

RAC has formulated its opinion on:

- the risks arising from the use applied for,
- the appropriateness and effectiveness of the risk management measures described,
- taking into account the information submitted by interested third parties, as well as
- other available information.

RAC concluded that it was possible to determine a DNEL for the reprotoxic properties of the substance in accordance with Annex I of the REACH Regulation

SEAC concluded that currently there are no technically and economically feasible alternatives available for the applicant or their downstream users with the same function and similar level of performance. Therefore, RAC did not evaluate the potential risk of alternatives.

Previously, on 16/02/2016 Acton Technologies Limited submitted an application for authorisation including information as stipulated in Articles 62(4) and 62(5) of the REACH Regulation for similar uses as in this application for authorisation. RAC's conclusion (opinion of 13/22/2017) on that first application was that adequate control was not demonstrated for Acton's own use and for 2 of the 5 Downstream uses. In this second application, Acton reports on the changes made to the operational conditions and risk management measures at the applicant's own site as well at the Downstream users' sites.

RAC concluded that the risk assessment presented in this second application demonstrates adequate control of risks from the use applied for, provided that the operational conditions and risk management measures as described in the application are adhered to.

The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in exposure and emissions over the authorisation period. This information should also be included in the review report.

THE OPINION OF SEAC

SEAC has formulated its opinion on:

- the socio-economic factors and
- the suitability and availability of alternatives associated with the use of the substance as documented in the application, taking into account the information submitted by interested third parties, as well as
- other available information.

SEAC took note of RAC's conclusion that it is possible to determine a DNEL for the reprotoxic properties of the substance in accordance with Annex I of the REACH Regulation.

SEAC took note of RAC's conclusion that the risk(s) to human health from the use of the substance is demonstrated to be adequately controlled.

The following alternatives have been assessed:

Alternative substances considered:

- Sodium – Ammonia
- Alternative solvents (tetrahydrofuran, monoglyme, triglyme, tetraglyme, 1,4-dioxane, dipropylene glycol dimethyl ether, diethyl glyme)

Alternative technologies considered:

- Other Reductive Pre-Treatments Involving Radical Anions

- Electrochemical Treatments
- Plasma Treatment.

(See Section 4 of the Justifications).

SEAC concluded on the analysis of alternatives and the substitution plan that:

- By the date of submission of this application of this authorisation (20/08/2020) there are no alternatives available with the same function and similar level of performance that are safer and technically and/or economically feasible for the applicant or their downstream users.
- The substitution plan was credible and consistent with the analysis of alternatives and the socio-economic analysis.

SEAC concluded on the socio-economic analysis that:

- The expected socio-economic benefits of continued use are at least €2.2-22 million (over the 12-year assessment period) and additional benefits to society have been assessed qualitatively but have not been monetised. These additional benefits comprise, in particular, the availability of PTFE catheters.
- Risks to the environment of shortlisted alternatives have not been quantified. There may therefore be a risk arising due to the use of an alternative should the authorisation not be granted.

SEAC has no substantial reservations on the quantitative and qualitative elements of the applicant's assessment of the benefits and the risks to the environment associated with the continued use of the substance.

SEAC considered that if an authorisation was refused, the use of the substance could:

- cease altogether
- the use would be taken up by market actors operating outside the EU

SEAC considered that, if an authorisation was refused, it was likely that in the European Union:[1]

- up to 12 jobs would be permanently lost

PROPOSED CONDITIONS AND MONITORING ARRANGEMENTS, AND RECOMMENDATIONS

Additional conditions for the authorisation or monitoring arrangements for the authorisation are proposed. These are listed in sections 7 and 8 of the justification to this opinion.

Recommendations for the review report are made. Those are listed in section 9 of the justification to this opinion.

REVIEW PERIOD

Taking into account the information provided in the application for authorisation submitted by the applicant and the comments received on the broad information on use, a **12-year** review period is recommended for this use.

[1] Wherever reference is made to the European Union, this shall apply also to EEA countries.
* exact figure claimed confidential but known to SEAC

SUMMARY OF THE USE APPLIED FOR

Role of the applicant in the supply chain	Upstream ☐ [group of] manufacturer[s] ☐ [group of] importer[s] ☐ [group of] only representative[s] ☒ formulator Downstream ☐ [group of] downstream user[s]
Number and location of sites covered	Two Downstream user sites (name and location unknown)
Annual tonnage of Annex XIV substance used per site (or total for all sites)	DU1: < 10 tonnes per year, DU2: < 2.5 tonnes per year
Function of the Annex XIV substance	Solvent
Type of products (e.g. articles or mixtures) made with Annex XIV substance and their market sectors	DU 1: surface modification of PTFE tubing during manufacture of catheters DU 2: manufacturing of hoses with perfluoropolymer liners that are used in the automotive sector.
Shortlisted alternatives discussed in the application	Alternative substances considered: • Sodium – Ammonia • Alternative solvents (tetrahydrofuran, monoglyme, triglyme, tetraglyme, 1,4-dioxane, dipropylene glycol dimethyl ether, diethyl glyme) Alternative technologies considered: • Other Reductive Pre-Treatments Involving Radical Anions • Electrochemical Treatments • Plasma Treatment
Annex XIV substance present in concentrations above 0.1 % in the products (e.g. articles) made	☐Yes ☒No ☐Unclear ☐Not relevant
Number of workers exposed per site (or total for all sites)	Directly: DU1: 24, DU2: 1 Indirectly: -
Number of humans exposed via the environment	Local scale: not considered relevant by the applicant as adequate control demonstrated

	Regional scale: not considered relevant by the applicant as adequate control demonstrated
Releases to the environmental compartments	☒Air ☒Water ☐Soil ☐None
The applicant has used the DNEL recommended by RAC	☒Yes – RAC/33/2015/08 rev 1 Final: DNEL SETTING FOR REPROTOXIC PROPERTIES OF DIGLYME ☐No – [alternative values used] ☐Not relevant
All endpoints listed in Annex XIV were addressed in the assessment	☒Yes ☐No if 'No' – which endpoints are not addressed
All relevant routes of exposure were considered	☒Yes ☐No if 'No' – which routes are missing and what was the reason given
Adequate control demonstrated by applicant for the relevant endpoint	☒Yes ☐No ☐Not Applicable – non-threshold substance
Level of combined exposure/release used by applicant for risk characterisation	Workers: Inhalation: 0.505 mg/m³ * Dermal: 0.068 mg/kg bw/day * Humans via environment: Inhalation: 1.02 × 10^{-5} mg/m³ (DU1) 7.62 × 10^{-4} mg/m³ (DU2) Dermal: - Oral: 6.16 × 10^{-4} mg/kg bw/day (DU1) 5.21 × 10^{-3} mg/kg bw/day (DU2) Environment: Air: 1 000 kg/year Water: 65 kg/year Soil: -

Risk Characterisation	Workers: RCR = 0.585 (Max RCR for both DU's, achieved by: DU1 – Process worker 3) Humans via environment: 3.40E-05 mg/m³ (inhalation) 6.84E-03 mg/kgbw/day (oral)
Applicant is seeking authorisation for the period of time needed to finalise substitution ('*bridging application*')	☐Yes ☒No ☐Unclear
Review period argued for by the applicant (length)	12 years
Most likely Non-Use scenario	Closure of operations; potential relocation outside the EU (DU1) Closure of operations (DU2)
Applicant concludes that benefits of continued use outweigh the risks of continued use	☐Yes ☐No ☒Not Applicable – threshold substance with adequate control
Applicant's benefits of continued use	€1-10 million per year (annualised) €2.2-22 million (over review period)
Society's benefits of continued use	Not quantified, impacts on patients and health care expected in case of shortage in supply of PTFE-catheters over short-term.
Monetised health impact on workers	Applicant demonstrates adequate control, hence no health impact on workers
Distributional impacts if authorisation is not granted	Not applicable
Job loss impacts if authorisation is not granted	up to 12 jobs would be permanently lost in the European Union, evaluated at € 0.3-10.2 million

* This refers to the revised combined risk assessment for downstream user 1 - production worker 3 (DU1 - PW3)

SUMMARY OF RAC AND SEAC CONCLUSIONS[2]

1. Operational Conditions and Risk Management Measures

1.1. Conclusions of RAC

Conclusion for workers

DU1 and DU2 follow the hierarchy of control principle in controlling the risks for workers. This is achieved by use of containment, (automated etching lines in both cases, mechanized transfer system at DU2, enclosed booth with local exhaust ventilation (LEV) for tip etching operations at DU1, etc.) and LEV at the point of use for all etching operations. Additionally, administrative controls (training and supervision by an external Health and Safety professional service) are in place. Overall, minimisation of exposure potential has been demonstrated with the measurement data provided for DU1. As the situation described at DU2 is even more controlled (no open handling of FSS at all) this assumption is also plausible for DU2.

Are the OCs/RMMs in the Exposure Scenario appropriate and effective in limiting the risk?

☒Yes ☐No

Does RAC propose additional conditions related to the operational conditions and risk management measures for the authorisation?

☒Yes ☐No

Does RAC propose monitoring arrangements related to the operational conditions and risk management measures for the authorisation?

☒Yes ☐No

Does RAC make recommendations related to the operational conditions and risk management measures for the review report?

☐Yes ☒No

2. Exposure Assessment

Exposure level used by RAC for risk characterisation:

Workers: highest level of individual, shift-long exposure[3]

- Inhalation: 0.66 mg/m³

[2] The numbering of the sections below corresponds to the numbers of the relevant sections in the Justifications.
[3] For details on exposure levels see section 2 of the Justifications, exposure levels and numbers of workers exposed are presented in Table 9 in section 5

- Dermal: 0.069 mg/kg bw/day

Humans via environment

- Inhalation: 7.62 × 10^{-4} mg/m³
- Dermal: -
- Oral: 5.21 × 10^{-3} mg/kg bw/day

Releases to the environmental compartments

- Air: 1 t/year
- Water: 65 kg/year
- Soil:

Conclusions of RAC

The exposure assessment covers both DUs individually. In case of DU1 the exposure assessments are based on measurement data and modelled data for WCS's where no air monitoring data were taken (WCS 3 – tip etch process). Where worker air monitoring data is used, the approach taken seems correct, but the sampling time is relatively short (30 minutes for each measurement). The dermal measurements on the other hand are not judged to be robust, as the sampling strategy is not suited for volatile (and easily absorbed) substances such as diglyme. In case of DU2 the exposure assessment is based on modelling, as only one workplace measurement was carried out so far (in September 2020). The data set is too limited to allow a robust assessment and is therefore only used as support for the modelled data.

On **16/02/2016 Acton Technologies Limited** submitted an application for authorisation including information as stipulated in Articles 62(4) and 62(5) of the REACH Regulation for similar uses as in this application for authorisation. RAC's conclusion (opinion of 13/22/2017) on that first application was that adequate control was not demonstrated for Acton's own use and for 2 of the 5 Downstream uses. In this second application, Acton reports on the changes made to the operational conditions and risk management measures at the applicant's own site as well at the Downstream users' sites.

The situation as described in the first application was characterised by manual handling (especially for filling activities) and open or semi-closed processes. Only for a few WCSs engineering controls (semi-closed processes or LEV) were in place. Additional protection for workers was provided by personal protective equipment (RPE, gloves, protective clothing).

On request of RAC the applicant revised the dermal exposure assessment and parts of the inhalation modelling. The assumptions made for the modelling in the revised assessment seem plausible and uncertainties regarding the exposure estimates are deemed to be minor enough to not change the conclusion of RAC

Does RAC propose additional conditions[4] related to exposure assessment for the authorisation?

☐Yes ☒No

[4] Conditions can be proposed where RCR is >1, OCs and RMMs are not appropriate and effective, risk is not adequately controlled, minimisation of emissions is not demonstrated.

Does RAC propose monitoring arrangements[5] related to exposure assessment for the authorisation?

☒Yes ☐No

Does RAC make recommendations related to exposure assessment for the review report?

☒Yes ☐No

3. Risk Characterisation

RCR calculated by RAC:

Workers: Direct exposure: 0.585

Humans via environment: 0.06

Conclusions of RAC

Overall the risk characterisation is plausible and robust.

RAC concludes that:

- The highest calculated RCR for workers is 0.537 (WCS 3 – DU1 – tip etching).
- The highest calculated combined RCR for workers (both DU's) is 0.585 (for Production Worker 3 – DU1- cleaning and maintenance and general production area).
- There are no significant uncertainties to the characterisation of risks for this use.

RAC considers that the estimates of risks for workers and for indirect exposure of humans, via the environment, calculated by the applicant allow a health impact assessment and that adequate control of risks has been demonstrated.

4. Analysis of alternatives and substitution plan[6]

What is the amount of substance that the applicant uses per year for the use applied for?

DU1: less than 10 tonnes per year

DU2: less than 2.5 tonnes per year

Are there alternatives with the same function and similar level of performance that are technically and economically feasible to the applicant by the date of submission of this application (20 August 2020)?

[5] Monitoring arrangements can be recommended where RCR is < 1, OCs and RMMs are appropriate and effective, risk is adequately controlled, minimisation of emissions is demonstrated – but minor concerns were identified.

[6] The judgment of the ECJ Case T-837/16 Sweden v Commission stated that the applicant has to submit a substitution plan if alternatives are available in general. The Commission is currently preparing the criteria, derived from the judgment for establishing when an alternative is available in general. Once these are prepared this opinion format will be amended accordingly. The European Commission informed the REACH Committee in 9-10 July 2019 of its preliminary views on the criteria. In that note that Commission considered that the criteria defining a 'suitable alternative' would imply that it was i) *safer* and ii) *suitable*. Suitability would not mean it to be *"in abstracto"* or "*in laboratory or exceptional conditions*" but it should be "*technically and economically feasible in the EU*" and "*available, from the point of view of production capacities of the substance or feasibility of the technology, and legal and factual conditions for placing on the market*".

☐Yes ☒No

Has the applicant submitted a substitution plan?

☒Yes ☐No

If yes, is the substitution plan credible and consistent with the analysis of alternatives and the socio-economic analysis?

☒Yes ☐No

Conclusions of SEAC

By the Sunset date there are no alternatives available with the same function and similar level of performance that are safer and technically and/or economically feasible for the applicant. The substitution plan and the described substitution activities and R&D are credible.

Does SEAC propose any additional monitoring arrangements related to the assessment of alternatives for the authorisation?

☐Yes ☒No

Does SEAC make any recommendations to the applicant related to the content of the potential review report?

☐Yes ☒No

5. Benefits and risks of continued use

Has the applicant adequately assessed the benefits and the [monetised] risks of continued use?

Conclusions of SEAC:

☒Yes ☐No

SEAC has no substantial reservations on the quantitative and qualitative elements of the applicant's assessment of the benefits and the risks to the environment associated with the continued use of the substance. This conclusion is made on the basis of:

- the application for authorisation,
- SEAC's assessment of the benefits of continued use,
- any additional information provided by the applicant or its downstream users,
- RAC's assessment of the risks to the environment.

6. Proposed review period for the use

☐ 4 years

☐ 7 years

☒ 12 years

☐ Other – … years

7. Proposed additional conditions for the authorisation

RAC

Additional conditions:

For workers	☒Yes	☐No
For Humans via Environment	☐Yes	☒No
For consumers	☐Yes	☒No
For the environment	☐Yes	☒No

SEAC

Additional conditions:	☐Yes	☒No

8. Proposed monitoring arrangements for the authorisation

RAC

Monitoring arrangements:

For workers	☒Yes	☐No
For Humans via Environment	☒Yes	☐No

SEAC

Monitoring arrangements	☒Yes	☐No

9. Recommendations for the review report

RAC

For workers	☒Yes	☐No
For consumers	☐Yes	☒No

SEAC

AoA	☐Yes	☒No
SP	☐Yes	☒No
SEA	☐Yes	☒No

10. Applicant comments on the draft opinion

Has the applicant commented the draft opinion?

☐Yes ☒No

Have action been taken resulting from the analysis of the applicant's comments?

☐Yes ☐No ☐Not applicable

JUSTIFICATIONS

0. Short description of use

Diglyme is used as a carrier solvent in the formulation and use of sodium naphthalide etchant for fluoropolymer surface modification.

The Applicant (Acton Technologies limited) uses diglyme as a carrier solvent in the formulation and use of sodium naphthalide to produce an etchant (Fluoroetch® Safety Solvent (FSS)) for the surface modification of perfluoropolymers by reductive defluorination in order to increase the surface adhesion properties of such polymers. Diglyme provides sufficient solvation of the radical anion salt to promote this reductive defluorination. The scope of the application encompasses formulation and use, i.e. the production of Diglyme mixtures used by Acton in its own etching applications (on site etching processes). Acton also supplies the mixtures to two regular DUs; their use of Diglyme is covered by use number 2 of the same Application for Authorisation.

0.1. Description of the process in which Annex XIV substance is used

Table 1: Contributing Scenarios presented in the Use of diglyme as a carrier solvent in the formulation and use of FSS etchant for fluoropolymer surface modification (Downstream User processes)

Contributing scenario	ERC / PROC	Name of the contributing scenario
ECS1	ERC 4	Use of diglyme as a carrier solvent in the formulation and use of FSS etchant
WCS 1 (DU 1)	PROC 8b	Filling of etch bath
WCS 2 (DU 1)	PROC 1	Operation of continuous etch line
WCS 3 (DU 1)	RPCO 13	Operation of Tip Etch Process
WCS 4 (DU 1)	PROC 1	Background work
WCS 5 (DU 1)	PROC 8b	Cleaning and maintenance
WCS 1 (DU 2)	PROC 8b	Filling of etch bath
WCS 2 (DU 2)	PROC 1	Etching line (automated)

Downstream user 1

WCS 1: Filling of etch bath

FSS etchant is used as part of an integrated process to produce etched PTFE[7] tubing of various thicknesses and diameters. Prior to the operation of the etching line the FSS bath is filled to the desired level (as dictated in the in-house procedure) via pouring pre-heated FSS into the bath. LEV is present.

WCS 2: Operation of continuous etch line

Once the etch bath has been filled the steel lid of the etch bath is secured and then secured with an outer case. The etching process is a batch operation, with each batch lasting

[7] PTFE=polytetrafluoroethylene (CAS Number 9002-84-0)

approximately 2 hours.

WCS 3: Operation of Tip Etch Process

Ends of PTFE tubes are dipped into 300 ml of etch contained in a stainless steel cylindrical flask. The task takes place in an enclosed ventilated room (30 air changes per hour) that is segregated from the rest of the site. The work takes place under LEV and PPE is worn during this activity (RPE, gloves, apron, and coveralls). The addition of LEV into the ventilated room is a recent engineering improvement, which was installed to remove the need for the full-face respirator. Measurements to confirm the efficiency of the RMM are pending and until the efficiency of this RMM has been confirmed DU1 will use respiratory protection during this process. The tip etching process is an infrequent work-stream and only takes place rarely (frequency is known to RAC/SEAC but was claimed confidential)

WCS 4: Background production

This WCS relates to the background concentration of diglyme in the production area arising from fugitive emissions not using diglyme.

WCS 5: Cleaning and maintenance

Every two weeks the etch tank is drained and cleaned and the spent etchant is stored in appropriately marked, closed containers that are taken to the secured storage cabinet.

Downstream user 2

WCS 1: Filling / emptying of etch bath

The process is carried out in specifically engineered equipment in which the PTFE tubing is passed through a bath (4 litre capacity) containing FSS. The FSS is poured from the storage container into the etchant bath by mechanized bottle pouring. This WCS also accounts for the emptying of the etchant bath as part of the cleaning operation. The spent etchant is drained into bottles with a volume of 4 litres which are then sent for disposal and the empty etchant bath is then is cleaned with water, which is collected and disposed of as hazardous waste. This process is carried out by the same operator wearing PPE (Tyvek suit, gloves, RPE, and safety glasses), the duration of the process is less than 2 minutes.

WCS 2: Etching line (automated)

Once filled, the FSS in the bath is warmed to operational temperature and the PTFE tube is passed through the bath at a controlled rate. Once the PTFE has been etched, it is passed through a wash bath containing wash solvent, through a "sponge" at the end of the bath that removes any solid residues from the treatment of the PTFE surface, and then washed with water and dried with an air knife. The continuous etching process operates for up to three hours, during which there is no manual operator intervention. The continuous etchant and wash baths are a specifically engineered enclosed system which itself is housed within a ventilated containment system.

0.2. Key functions and properties provided by the Annex XIV substance

Fluoropolymers are a group of polymers that possess unique physico-chemical properties (excellent chemical ultra-violet radiation resistance, high temperature resistance, good insulating properties, stability to weathering, low surface energy, low coefficients of friction and low dielectric constant).

However, as a consequence of the stability of the carbon-fluorine covalent bonding and the unique intra and intermolecular interactions within the polymer matrix it is extremely difficult to achieve any adhesion to fully fluorinated polymers.

Therefore, in some applications where there is a technical application requirement to achieve adhesion to the polymer surface there is a requirement to modify the surface of fluoropolymers to achieve adhesion to the polymer surface. This is done by reactive wet chemical treatment systems in which diglyme has become the primary solvent of choice for wet chemical etchants

Diglyme is used as a solvent for sodium naphthalide to produce an etchant for fluoropolymer surface modification. Naphthalene is reacted with sodium metal, which is used for the efficient reduction of fluoropolymer surfaces. Diglyme is a good solvent for sodium naphthalide while not being affected by this very reactive reduction agent under the operational conditions.

0.3. Type(s) of product(s) made with Annex XIV substance and market sector(s) likely to be affected by the authorisation

DU1 uses FSS in the production of medical devices, such as catheters.

DU2 uses FSS for the surface modification of PTFE tubing.

1. Operational Conditions and Risk Management Measures

1.1. Workers

The applicant (Acton Technologies LTD) confirms in their application that both downstream users identified in the CSR of the application for authorisation follow the hierarchy of control principles. DU1 follows the hierarchy of controls with segregation of the site into specific work areas; containment and LEV in operation; standard operating procedures in place to minimise worker exposure; and all workers being required to wear the PPE as specified in the on-site training manuals and risk assessments. DU2 follows the hierarchy of controls with containment and LEV in operation; standard operating procedures in place to minimise worker exposure; and all workers being required to wear the PPE as specified in the on-site training manuals and risk assessments.

Table 2: Operational Conditions and Risk Management Measures (sub-set of Succinct Summary of RMMs and OCs)

Contributing scenario	Concentration of the substance*	Duration and frequency of exposure	Engineering controls (e.g. containment, segregation, automation, LEV)+	PPE (RPE and Skin protection used) + effectiveness as stated by the applicant	Organisational controls (access control, procedures, training)

			effectiveness as stated by the applicant		
WCS 1 – DU1 Filling of etch bath PROC: 8b	90 %	20 seconds per batch; 3 batches per shift	Prior to the operation of the etching line the FSS bath is filled to the desired level (as dictated in the in-house procedure) via pouring pre-heated FSS into the bath. LEV in place Basic general ventilation (1-3 air changes per hour)	Dermal Protection: (a combination of LLDPE liner under chemical resistant butyl rubber glove gloves conforming to EN374 with a breakthrough time > 480 mins and with specific activity training)	The hierarchy of control is used Acton provides DU with a Declaration of Conformity (DoC) and Safety Data Sheet.
WCS 2 – DU1 Operation of continuous etch line PROC: 1	90 %	3 batches per shift; approx. 2 hours per batch	Closed system (minimal contact during routine operations) Primary and Secondary containment LEV in place	Dermal Protection: (a combination of LLDPE liner under chemical resistant butyl rubber glove gloves conforming to EN374 with a breakthrough time > 480 mins and with specific activity training)	The hierarchy of control is used Acton provides DU with a Declaration of Conformity (DoC) and Safety Data Sheet.
WCS 3 – DU1 Operation of Tip Etch Process PROC: 13	90 %	10-16 hours per batch; batch split over 2 days. One worker will therefore operate this task for approx. 8 hours.	Enhanced general ventilation (30 air changes per hour) LEV in place	Dermal Protection: (a combination of LLDPE liner under chemical resistant butyl rubber glove gloves conforming to EN374 with a breakthrough time > 480 mins and with specific activity training) RPE (APF 20)	The hierarchy of control is used Acton provides DU with a Declaration of Conformity (DoC) and Safety Data Sheet.
WCS 4 – DU1 Background work PROC: 1		< 8 hours	Other production activities (not using diglyme)	Dermal Protection: (a combination of LLDPE liner under chemical resistant butyl rubber glove gloves conforming to EN374 with a	The hierarchy of control is used Acton provides DU with a Declaration of Conformity (DoC) and Safety Data Sheet.

				breakthrough time > 480 mins and with specific activity training)	
WCS 5 – DU1 Cleaning and maintenance PROC: 8b	90 %	< 15 minutes		Dermal Protection: (a combination of LLDPE liner under chemical resistant butyl rubber glove gloves conforming to EN374 with a breakthrough time > 480 mins and with specific activity training)	The hierarchy of control is used Acton provides DU with a Declaration of Conformity (DoC) and Safety Data Sheet.
WCS 1 – DU2 Filling of etch bath PROC: 8b	90 %	2 minutes	Prior to the operation of the etching line the FSS bath is filled to the desired level (as dictated in the in-house procedure) via pouring pre-heated FSS into the bath. Pour carried out via equipment that limits dermal contact LEV in place Basic general ventilation (1-3 air changes per hour)	Dermal Protection: (a combination of LLDPE liner under chemical resistant butyl rubber glove gloves conforming to EN374 with a breakthrough time > 480 mins and with specific activity training) Full face mask with ABEK1 filter (protection factor 20)	The hierarchy of control is used Acton provides DU with a Declaration of Conformity (DoC) and Safety Data Sheet.
WCS 2 – DU1 Operation of continuous etch line PROC: 1	90 %	3 hours	Closed system (minimal contact during routine operations)	N/A – closed system	The hierarchy of control is used Acton provides DU with a Declaration of Conformity (DoC) and Safety Data Sheet.

*If changing through the process

The applicant confirms that both DUs identified in the CSR follow the hierarchy of control when assessing the risk associated with the use of diglyme.

DU1 has the following engineering controls in place:

- Use of containment once the bath is filled the etching line is closed
- Use of LEV for all transfer and sampling operations

- Storage of FSS in closed and locked cabinets
- site segregation into specific work areas.

In September 2019 DU1 undertook a review of their engineering controls. The report proposed the following upgrades, which are all subject to a feasibility study:

- Enclosing the etch tanks and associated equipment in protective enclosures that will be maintained under negative pressure. Operations involving etchant-containing diglyme will be carried out inside the enclosure by an operator wearing appropriate personal protective equipment (PPE).
- Re-design of the etchant pouring process (WCS 2) in a manner that will reduce or preclude accidental contact.
- The tip etching process will be reviewed to determine feasibility of improving engineering controls. It is proposed that sealing the FSS bath in a secure enclosure which allows an operator to handle the non-etched portion of tubing.

Pouring of the etchant – WCS 2: Due to the COVID19 Pandemic, this project was deferred at the end of Quarter 1, 2020 until the reactivation in Quarter 3, 2020. DU 1 ordered the pump on 9th July and it is currently waiting installation. DU1 have set a target completion date of 31st December 2020 to install the pump transfer system.

Upon installation this WCS will provide the same controls as provided by WCS 2 and WCS 4 in Use 1. Namely that there will be no dermal contact and the transfer will be enclosed, thus limiting inhalation exposure.

Implementation of these additional risk management measures is expected to improve the situation in DU1 further.

The following Operational controls are in place at DU1:

- DU1 has signed the Declaration of Conformity (DoC).
- Acton provide DU 1 with a Safety Data Sheet.
- Exposure to diglyme is contained within the area of the site.
- There are written procedures for the specific tasks.
- Workers are trained for their specific work task. Only employees trained on that task can be assigned to a task.
- Risk assessment is carried out by an independent third party.

Personal Protective Equipment (PPE) use at DU1 includes:

- Chemical Resistant Gloves
- Chemical Resistant Apron
- 3M Full Face Respirator

DU2 follows the hierarchy of controls with containment and LEV in operation; standard operating procedures in place to minimise worker exposure; and all workers being required to wear the PPE as specified in the on-site training manuals and risk assessments.

Engineering Controls are in place which ensure that there is no manual operator intervention when handling FSS. The continuous etching line has a specifically engineered enclosed system which itself is housed within a containment system which provides local exhaust ventilation. All associated equipment/areas where Diglyme is handled directly are in protective enclosures separated from surrounding factory space.

Operational controls at DU2 include:

- DU 2 has signed the Declaration of Conformity (DoC) and returned this to Acton.
- Specific written operating instructions for the process.

- specific chemical risk assessments for the process; and in-house training.
- All operators are educated to university degree level in chemistry and are given specific training in the correct operation of the process, the inherent hazards of the chemicals used and the correct use of PPE.
- Housekeeping/cleaning procedures and practices are written and implemented to ensure that the surface contamination is minimized and not transferred.
- There is annual maintenance of the LEV.
- All spent etchant solutions and wash water contaminated with diglyme is sent to a licenced hazardous waste disposal contractor for disposal via incineration. All wash water is collected and disposed of as hazardous waste. There are no discharges of wastewater containing diglyme to sewer or natural water courses from DU2.

Personal Protective Equipment (PPE) at DU2 include:

Tyvek suit, chemical resistant gloves, RPE (Full face mask with ABEK1 filter (protection factor 20)) and safety glasses.

1.2. Environment/Humans via Environment

Operational Conditions and Risk Management Measures in place for control of emissions to:

Air

DU1 and DU2: Emissions from the air extraction system are vented into the atmosphere.

Water

DU1: The process water on site that may contain diglyme is separated from the wastewater stream. According to the applicant, any releases to the aquatic environment are essentially negligible.

DU2: All wash water is collected and disposed of as hazardous waste. According to the applicant, any releases to the aquatic environment are essentially negligible.

Soil

DU1 and DU2: No release to soil is expected.

Waste

DU1: No release to waste expected as all spent FSS etchant is returned to Acton for recovery and recycling.

DU2: All spent etchant solutions and wash water contaminated with diglyme is sent to a licenced hazardous waste disposal contractor for disposal via incineration.

Table 3: Environmental RMMs DU1 - summary

Compartment	RMM	Stated Effectiveness
Air – DU1	LEV and closed system for continuous etching	99.795 %
Water – DU1	No release to water	99 % (conservative estimate)
Soil – DU1	No release to soil	100 %
Air – DU2	LEV and closed system for continuous etching	0 % (worst case scenario)
Water – DU2	No release to water	100 %
Soil – DU2	No release to soil	100 %

The application for authorisation and review report need to cover only risks arising from the intrinsic hazardous properties specified in Annex XIV. In case of diglyme, the risk assessment is only related to human health (toxic for reproduction). The environmental contributing scenario (ECS) describes therefore only exposure of humans via the environment.

Release rates used for modelling at DU 1 are based on mass balances and air monitoring results for emissions into air. For emissions into water 1 % release is assumed as a conservative estimate (according to the applicant there is no release of diglyme to water or soil).

Release rates to the air at DU2 are based on mass balances and worst-case assumptions. According to the applicant there are no emissions into water or soil, as all spent FSS from wash water is collected and disposed as hazardous waste.

1.3. Discussion on OCs and RMMs and relevant shortcomings or uncertainties

DU1: According to the applicant most of the FFS is used in closed systems (continuous etch bath) and in case of open handling during tip etching, which is done on relatively small scales (small amounts of FSS are applied at once), LEV is present.

It should be noted that this "critical" situation (tip etching) is supposed to change as DU1 is planning to install a fully enclosed cabinet with integrated gloves (glove box) for tip etching operations. Assuming regular maintenance of the device and the use of gloves, the situation should improve significantly with regard to workers exposures. Exhaust air from LEVs is vented into the atmosphere and emissions to the atmosphere were monitored by VOC sampling at the stack. While the measurement data support the release-rate derived in the exposure assessment, the number of emission measurements is limited (4 from 2012 to 2015).

DU2: According to the applicant the use of FSS is limited to the automated etching in a closed system at DU2. The only semi-open handling is the transfer (filling/emptying) of FSS to the etching line by a mechanized transfer system with LEV present. All exhaust air is directed into the atmosphere and it is assumed for the assessment that all diglyme spent during the process is released as emissions to air. As this estimation is based on a worst-case scenario, i.e. 100 % release into the environment, it is likely that this assumption leads to overestimation of risk.

1.4. Conclusions on OCs and RMMs

DU1 and DU2 follow the hierarchy of control principles in controlling the risks for workers. This is achieved by use of containment (automated etching lines in both cases, mechanized transfer system at DU2, enclosed booth with LEV for tip etching operations at DU1, etc.) and LEV at point of use for all etching operations. Additionally, administrative controls (training and supervision by an external Health and Safety professional service) are in place. Overall, minimisation of exposure potential has been demonstrated with the measurement data provided for DU1.

As the situation described at DU2 is even more controlled (no open handling of FSS at all) this assumption that there is also minimization of exposure is also plausible for DU2. However, more uncertainties are identified for DU2, as no monitoring information is available that could confirm the effectiveness of the RMMs and OCs.

Overall conclusion

Are the operational conditions and risk management measures appropriate[8] and effective[9] in limiting the risk for workers, consumers, humans via environment and / or environment?

Workers	☒Yes	☐No	☐Not relevant
Consumers	☐Yes	☐No	☒Not relevant
Humans via Environment	☒Yes	☐No	☐Not relevant
Environment	☐Yes	☐No	☒Not relevant

Moderate concerns related to OCs and RMMs lead to additional conditions or monitoring arrangements for authorisation presented in section 7 and 8.

2. Exposure assessment

2.1. Inhalation exposure

Monitoring

For DU1 the exposure assessment is based on personal air monitoring data (N = 33). According to the CSR, workplace monitoring is carried out twice per year.

DU2 is to begin a monitoring programme including inhalation exposure measurements, which was planned to begin in June 2020. In the original application for authorisation no measurement data were provided. The applicant submitted additional measurement data for DU2 later in the process. However, as the data set only consists of one personal air monitoring sample it is too limited to allow a robust workplace assessment and is therefore used as support for the modelled estimates.

Modelling

In the initial CSR of the application for authorisation the applicant applied tier 1 modelling (ECETOC TRA Worker v3) to support the measurement data used for the exposure assessment. However, as some of the modelled results were lower than the measured exposures, RAC asked the applicant to revise parts of the exposure modelling by applying more conservative PROCs as input parameter for those worker contributing scenarios where the modelled values were lower than the measured ones. This was done by the applicant and higher tier estimates based on ART 1.5 were also given in the response to RAC's questions. There was no further shortcoming identified by RAC concerning the revised exposure estimations.

[8] 'Appropriateness' – relates to the following of the principles of the hierarchy of controls in application of RMMs and compliance with the relevant legislation.
[9] 'Effectiveness' – evaluation of the degree to which the RMM is successful in producing the desired effect – exposure / emissions reduction, taking into account for example proper installation, maintenance, procedures and relevant training provided.

2.2. Dermal exposure

Modelling

Dermal exposure modelling was done with ECETOC TRA Worker v3. In case of DU1 the modelled estimates were only used to support the dermal measurement data, as workplace monitoring included both, inhalation and dermal measurements. For DU2 only modelled estimates were given in the original application for authorisation as results of the planned monitoring campaign were not available at the time of drafting. The applicant submitted additional monitoring data for DU2 on request of RAC later in the process (one sample at the end of shift and one after end of work after washing).

However, in the opinion of RAC the chosen sampling method is not suited to be applied to volatile substances and the applicant revised the dermal exposure assessment accordingly using ECETOC TRA Worker v3 estimates instead.

As ECETOC TRA is a tier 1 tool, the results of the dermal estimates are subject to correspondingly large uncertainties, but the approach taken in the revised version seems plausible within the domain of the model.

Monitoring

In case of DU1 the dermal exposure assessment is based on dermal workplace measurements (N = 11) and two samples for DU2 that were submitted later in the process. In the opinion of RAC the chosen sampling method is not suited to be applied to volatile substances.

The method originated from a comparative study on different methods for assessment of hand exposure to a non-volatile solid (adopted from Fenske, R. A. et al. (1999)).[10] Diglyme on the other hand is both, known to absorb quickly into the skin (www.who.int/ipcs/publications/cicad/en/cicad41.pdf), as well as to evaporate relatively quickly as it is noted in the CSR of the application for authorisation. It is noted on page 35 of the CSR that diglyme will evaporate relatively quickly form a surface (e.g. protective glove) in comparison to the time in which a particular operation might be carried out.

However, the applicant argues that dermal exposure is controlled as far as the operations are run in closed systems. Therefore, a qualitative exposure assessment (supported by modelling) is sufficient to demonstrate adequate control of dermal exposure.

2.3. Biomonitoring

Biomonitoring was not carried out within the current assessment. However, in the opinion of RAC biomonitoring would be a viable option[11] (if not the only suitable one) to access the total exposure including the impact of dermal exposures in a robust way.

Table 4: Exposure – dermal and inhalation

Contributing scenario	Route of exposure	Method of assessment	Exposure value (8-h	Exposure value	Exposure value

[10] Fenske, R. A., Simcox, N. J., Camp, J. E., & Hines, C. J. (1999). Comparison of three methods for assessment of hand exposure to azinphos-methyl (Guthion) during apple thinning. Applied Occupational and Environmental Hygiene, 14(9), 618-623.

[11] Analytische Methoden Propylen- und Diethylenglykolether, Analysen in biol. Material, Bd. 2, Seite D 1, https://onlinelibrary.wiley.com/doi/pdf/10.1002/3527600418.bi10798d0018

			TWA)	corrected for PPE	corrected for PPE and frequency *
WCS 1 DU1 – Filling of etch bath	Inhalation	measurement	0.04 mg/m³	0.04 mg/m³	
	Dermal	modelling	3.45 × 10^{-3} mg/kg bw/day	3.45 × 10^{-3} mg/kg bw/day	
	Biomonitoring	N/A			
WCS 2 DU 1 – Operation of continuous etch line	Inhalation	measurement	0.04 mg/m³	0.04 mg/m³	
	Dermal	modelling	1.7 × 10^{-3} mg/kg bw/day	1.7 × 10^{-3} mg/kg bw/day	
	Biomonitoring	N/A			
WCS 3 DU1 – Operation of Tip Etch Process	Inhalation	modelling	0.419 mg/m³	0.419 mg/m³ #	
	Dermal	modelling	0.069 mg/kg bw/day	0.069 mg/kg bw/day	
WCS 4 DU1 – Background production	Inhalation	measurement	0.49 mg/m³	0.04 mg/m³	
	Dermal	modelling	0.034 mg/kg bw/day	0.034 mg/kg bw/day	
	Biomonitoring	N/A			
WCS 5 DU1 – Cleaning and maintenance	Inhalation	measurement	0.015 mg/m³	0.04 mg/m³	
	Dermal	modelling	0.034 mg/kg bw/day	0.034 mg/kg bw/day	
	Biomonitoring	N/A			
WCS 1 DU2 – Filling / emptying of etch bath	Inhalation	modelling [measurement]	0.035 mg/m³ [4.38 × 10^{-4} mg/m³]	0.035 mg/m³ [4.38 × 10^{-4} mg/m³]	
	Dermal	modelling	3.43 × 10^{-3} mg/kg bw/day	3.43 × 10^{-3} mg/kg bw/day	
	Biomonitoring	N/A			
WCS 2 DU 2 – Etching line (automated)	Inhalation	modelling [measurement]	0.66 mg/m³ [5.25 × 10^{-3} mg/m³]	0.66 mg/m³ [5.25 × 10^{-3} mg/m³] #	
	Dermal	modelling	2.07 × 10^{-3} mg/kg bw/day	2.07 × 10^{-3} mg/kg bw/day	
	Biomonitoring	N/A			

PPE included in the initial modelling

Table 5: Exposure data for downstream users, combined exposures

	WCS combined	Route of exposure	Exposure value (8-h TWA)
DU1	PW1: 1+2+4	inhalation	0.57 mg/m³
		dermal	0.039 mg/kg bw/day
	PW2: 3	inhalation	0.419 mg/m³
		dermal	0.069 mg/kg bw/day
	PW3: 4+5	inhalation	0.505 mg/m³
		dermal	0.068 mg/kg bw/day
DU2	1+2	inhalation	0.695 mg/m³

		dermal	5.5 × 10^{-3} mg/kg bw/day

Comparison of current data with the exposure values from the initial application for authorisation

In the first application for authorisation for use of diglyme submitted by Acton Technologies Ltd the applicant calculated combined exposure for overall five downstream users, taking into account two different types of production worker (PW1 and PW2) for DU1. The current application for authorisation only covers two DUs, but differentiates three PW in case of DU1. Exposure levels of the two application for authorisation are therefore not easily comparable. The following table shows the combined exposure values of the current application for authorisation (DU1-2, as in Table 9), the full comparison including a mapping between the DU's covered in this application for authorisation and in the previous application for authorisation can be found in Annex I:

Table 6: Exposure data for production workers, combined exposures

	First application for authorisation (2016)			**Current application for authorisation**		
	WCS combined	Route of exposure	Exposure value (8-h TWA)	WCS combined	Route of exposure	Exposure value (8-h TWA)
DU1	PW1: 1+2+4*	inhalation	0.612 mg/m³	PW1: 1+2+4**	inhalation	0.57 mg/m³
		dermal	0.010 mg/kg bw/day		dermal	0.039 mg/kg bw/day
	PW2: 3*	inhalation	0.084 mg/m³	PW2: 3**	inhalation	0.419 mg/m³
		dermal	0.69 mg/kg bw/day		dermal	0.069 mg/kg bw/day
				PW3: 4+5**	inhalation	0.505 mg/m³
					dermal	0.068 mg/kg bw/day
DU2	1+2*	inhalation	1.1 mg/m³	1+2**	inhalation [measurement]	0.695 mg/m³ [5.69 × 10^{-3} mg/m³]
		dermal	0.010 mg/kg bw/day		dermal	5.5 × 10^{-3} mg/kg bw/day
DU3	1+2*	inhalation	0.154 mg/m³			
		dermal	0.347 mg/kg bw/day			
DU4	1+2*	inhalation	0.07 mg/m³			
		dermal	1.03 mg/kg bw/day			
DU5	1*	inhalation	0.04 mg/m³			
		dermal	0.001 mg/kg bw/day			

* As assigned in first application for authorisation
** As assigned in the current application for authorisation

Comparison of the exposure values for all combined DU scenarios of the current application for authorisation with the values in first application for authorisation show a significant reduction of dermal exposures for all scenarios (c.f. Annex I exposure data for downstream users compared with previous application).

2.4. Environmental emissions.

Water

At DU1 the assessment is based on a conservative assumption that 1 % of diglyme is released into water. According to the CSR all process water that may contain diglyme is collected and releases to the aquatic environment are therefore negligible.

At DU2 all wash water is collected and disposed of as hazardous waste. According to the applicant there are no discharges of wastewater containing diglyme to sewer or natural water courses from DU2.

Air

DU 1 employed a consultant to monitor environmental emissions and release rates to the air were measured.

DU2 is to begin a monitoring program including emissions to the atmosphere. As this program has not started until the drafting the application for authorisation a worst-case scenario modelling in CHESAR2 has been applied.

Soil

There is no release of diglyme to soil expected at DU1 and DU2 and was therefore not taken into account for the assessment.

Table 7: Summary of environmental emissions

Release route	Release factor	Release per year (tonnes or kilograms)	Release estimation method and details
Water	DU1: 1 % DU2: 0 %	DU1: 3.25 kg/day (< 100kg/year) DU2: 0 kg	DU1: Conservative estimate of 1 % release to water. DU2: No release to water.
Air	DU1: 0.205 % DU2: 100 %	DU1: 0.665 kg/day (133 kg/year) DU2: < 50 kg/day (2.5 tonne/year)	DU1: Measured release of Diglyme (90th percentile monitoring results). DU2: worst case scenario.
Soil	DU1 + DU2: 0 %	0 kg	DU1 + DU2: No release to soil.

Table 8: Summary of indirect exposure to the environment[12] and humans via the environment

Parameter	Local	Regional
PEC in air (mg/m^3)	DU1: 1.02 × 10^{-5} mg/m³ DU2: 7.62 × 10^{-4} mg/m³	Not applicable
PEC in surface water (mg/L)	Not applicable	Not applicable
Daily dose via oral route (mg/kg bw/d)	DU1: 6.16 × 10^{-4} mg/kg bw/day DU2: 5.21 × 10^{-3} mg/kg	Not applicable

[12] PECs other than those included in the table may be added, where relevant.

	bw/day	

2.5. Discussion of the information provided and any relevant shortcomings or uncertainties related to exposure assessment

Workers exposure

DU1: In case of DU1 the workers exposure assessment is based on measurement data, both for inhalation and dermal exposures. An external consultant carries out workplace monitoring twice a year. The air monitoring data used for the exposure assessment (32 personal and 1 static measurement) covers the period from 2018 to 2019. Out of these, 10 measurements were carried out on workers involved in the etching process and 22 on those who did not directly carry out etching processes. The sampling time of the air measurements was given as 30 minutes, which RAC considers to be to be relatively short, especially for activities with long durations (e.g. tip etching) that are carried out for (almost) a full shift. In addition, the applicant used modelling data (ECETOC TRA Worker v3) to support the measurement results for each WCS. On request of RAC the applicant refined the initial exposure estimates based on modelling for those WCSs attributed to PROC 1 by using higher tier modelling (ART 1.5). The chosen input parameters and underlying assumptions for the modelling seem plausible. 90th-percentile values of the ART estimates were chosen for comparison with the measurement data.

For assessment of dermal exposure, the applicant applied a monitoring methodology originally applied to a non-volatile solid. In addition to being volatile, diglyme has a high dermal absorption. In the opinion of RAC the method applied by the applicant is therefore not suited for measuring dermal exposure to diglyme. Out of 11 dermal measurement data presented in the CSR, in only one case diglyme was found to be present (> LOD) and could be measured (Tip Etch Operator Glove Off). In the opinion of RAC, biomonitoring would be a much better way to assess the total exposure of workers and could be effectively used to demonstrate control of both, inhalation and dermal exposure in a quantitative way.

DU2: In case of DU2 a monitoring programme started in September 2020. At the time of submission of the application for authorisation no monitoring data were provided for DU2. The first exposure assessment therefore was based on modelling. Initially the applicant used ECETOC TRA Worker v3 to estimate the exposure levels but on request of RAC refined the estimate the WCS attributed to PROC 1 (Etching line (automated)) by using higher tier modelling (ART 1.5). The chosen input parameters and underlying assumptions for the modelling seem plausible. 90th-percentile values of the ART estimates were chosen for comparison with the measurement data. Later in the process the applicant submitted results from a measurement campaign carried out on 03/09/2020 on the one worker who had the potential to be exposed to diglyme at DU2. However, with only one workplace measurement this data set is considered too limited to allow a robust workplace assessment and is therefore used as support for the modelled estimates.

For dermal exposures the modelled estimates are based on ECETO TRA Worker v3. As the working environment is described to follow the hierarchy of controls by applying closed systems with no manual operator intervention when handling diglyme, it is plausible to assume that the given estimates are sufficiently conservative. In addition to the modelled data also dermal measurement data were submitted later (one sample of the workers right hand at end of shift and one after work after washing). As the measurement is based on the same method as for DU1 the same limitations apply. Also with only two measurements, the dataset is

considered to be too limited to allow a robust, i.e. representative assessment.

Humans via the environment

DU1: In case of DU1 the assessment of the environmental air concentrations is based on mass balances and air monitoring data. For the release to water a conservative approach has been taken by assuming 1 % release to water. According to the applicant the actual release is much lower.

DU2: The assessment of the release to air is based on the worst-case assumption that all diglyme used is released to air. It is most likely that this is a high overestimation of actual releases considering similarities in RMMs (closed systems, LEV) between DU1 and DU2 for the etch lines in place. However, the applicant is still able to demonstrate adequate control also based on the worst-case scenario. No measurement data to support the exposure assessment to air has been provided. No release to water is assumed as all wash water potentially containing diglyme is collected and disposed of as hazardous waste.

For both DUs the exposure estimates have been obtained with EUSES 2.1.2 and the assumptions made seem plausible or highly conservative so that actual exposures are supposed to be lower than the estimated ones.

2.6. Conclusions on exposure assessment

In case of DU1 the exposure assessments are based on measurement data and modelled data for WCS where no air monitoring data were taken (WCS 3 – tip etch process). In case of worker air monitoring the approach taken seems correct, but the sampling time is relatively short (30 minutes for each measurement).

The dermal measurements on the other hand are not judged to be robust, as the sampling strategy is not suited for volatile (and easily absorbed) substances such as diglyme. The used sampling method for dermal monitoring was developed for non-volatile substances. Therefore, the dermal exposure is assessed by RAC based on modelling which is supported by the presented measurements and the RMMs and OCs in place.

In case of DU2 the exposure assessment was based on modelling only in the submitted CSR, as there were no results presented from a monitoring program. Workplace measurement was carried out at DU2 on 03/09/2020 but with only one measurement of the one worker at DU2 who has the potential to be exposed to diglyme. The measurement data is therefore considered too limited to allow a robust assessment and only taken as support for the modelled data.

On request of RAC the applicant revised the dermal exposure assessment and parts of the inhalation modelling. The assumptions made for the modelling in the revised assessment seem plausible and uncertainties regarding the exposure estimates are deemed to be such that they lead in a conservative direction.

RAC concludes that the exposure assessment for workers has a number of short comings/uncertainties (number of measurements, duration of measurements, not all relevant activities are monitored, inappropriate dermal measurement method, only one measurement

for DU2 so far) that need to be addressed as monitoring arrangements if the authorisation is granted.

3. Risk characterisation

3.1. Workers

Diglyme causes both fertility impairment and developmental toxicity (Repr. 1B, H360FD) and is considered the critical effect for risk characterisation. The DNELs derived by are considered to cover both reproductive toxicity endpoints (infertility and developmental effects). Because it cannot be excluded that developmental toxicity might be elicited even within a rather short sensitive time window of prenatal development of the embryo, frequency adjustment of exposure data is not considered appropriate. For inhalation, the DNEL for workers is 1.68 mg/m³, the dermal DNEL for workers is 0.24 mg/kg bw/day.

Table 9: Combined exposure and risk characterisation[13]

Contributing scenario	Route	Exposure value corrected for PPE and frequency	RCR	
				Combined
WCS 1 – DU1	Inhalation	0.04 mg/m³	0.024	0.038
	Dermal	3.43 × 10^{-3} mg/kg bw/day	0.014	
WCS 2 – DU1	Inhalation	0.04 mg/m³	0.024	0.031
	Dermal	1.7 × 10^{-3} mg/kg bw/day	0.007	
WCS 3 – DU1	Inhalation	0.419 mg/m³	0.249	0.537
	Dermal	0.069 mg/kg bw/day	0.288	
WCS 4 – DU1	Inhalation	0.49 mg/m³	0.292	0.434
	Dermal	0.034 mg/kg bw/day	0.142	
WCS 5 – DU1	Inhalation	0.015 mg/m³	0.009	0.151
	Dermal	0.034 mg/kg bw/day	0.142	

Table 10: Combined exposure and risk characterisation for production workers

Contributing scenario	Route	Exposure value corrected for PPE and frequency	RCR	
WCS 1 + WCS 2 + WCS 4 (PW1 DU1)	Inhalation	0.57 mg/m³	0.340	0.503
	Dermal	0.039 mg/kg bw/day	0.163	
WCS 3 (PW 2 DU1)	Inhalation	0.419 mg/m³	0.249	0.537
	Dermal	0.069 mg/kg bw/day	0.288	
WCS 4 + WCS 5 (PW 3 DU1)	**Inhalation**	**0.505 mg/m³**	**0.301**	**0.585**
	Dermal	**0.068 mg/kg bw/day**	**0.284**	
WCS 1 – DU2	Inhalation	0.035 mg/m³	0.021	0.035
	Dermal	3.43 × 10^{-3} mg/kg bw/day	0.014	

[13] The numbering of the WCS is different as the one in the applicant's CSR.

WCS 2 – DU2	Inhalation	0.66 mg/m³	0.39	0.399
	Dermal	2.07 × 10^{-3} mg/kg bw/day	0.009	
WCS 1 + WCS 2 (DU2)	**Inhalation**	**0.695 mg/m³**	**0.411**	**0.434**
	Dermal	**5.5 × 10^{-3} mg/kg bw/day**	**0.023**	
Highest total exposure for 8 hours (PW3 DU1)	**Inhalation**	**0.505 mg/m³**	**0.301**	**0.585**
	Dermal	**0.068 mg/kg bw/day**	**0.284**	

For the worker contributing scenarios at DU1 three different categories of production workers have been identified:

Production Worker 1 (PW1): works on the continuous etching line (WCS1 and WCS2), and general production areas (WCS4).

Production Worker 2 (PW2): works on tip etching (WCS3) and in general production areas (WCS4).

Production Worker 3 (PW3): works on cleaning and maintenance (WCS5) and general production areas (WCS4).

The worker contributing scenarios at DU2 are carried out by one member of staff and comprise filling/emptying the etch bath and works on the continuous etching line (WCS1 and WCS2).

Using the most conservative daily RCR (i.e. the highest combined RCR as shown above) demonstrates that adequate control of Diglyme use is achieved.

3.2. Humans via Environment

Environmental risk assessment on a regional scale is not considered to be relevant for use 2 as there are no widespread uses covered.

Table 11: Exposure and risk to humans via the environment – local and regional scale

Parameter	**Local**		**Regional**	
	Exposure	**RCR**	**Exposure**	**RCR or Excess risk**
Human via Environment – Inhalation	1.02 × 10^{-5} mg/m³ (DU1 7.62 × 10^{-4} mg/m³ (DU2)	3.40 × 10^{-5} (DU1) 2.54 × 10^{-3} (DU2)		
Human via Environment – Oral	6.16 × 10^{-4} mg/kg bw/day (DU1) 5.21 × 10^{-3} mg/kg bw/day (DU2)	6.84 × 10^{-3} (DU1) 5.79 × 10^{-2} (DU2)		
Human via Environment - Combined		6.87x 10^{-3} (DU1) 6.04 × 10^{-2} (DU2)		

3.3. Environment

Only relevant as far as human exposure via environment is considered. Overall, the risks arising from diglyme exposure via environment are in the magnitude of 10^{-10} for the regional environment and 10^{-4} for the local environment. As these RCR are far below 1, the applicant demonstrates adequate control.

3.4. Shortcomings or uncertainties in the risk characterisation

The measurement data basis for the exposure assessment is limited this also affects the quality and robustness of the risk assessment. On the other hand, in case of DU2 there is no open handling (tip etching) and the RMMs at place (closed system for automated etching, mechanized bottle pouring) support the assumption that exposure is effectively limited, and risks adequately controlled. Shortcomings or uncertainties in the risk characterisation are considered to be low.

3.5. Conclusions on risk characterisation

Overall, the risk characterisation seems plausible and robust.

RAC concludes that:

- The highest calculated risk for workers is 0.537 (WCS 3 – DU1 – tip etching).
- The highest calculated combined risk for workers is 0.585 (for Production Worker 3 – DU1- cleaning and maintenance and general production area).
- There are no significant uncertainties to the characterisation of risks.

RAC considers that the estimates of risks for workers and for indirect exposure of humans, via the environment, show that adequate control of risks has been demonstrated.

4. Analysis of Alternatives and substitution plan[14]

What is the amount of substance that the applicant uses per year for the use applied for?

The applicant indicates that the foreseen annual use of Diglyme is:

DU1: less than 10 tonnes per year,

DU2: less than 2.5 tonnes per year

the actual figures are claimed confidential but are known to RAC/SEAC

[14] The judgment of the ECJ Case T-837/16 Sweden v Commission stated that the applicant has to submit a substitution plan if alternatives are available in general. The Commission is currently preparing the criteria, derived from the judgment for establishing when an alternative is available in general. Once these are prepared this opinion format will be amended accordingly. The European Commission informed the REACH Committee in 9-10 July 2019 of its preliminary views on the criteria. In that note that Commission considered that the criteria defining a 'suitable alternative' would imply that it was i) *safer* and ii) *suitable*. Suitability would not mean it to be *"in abstracto"* or "*in laboratory or exceptional conditions*" but it should be "*technically and economically feasible in the EU*" and "*available, from the point of view of production capacities of the substance or feasibility of the technology, and legal and factual conditions for placing on the market*".

4.1. Summary of the Analysis of Alternatives and substitution plan by the applicant and of the comments received during the consultation and other information available

In its Analysis of Alternatives, the applicant considers seven possible alternative solvents to replace diglyme in the existing sodium-naphthalene system, and three alternative technologies (sodium-ammonia system, electrochemical treatment and plasma treatment). None of the alternatives technologies and solvents meet the required characteristics; the shortcomings of these and the reasoning for not pursuing substitution with the identified alternatives are clearly described.

Since Acton is currently using diglyme as a solvent in the sodium-naphthalene system, the simplest and least impactful choice for the applicant would be to find an alternative solvent, whilst keeping the sodium-naphthalene system.

The applicant performed an extensive search for possible alternatives to diglyme as a solvent in the sodium-naphthalene system. These solvents are selected primarily focusing on the solubility of sodium napthalide and the generation of the solvated anion. None of the alternative solvents offer any significant advantage in the reduction of risk, apart from dipropylene glycol dimethyl ether and diethyl glyme, so the applicant focused his research on these solvents.

To compare the performance of sodium naphthalide in different solvents for the surface modification of the same fluoropolymer surface, a bonding adhesion test can be used. Dipropylene glycol dimethyl ether and diethyl glyme based etchants gave good results in laboratory tests. However, when transferred to the production plant for plant trials, significantly worse results were obtained with lower and less consistent colour, less wettability and higher contact angles in comparison with a diglyme-based etchant.

In the Analysis of Alternatives the applicant reports that both Acton Technologies Ltd and Maflon Spa[15], have concluded that although these two solvents are, theoretically, potential alternative solvents for the formulation of sodium-naphthalene etchants. The performance of such etchants has not been successful during production pilot trials, for neither batch applications nor for continuous etching applications.

Sodium-ammonia systems are currently the only alternative system ready to be used at industrial level. This alternative was the original surface treatment method for etching of PTFE polymers before a switch was made to sodium-napthalene systems.

The adhesion achieved from etching PTFE with a sodium–ammonia solution is stated to be 15 % weaker than that observed with a corresponding diglyme system etchant. In addition, the reductant power of this system is often too aggressive for the article or surface to be etched. The small molecular size of the ammonia system creates an aggressive and deep penetrating behaviour that in many instances makes it ineffective when the thickness of the materials that must be etched is less than 0.25mm thick. Fluoropolymer skived tapes, sheet or tubes with a wall thickness of less than 0.25 mm cannot be treated in a controlled manner by this etchant, in applications of PTFE in the automotive, electronics, aerospace and medical sectors where smaller and lighter components are being developed continuously, this is a significant disadvantage.

Electrochemical methods for the reduction of PTFE have also been reported in the literature, however, the applicant is not aware of any commercial applications of electrochemical methods

[15] See also ECHA's opinion on the application for the use of diglyme for Maflon: https://echa.europa.eu/documents/10162/aa11a175-3d3e-dffe-d85c-8ca11296ffca

for the surface modification of perfluoropolymers. The applicant has not investigated them in its own research and development activities on etching technologies.

Plasma treatment is a common method for the surface modification of polymers to improve adhesion and wettability characteristics and there has been a significant research effort into the development of these techniques for the pre-treatment of fluoropolymers in response to the increasing regulatory pressure on many substances used for the wet chemical treatment techniques. Plasma treatments, which are all based on the dielectric barrier discharge phenomenon, include:

1. 1. Flame treatment;
2. 2. Corona discharge treatment;
3. 3. Plasma treatment at reduced pressures (LPT);
4. 4. Plasma treatment at atmospheric pressure (APT).

The major developments in the use of plasma technology for the surface modification of perfluoropolymers have been made in LPT treatments and these are now available for commercial scale application for the routine treatment of polymer surfaces.

Plasma treatment has the following advantages:

5. 1. Ability to treat complex tribologies (surfaces with complex interaction of shape, friction and lubrification)
6. 2. Do not produce chemical wastes;
7. 3. Can be modified to deliver specific surface modifications;
8. 4. Can be used to treat heat sensitive materials;
9. 5. Processes are controllable through regulation of the process parameters such as power, pressure, gas type and processing time.

However, it has been observed in tests that perfluoropolymers do not respond to plasma treatments as well as to other fluoropolymers. According to the applicant most plasma systems provide a surface modification that provides considerably lower bond strengths than diglyme system.

In addition, the shelf life of the treated surface is much shorter than that for the wet chemical sodium naphthalide technique that the applicant is using now. While atmospheric plasma treated PTFE surfaces have shelf lives in the order of minutes to days and vacuum plasma treatment may extend this shelf life to a number of weeks, the guaranteed shelf life for sodium naphthalide etched surfaces, protected from ultraviolet light and moisture, is at least one year. The consequence of this is that using plasma treatment would require immediate use of the etched PTFE surface for the bonding applications which is not considered possible for the products the applicant etches.

There may be specific applications where plasma etching on perfluoropolymers is the preferred methodology, especially where a colour change of the surface is undesirable or where chemical residues may be problematic

If Acton would be able to identify an alternative solvent to diglyme, downstream users could continue etching in their facility, using a product similar to FSS, but that does not contain diglyme. Substitution with a different solvent would allow to Applicant and its DU's to continue using Acton's etching business model in which the flexibility of etching in small scale operations at the customer's facility is essential as it provides advantages in terms of on-demand, on-

time etching. The investment required with other etching systems, would discourage Acton's DU's to continue with this busines model and force these DU's to resort to Acton's in-house etching process, losing the advantages of the current etching business model.

Based on the explanation above the applicant states that, in order to satisfy demand for etching products provided through the same business model, alternative solvents would be more viable.

The applicant provided a substitution plan as part of their applied-for-use scenario. Even though no specific alternative was identified by the applicant up to now, the plan outlines an approach to search for a substitute. Whilst the applicant's R&D plan is currently very broad in scope, Acton aims to fine-tune and consolidate this R&D plan depending on results that are obtained from field and lab tests.

To support this work stream, Acton will set up an internal team that will meet every 3 months to address the R&D plan and any results that may have achieved. Acton outlines that even if an alternative would be found now, it would take at least five years for Acton to develop the formulation using the alternative to the point where the required degree of consistency in bond strength and subsequent validation for the variety of downstream applications could be attained. The overall time required for substitution will be much longer than five years, as a suitable alternative must first be identified and made available on the market

Two comments were submitted in the public consultation. One was in support of the application. The other comment (not in support of the applicant) mentioned, as possible alternatives, the same alternative techniques indicated by the applicant in the AoA: ammonia system, electrochemical system, plasma treatment. The comment argues that two alternatives are commercially available, and one is still under development.

The only real new information presented in the comment is that there is a company in the USA which treats articles with a thickness of less than 0.25 mm with an ammonia system. On this point the applicant replied that, while it may be technically possible to perform this surface treatment, it is highly difficult to control it and to reproduce in a standard process with the desired uniformity of treatment and not cause damage to the substrate. More in general, the applicant reiterates the negative aspects these alternative techniques present in applications relevant for Acton's customers: insufficient process reliability, high risk of failure, much higher operating costs. Furthermore, as concerns ammonia system, the applicant reiterated that this system is suitable only for a different business profile than that of the applicant and its DUs (see section 4.3).

4.2. Risk reduction capacity of the alternatives

Would the implementation of the short-listed alternatives lead to an overall reduction of risks?

☐Yes

☐No

☒Not applicable

SEAC concluded that by the Sunset date there are no alternatives with the same function and similar level of performance that are safer and technically and/or economically feasible for the

applicant. Therefore, RAC did not evaluate the potential risk of alternatives.

4.3. Availability and technical and economic feasibility of alternatives for the applicant and its Downstream Users

Are there alternatives with the same function and similar level of performance that are technically and economically feasible to the applicant and its DUs by the date of submission of this application (20 August 2020)?

☐Yes ☒No

The possible alternative solvents are all considered commercially available on the basis that they have all been registered in full at an appropriate tonnage band by at least one EU legal entity under REACH. Unfortunately, all these alternatives have safety issues or have failed to produce the required consistency of results in etching applications on the production scale for the products of the customers of Acton's and its Downstream Users.

Regarding sodium-ammonia system, only a few companies in the world can run and manage this process given the aggressive nature of the reduction conditions. Whilst implementing such a system may be possible for fixed installations, operating a contracted etching service for large surfaces, a sodium ammonia system is not considered suitable for smaller scale fluoropolymer etching operations such as the ones run by Acton and their downstream users.

Ammonia-systems are very aggressive and not suitable when the thickness of the material to treat is less than 0.25 mm. In today's applications of PTFE in the electronics, aerospace and medical sectors, where smaller and lighter components are being developed continuously, this is a significant disadvantage. The use of a sodium-ammonia etching system is also a less economic alternative, it requires a significant op-front investment in equipment to handle the sodium and liquid ammonia reactants and in the operating of such a system, ammonia is not recovered adding to an increased cost of the consumables.

The applicant reports that commercial plasma treatments for the surface modification of PTFE are available from Diener Electronic or Henniker Plasma.

Acton Technologies has developed its own plasma treatment system. According to Acton this is the most effective and longest-lived plasma surface treatment in the marketplace. However, despite more than ten years of application development, the technique and products produced have not gained market acceptance. Acton has limited information on why this has not happened, the downstream user of etched products does not always reveal to the etchant technology supplier (Acton) the reasons for end application failure and whether this lies with the etchant technology, the adhesion technology or the application characteristics, making it difficult for a company such as Acton to develop and fine-tune the method further.

Finally, the applicant demonstrates that the cost of operating of LPT technology comes at a higher cost due to:

- Higher capital cost equipment – each discreet material type requires specific equipment for their configuration: for example, PTFE film, machined parts or tubing each require at least a different equipment for their material profile and therefore multiple set-ups may be required for differing sizes of the same part types.
- The requirement for low pressure systems, requiring installation of additional pumps
- Lower productivity throughput

The applicant states that, whilst there may be niche markets for the plasma technology in perfluoropolymer surface modification, wet chemical methods will remain the predominant technology because of the ease of use for multiple configurations of surfaces and consistency of performance in a number of validated product areas.

From the DU'S perspective, Acton highlights that it is providing much needed services and products for a variety of business sectors, as shown by their own and their direct customers' operations in the EU. Acton's strategic business objectives are the continuation of their services so that their customers can offer quality products to the EU businesses and consumers.

The company has a long-term perspective on its economic performance and its staff are invested in the ongoing success of the business. This long-term commitment leads to a better understanding of the industry and builds stronger customer relationships and drives more effective sales and marketing.

As a result, Acton places importance on its good relationship with their long-standing customers and does not want to leave them without means of continuing their operations, even in short-term, if supply of the etchant and Acton's etched products ceased.

Ceasing the etching and formulation operations completely is against Acton's goal of maintaining consistent, long-standing relationships with their customers and in maintaining a business that looks far to the future.

SEAC's evaluation/view on the availability and technical and economic feasibility of alternatives for the applicant and its downstream users

SEAC consider that the AoA offers a consistent overview of the shortcomings of potential alternatives to diglyme in terms of functional properties. The review was performed based on the functional requirements of diglyme, based on research and development and external consultations with chemical suppliers of alternatives. SEAC notes that the applicant has clearly explained the key parameters used to assess the potential alternatives. SEAC further notes that the applicant convincingly explained why its substitution efforts are focused on alternative solvents and plasma treatments.

Despite the development and research activities for alternatives, the pursuit for alternative solvents or technologies has been unsuccessful so far. Alternative solvents and etching technologies do not produce the functionalities required to achieve qualification standards and end user requirements.

SEAC recognise the efforts made by the applicant to identify possible alternatives to diglyme as a carrier solvent in the formulation use of sodium naphthalide and the fact that none of the alternatives offer the same process functionalities as diglyme. SEAC appreciates that the applicant conducted experimental campaigns in its laboratories on the two non-toxic alternative solvents. SEAC recognises that sodium ammonia system which is used by another actor is not suitable for the most important and profitable applications and customers, like downstream users 1 and 2. SEAC furthermore marks that operating this type of plant would require a completely different type of professional skill and industrial structure.

SEAC points out that the applicant has not performed any experimental tests was conducted on the electrochemical system. In the opinion of SEAC, the fact that academic reports exist on this system should be an incentive for the applicant to conduct an experimental campaign on a promising system.

The applicant claims that alternatives are technically and economically not feasible as they display shortcomings vis-a-vis key technical properties that are required. SEAC considers that

the applicant provides clear, well substantiated arguments in demonstrating technical feasibility and SEAC agrees with the applicant , that, at present, available alternatives exhibit technical deficiencies and none of them could be used as feasible alternative at the date of submission of this second application.

SEAC was not able to assess the economic feasibility of alternatives in detail, because the applicant did not provide a comparison of potential alternatives in terms of their incremental costs. However, the applicant provided a solid, qualitative description of the economic burden of the alternative solvents/techniques. This limitation in the assessment would not change the overall conclusion that substitution is not feasible before the date of application, because of the technical insufficiencies of the alternatives.

SEAC considers that the applicant's assessment of the availability, technical and economic feasibility of the shortlisted alternatives has been performed in an appropriate way and has no reservation regarding the applicant's conclusions.

SEAC agrees with the applicant's conclusion that no technically feasible alternatives to the use applied for are available before the date of submission of this second application due to the need to meet the performance required by DU1 and DU2.

SEAC recognises that the only really promising alternative technique, plasma treatment using LPT technique, has not yet been accepted by DU1 and DU2, mainly because of the short shelf life of the etched material.

SEAC considers the information provided by the applicant and its responses to the comments in the public consultation as sufficient for concluding on the validity of the assessment of alternatives and concludes that the applicant's assessment is appropriate.

Based on the available information, SEAC concludes that there are no technically and economically feasible alternatives at the date of submission of this application (20/08/2020)

4.4. Substitution activities/plan

Has the applicant submitted a substitution plan?

☒Yes ☐No

The Substitution plan submitted by Acton is also applicable, mutatis mutandis, to the two Downstream users of Acton.

If yes, is the substitution plan credible and consistent with the analysis of alternatives and the socio-economic analysis?

☒Yes ☐No

The applicant has chosen to focus medium term R&D efforts on two possible alternatives:

1. Plasma treatment technology, and
2. Two alternative solvents using the same wet technology of the current diglyme system.

The two solvents are dipropylene glycol dimethyl ether and diethyl glyme. Both of these solvents have similar physicochemical properties to diglyme and have demonstrated in laboratory conditions to produce etchants of reasonable characteristics. However, such formulated etchants have failed to produce the required consistency and performance of results in etching applications on the production scale and this is the reason why these solvents were classified in the AoA-SEA as not currently technically feasible. The positive lab results have convinced Acton that a focus on these substances is currently the best approach.

Acton Technologies have made a significant investment in the development of plasma treatment technology for perfluoropolymer surface treatment over the last 20 years but have not seen a return on that investment through the widespread adoption of either the technology or the etched items that are produced using this technology, in part due to the technical limitations of plasma treatment. Acton committed itself to continue using this approach as it is feasible for some applications and technological improvements are always possible, as there are many operational aspects that can be fine-tuned and improved.

In response to SEAC's question about research on other alternatives such as electrochemical methods, the applicant claims that Acton is a SME and has a limited R&D budget within which they can pursue development of alternatives relevant to their main operations (i.e. formulation of etchant and etching). Therefore, Acton carefully considers its investment strategy regarding alternatives for their diglyme-based etching process. Acton plans to evaluate potential alternatives in the future in a cost-effective manner. Acton's priority is to pursue alternative solvents, as they would be easier to implement than a completely different technology such as reductive pre-treatments or electrochemical methods. Different technologies would carry a very high cost, including the potential re-design of Acton's and Acton's DU's manufacturing processes.

Additionally, Acton does not have the in-house capacity and expertise to further assess these technologies. Further research would involve contracting a 3rd party to evaluate the options and then to investigate further based on the studies of the 3rd party. However, continued monitoring for commercial breakthroughs in the industry will be performed and pursued if identified.

Acton's current aim is to split the R&D programme into two phases:

The first phase is dedicated to identifying an alternative substance / technology that meets the key criteria, this phase is the most critical of the two phases described by the applicant. The difficulty lies in the fact that no suitable alternative has been identified so far and it is not sure that the most promising alternatives that are available now will work in the applicant's processes. This first phase is expected to last approximately six years.

The second phase aims at investigating the economic and technical feasibility, i.e. extensive testing against the criteria set in the AoA. This second phase is expected to last approximately five years.

The two phases together could last for 11 years. After that it will be necessary to revalidate the properties of the final products by the customers. For example: in the Automotive industry, the Production Part Approval Process (PPAP) is used to ensure that a supplier meets the manufacturing, quality and technical requirements for the parts supplied. This is a documented process whereby the supplier certifies the manufacturing and technical specifications, and these are then approved by the customer.

Downstream user 1 produces medical devices. They would therefore have to revalidate their products, an expensive process in both time and money, with a new validation taking years to be approved.

Acton will also have an oversight committee that will encompass Acton Senior Leadership and other relevant stakeholders, including external consultants, industry representatives, and other experts / interested parties who will be assessed and invited upon the granting of the application for authorisation. This group will aim to meet annually to review the results of the internal Acton substitution team and provide guidance / steering on the path forward. This group will also lead when assessing alternatives outside of the Acton organisation.

SEAC's evaluation/view on the substitution activities/plan

The Applicant has stated that the resources devoted to finding an alternative will be limited. The Applicant has invested substantially in the new automatic system which allows them to operate now in conditions of adequately controlled risk using diglyme system.

Overall, the substitution plan is well outlined and clear. As such it provides a clear description of the tasks to be undertaken and description of elements affecting the timelines of the substitution. The applicant illustrated the need to follow each step in the order indicated and the risk of failure in each step due to unforeseen circumstances such as adverse findings. Any adverse results from any phase may result in a delay in substitution.

The presence of an oversight committee other relevant stakeholders, including external consultants, industry representatives, and other experts should ensure sufficient feedback on Acton's actual commitment to finding alternatives. The applicant claims that this group will meet annually to review the results of the internal Acton substitution team and provide guidance / steering on the path forward.

The revalidation costs of DU1 and DU2 would be significant, particularly considering the strict product safety requirements of the medical devices, aerospace, and automotive sectors.

In the AoA, the applicant claims that even if a promising alternative would become available and would likely be technically and economically feasible, it would take at least five years for Acton to develop the product formulation using the alternative to the point where the required degree of consistency in bond strength and subsequent validation for the variety of downstream applications could be attained. However, the overall time required for substitution will be much longer than five years, as the alternative once identified must be made available on the market and go through several qualification process including qualification processes in the medical sector which SEAC understands to be of such length that a 12 year review period could well be justified. For the DU's this is highlighted in the opinion by the following statements

For the medical sector (DU1) The lubricity of the PTFE is required for the high performance in demanding applications such as endoscopes and guiding catheters. However, in order to use PTFE they must be bonded and chemical etching is required to create an acceptable bond. DU1 and its customers would therefore have to revalidate their products, an expensive process in both time and money, with a new validation taking several years to approve. In the past, DU1 has had its own customers push back on even minor changes to products because of these revalidation costs.

For the automotive sector (DU2) It would take several months to go through the performance trials to justify a significant change to the manufacturing process that would potentially affect PTFE surface adhesion characteristics. The average cost of this process can be expected to be measured in tens of thousands of Euros per component. If this is replicated across several engine platforms for several different automotive manufacturers, the potential cost and time impact upon the industry from a change in etching solvent would be significant, one request the applicant clarified that for this process costs depend on the level of detail required by the customer and can be expected to be in the range of tens of thousands of euros per component and it could take between 6 months and a year.

SEAC understands that from the moment an alternative is found, the overall time required for substitution will be much longer than five years, as a suitable alternative must first be identified and made available on the market and go through several qualification process including qualification processes in the medical and automotive sector which SEAC understands to be of such length that substitution and relevant requalification of products would not be achieved

within a normal review period.

Conclusions of SEAC

SEAC concludes that:

- The scope of the analysis of alternatives provided by the applicant covers the use applied for, which entails the use of diglyme as a carrier solvent in the formulation and use of sodium naphthalide to produce an etchant (Fluoroetch® Safety Solvent (FSS)) to be sold to their downstream users
- By the application date there were no alternatives available with the same function and similar level of performance that are safer and technically and/or economically feasible for the applicant
- The applicant provided appropriate information on the shortlisted alternative solvents and techniques and their focus on the most promising alternative and the steps undertaken so far to test its feasibility including future timelines.

The substitution plan and the described substitution activities and R&D are credible and robust, including the description of the main steps to be completed, the expected outcome of each main step and the timelines for completion assigned to each of them. The timelines presented in the substitution plan indicate that a 12-year review period may be warranted.

4.5. Conclusions on the analysis of alternatives and the substitution plan

SEAC notes that there are no alternatives available with the same function and similar level of performance that are safer and technically and/or economically feasible for the applicant before the sunset date.

The substitution plan is well outlined and credible and consistent with the analysis of alternatives and the socio-economic analysis. Given the strong performance requirements by the customers and the great difficulty in finding valid alternatives encountered in all these years of research, SEAC considers that the review period requested by the applicant is well justified.

5. Benefits and risks of continued use

Has the applicant adequately assessed the benefits and the risks of continued use?

☒ Yes

☐ No

5.1. Human health and environmental impacts of continued use

RAC has supported the conclusion of the applicant's assessment that all exposures associated with the current use of diglyme are below the DNEL. Therefore, the application can proceed under the 'adequate control' route. On this basis, the monetised human health impacts for the reproductive toxicity end-point are effectively zero.

The applicant has, despite this, provided a break-even analysis, arguing that the number of infertility cases that are needed for the monetized risks to exceed the costs of continued use are not likely to be observed. Since adequate control of risk was confirmed by RAC, the break-

even analysis of the applicant was not further scrutinized by SEAC.

5.2. Benefits of continued use

Non-use scenario

For Use 2 the applicant presented two non-use scenarios for its Downstream user DU1:

1. Permanent closure of etching operations;
2. Relocation to outside of the EU.

In the non-use scenario DU1 and DU2 are no longer able to use FSS and are forced to either close their activity or relocate their activities outside of the EU. Although in principle a different supplier could be found, in practice this would not work. The only other authorisation holder (Maflon Spa, referred to earlier) does not hold an authorisation for downstream processes. Maflon Spa holds an authorisation for etching using FSS, but this refers to an in-house process and the current authorisation does not cover any downstream use of FSS.

DU1 reported to Acton that it expects closure and relocation of its EU business operations to the US in case FSS will no longer be available. For Acton's smaller downstream user (DU2) no non-use scenario was reported. On request the applicant clarified that DU2 is unsure whether relocation of its operations would be feasible. For the analysis, it has been implicitly assumed that DU2 would close down its operations in case of not being granted authorisation.

What is likely to happen to the use of the substance if an authorisation was not granted?

- The use would cease altogether.
- The use would be taken up by market actors operating outside the EU.

What is likely to happen to jobs in the European Union if an authorisation was refused?

- Up to 12 jobs would be permanently lost in the European Union.

Economic impacts of continued use

Economic impacts

In case of a refused authorisation the downstream use of the FluoroEtch® Safety Solvent (FSS) based on diglyme would have to stop. Therefore, economic impacts for DU1 and DU2, but also for Acton will arise since DU1 and D2 are the main customers of Acton.

The economic impact on Acton of a stop in supplying FFS to DU1 and/or DU2 was not quantified. However, SEAC notes that a fraction of up to 50 % of Acton's profits is based on downstream use.[16]

The downstream user market of Acton is dominated by one customer (DU1) with a share of the total EU-sales volume of FluoroEtch® Safety Solvent (FSS) above 50 %[17]. This customer

[16] Actual share of sales is claimed confidential but are known to SEAC.
[17] Actual share of sales is claimed confidential but are known to SEAC.

uses FSS mainly for the etching of Polytetrafluoroethylene (PTFE) in the manufacture of medical applications such as catheter liners, artificial tendons and ligaments, blood vessels prosthetics, and vascular grafts. In this growing market it is the main supplier and has a market share on the global guiding catheter market of more than 50 %[18]. On request, the applicant clarified that this market share is based on the assessment of PTFE as a material component of these devices, the inherent need for surface treatment and that, based on Acton market intelligence, no other surface treatment is used in these applications. Acton notes that this statement holds only for PTFE-based catheters, and that there are also other catheters that do not use PTFE liners.

DU1 reported to Acton that it expects closure and relocation of its EU business operations to US in case it will no longer be able to use FSS, with relocation costs mainly for constructing of a plant in the range €1-10 million. On request the applicant clarified that DU1 declined to provide profit losses due to relocation. For DU1's customers, requalification costs for its different product lines in the range €1-10 million are expected to arise[19].

In response to SEAC's questions, for Acton's smaller downstream user (DU2) it was clarified that DU2 is unsure whether relocation of its operations would be feasible. An annual profit loss in the range €1-10 million is estimated as to be connected to the non-availability of the diglyme-based etchant (under the implicitly assumed closure scenario). SEAC considers plausible to use a single year of lost profits to account for the net changes in producer surplus. Considering the profit losses of the applicant over a longer time does not consider the possibility of mitigating actions that could reduce the economic impacts and would overestimate economic impacts.

Social impacts related to job losses

For estimating the job losses, the applicant has assumed DU1's relocation of etchant formulation and etching activities to US, resulting in redundancy of 10-100 employees at DU1. The job losses correspond to welfare losses for DU1 in the range €0.1-10 million[20]. For DU2 costs of unemployment were considered low compared to DU1 and thus not reported.

The calculation of social impacts follows the approach outlined in Dubourg (2016)[21] and endorsed by SEAC (2016)[22] and uses updated parameters for country-specific mean unemployment duration and country-specific average real gross salaries.

Impacts on the health care system and patients

Acton's and their customers' operations are offering significant services and products in the EU. The catheters manufactured by DU1, for example, are an essential medical device for the EU healthcare sector. In case of a not granted authorisation DU1 would not be able to meet the market demand for PTFE-based catheters. Due to the large market share owned by DU1 and the uncertainty around competitors being able to cover DU1's market share, potential adverse health impact on patients at least over the short term cannot be excluded.

Wider economic impacts

Acton notes that in case of relocation to outside EU, Acton's and DUs expertise would be lost

[18] Actual share is claimed confidential but is known to SEAC.
[19] Actual requalification costs are claimed confidential but are known to SEAC.
[20] Actual unemployment costs are claimed confidential but are known to SEAC.
[21] Dubourg (2016): https://echa.europa.eu/documents/10162/13555/unemployment_report_en.pdf/e0e5b4c2-66e9-4bb8-b125-29a460720554
[22] SEAC (2016): https://echa.europa.eu/documents/10162/13555/seac_unemployment_evaluation_en.pdf/af3a487e-65e5-49bb-84a3-2c1bcbc35d25

to the EU, having a negative impact on the competitiveness of the EU industry.

Table 12: Socio-economic benefits of continued use

Description of major impacts	**Quantification of impacts (over the 12-year assessment period)**
1. Benefits to the applicant and/or their supply chain	
1.1 Avoided profit loss due to investment and/or production costs related to the adoption of an alternative	Not applicable
1.2 Avoided profit loss due to ceasing the use applied for[23]	DU2: €1-10
1.3 Avoided relocation or closure cost	DU1: €1-10 million (construction costs)
1.4 Avoided residual value of capital	Not applicable
1.5 Avoided additional cost for transportation, quality testing, etc.	DU1: €1-10 (requalification costs)
Sum of benefits to the applicant and / or their supply chain	€3-30 million
2. Quantified impacts of the continuation of the SVHC use applied for on other actors	
2.1 Avoided net job loss in the affected industry[24]	DU1: €0.1-10
2.2 Foregone spill-over impact on surplus of alternative producers	Not applicable
2.3 Avoided consumer surplus loss (e.g. because of inferior quality, higher price, reduced quantity, etc.)	Not quantified
2.4 Avoided other societal impacts (e.g. avoided CO_2 emissions or securing the production of drugs)	Not available
Sum of impacts of continuation of the use applied for	€0.1-10
3. Aggregated socio-economic benefits (1+2)	€3.1-40

Notes:

SEAC considered one year of profit loss only as explained under *Economic impacts* in Section 5.2 above. This one-year profit loss is considered to represent the net changes in producers' surplus across the EU economy over the 12-year assessment period.

5.3. Combined assessment of impacts

The applicant argues that quantified economic and social benefits for Acton which are €0.4-4 million outweigh the costs of continued use for human health which are effectively zero since

[23] Profit losses to be counted in only for the first 1 year, see SEAC note on economic surplus changes (not yet available).
[24] Job losses to be accounted for only for the arithmetic mean period of unemployment in the concerned region/country as outlined in the SEAC paper on the valuation of job losses (See The social cost of unemployment and Valuing the social costs of job losses in applications for authorisation).

the use is considered to be adequately controlled. As wider economic impacts were mentioned that a refused authorisation would cause loss of expertise in the EU and be detrimental for competitiveness of the EU industry.

Table 13: Socio-economic benefits and risks of continued use

Socio-economic benefits of continued use		**Excess risks associated with continued use**	
Benefits [€ million over 12 year assessment period]	€3.1-40	Monetised excess risks to workers directly exposed in the use applied for	the monetised human health impacts for the repro end-point are effectively zero"
Quantified impacts of the continuation of the SVHC use applied for	-	Monetised excess risks to the general population and indirectly exposed workers	the monetised human health impacts for the repro end-point are effectively zero"
Additional qualitatively assessed impacts	Shortage in supply of PTFE-catheters at least over short-term (during period of relocation) Loss of expertise in EU	Additional qualitatively assessed risks	Not applicable
Summary of socio-economic benefits	**Economic impacts: €3-30** **Social impacts: €0.1-10** **Sum: 3.1-40** **Shortage in supply of PTFE-catheters over short-term** **Loss of expertise in EU**	**Summary of excess risk**	**Not applicable**

5.4. SEAC's view on Socio-economic analysis

SEAC cannot conclude on the non-use scenarios of the DU1 and DU2. But it is plausible that the impossibility of using FluoroEtch® Safety Solvent (FSS) will have economic impacts for DU1 and DU2. They are forced to either close their activity, use another etching solution and be confronted with a process of revalidation and regulatory approval and the costs associated to this, or to relocate. Since DU1 and D2 are the main customers of Acton it is also plausible that economic impacts for Acton will arise in case of a not granted authorisation for DU1 and DU2.

SEAC notes that is it credible that production would not be taken up by actors within the EU as other Authorisation holders (most notably Maflon Spa) hold an authorisation that does not cover downstream use of FSS.

The main economic impact considered by DU1 are costs of relocation to the US. These costs cannot be verified, but it is plausible that considerable costs for new buildings and for shipment from US to EU will arise. It is also plausible that for DU1 costs for requalification of products will arise in case of major changes to the formulation of the etchant (such as caused by a relocation to the US). Since Acton's main customer operates in the field of medical devices also costs for the process of regulatory re-approval have to be taken into account as welfare

costs of the non-use scenario.

SEAC considers that the most plausible non-use scenario would result in unemployment of some of the DU1 workers. The assumption of a longer average duration of unemployment compared with the EU-28 average is plausible also the assumed average wage cost for Ireland is also plausible. The approach used by the applicant to monetize the welfare loss associated with the unemployment of some of their workers follows the SEAC note on the social cost of unemployment.

The applicant considers that impacts of non-authorisation for patients and the health care system will arise in the short term, during the period to relocate DU1's business to the US. The main customer of Acton has a considerable market share in the PTFE-based guiding catheter market worldwide. Although no information on production capacities and dependency of catheter production on diglyme etchants is available it seems plausible that non-availability of the etchant will cause some market shortage at least over the short term.

5.5. Conclusion on the socio-economic analysis

SEAC has no reservations on the quantitative and qualitative elements of the applicant's assessment of the benefits and the risks for human health associated with the continued use of the substance. This conclusion is made on the basis of:

- the application for authorisation,
- SEAC's assessment of the benefits of continued use,
- SEAC's assessment of the availability, technical feasibility and economic viability of alternatives,
- any additional information provided by the applicant or their downstream users,
- RAC's assessment of the risks.

6. Proposed review period

☐ Normal (7 years)

☒ Long (12 years)

☐ Short (…. years)

☐ Other: _____ years

When recommending the review period SEAC took note of the following considerations:

6.1 RAC's advice

RAC has no advice with regard to the review period.

6.2. Substitution and socio-economic considerations

In identifying the proposed review period SEAC took note of the following considerations:

- The analysis of alternatives and the public consultation demonstrated without significant uncertainties that currently there are no suitable alternatives available for Acton for the use applied for.

- SEAC considers that the applicant has been proactive in undertaking research to develop alternatives and is committed to continuing the R&D efforts to implement alternatives for diglyme.
- As noted in the AoA, an economically and technically feasible alternative has yet to be identified, thus adding a lot of unknown variables and complexities into the R&D programme and in its foreseeable duration. If an alternative is eventually identified, then this new solvent and etchant mixture and / or technology must then be accepted by the downstream users of etchants before it is placed on the market.
- Due to high performance requirements of its customers, SEAC finds it credible that it would not be possible for the applicant to substitute within a normal (seven year) review period.
- The Substitution plan is credible, and its timelines justify a long (12 year) review period.
- RAC has supported the conclusion of the applicant's assessment that all exposures associated with the current use of diglyme are below the DNELs. Therefore, the monetised human health impacts for the reprotoxic end-point are effectively zero.
- SEAC has no substantial reservations on the quantitative and qualitative elements of the applicant's assessment of the benefits. The applicant's impact assessment was considered by SEAC to provide robust conclusions in this respect.

Taking into account these points, SEAC recommends a **12**-year review period.

7. Proposed additional conditions for the authorisation

Were additional conditions[25] proposed for the authorisation?

☒ Yes

☐ No

7.1 Description

RAC

Proposed additional conditions

Downstream User 1 shall implement further RMM, already planned, for further containment of the process for tip etching. Specifically, this relates to the WCS2: Pouring of the etchant where a pump transfer system is still planned to be installed (See p. 22 of this opinion)

SEAC

Proposed additional conditions

None

[25] Conditions are to be proposed where RCR is > 1, OCs and RMMs are not appropriate and effective, risk is not adequately controlled, minimisation of emissions is not demonstrated.

7.2 Justification

According to the applicant most of the FFS is used in closed systems (continuous etch bath) and in case of open handling during tip etching (DU1), which is done on relatively small scales (small amounts of FSS are applied at once), LEV is present.

It should be noted that this "critical" situation (tip etching) is supposed to change as DU1 is planning to install a fully enclosed cabinet with integrated gloves (glove box) for tip etching operations. Assuming regular maintenance of the device and the gloves used, the situation should improve significantly with regard to workers exposures.

8. Proposed monitoring arrangements for the authorisation

Were monitoring arrangements[26] proposed for the authorisation?

☒ Yes

☐ No

8.1 Description

The applicant and the downstream users shall:

Both downstream User 1 and User 2 shall continue their air and dermal monitoring activities, given that for dermal monitoring an appropriate monitoring method is available. Both downstream users shall additionally investigate the possibility of biomonitoring and if an appropriate method exists, implement a biomonitoring campaign to verify and support the results from air and dermal monitoring. These measurements must be based on relevant standard methodologies or protocols and the use of a method with detection limit and limit of quantification allowing meaningful exposure evaluation. The downstream users may choose to replace the air and dermal monitoring activities with biomonitoring if a method is found and validated that is equally suitable in the detection of diglyme and can be used to ensure that the exposure is below the DNEL.

Downstream user 1 and 2 shall continue their environmental monitoring campaigns, Environmental emissions of diglyme from applicant's site shall be subject to measurements with the results of monitoring made available to enforcement bodies on request. Measurement programs shall be performed according to standard sampling and analytical methods, where available.

8.2 Justification

Even though the applicant and the downstream users have made major improvements (or plan additional improvements) in their management of occupational risks related to the use of diglyme, the applicant and the downstream users have (partly due to unforeseen situations)

[26] Monitoring arrangements for the authorisation are to be proposed where RCR is < 1, OCs and RMMs are appropriate and effective, risk is adequately controlled, minimisation of emissions is demonstrated – but there are some moderate concerns.

compiled only a limited set of monitoring data (air and dermal) to base the exposure assessment on. Although the current dataset allows for drawing conclusion on adequate control and indeed support the conclusion that the applicant and the downstream users adequately control the risk associated with the use of Diglyme; RAC is of the opinion that the dataset set should be enlarged in order to increase further the robustness of the risk assessment.

Adequate control has been demonstrated for the general population exposed via the environment. However, RAC considers that the dataset supporting the risk assessment for man via environment should be improved to increase its reliability by providing measurement data to air compartment.

9. Recommendations for the review report

Were recommendations for the review report made?

☒ Yes

☐ No

9.1 Description

Results of the monitoring activities in 8.1 must be included in any subsequent authorisation review report.

9.2 Justifications

See section 8.2

10. Comments on the draft final opinion

Did the applicant provide comments on the draft final opinion?

☐ Yes

☒ No

10.1 Comments of the applicant

Was action taken resulting from the analysis of the comments of the applicant?

☐ Yes

☐ No

☒ Not applicable – applicant did not comment

10.2 Reasons for introducing the changes and changes made to the opinion

Not applicable

10.3 Reasons for not amending the opinion

Not applicable

Annex I exposure data for downstream users compared with previous application

Exposure data for production workers, combined exposures

On **16/02/2016 Acton Technologies Limited** submitted an application for authorisation including information as stipulated in Articles 62(4) and 62(5) of the REACH Regulation for the following two uses:

Use 1: Use of bis(2-methoxyethyl) ether (diglyme) as a carrier solvent in the formulation and subsequent application of sodium naphthalide etchant for fluoropolymer surface modification whilst preserving article structural integrity (in-house processes) [27]

Use 2: Use of bis(2-methoxyethyl) ether (diglyme) as a carrier solvent in the application of sodium naphthalide etchant for fluoropolymer surface modification whilst preserving article structural integrity (downstream user processes).

RAC concluded that for the applicant's own use, the applicant had not demonstrated adequate control.

One of the key points of the applicant in claiming adequate control is that the use of Local Exhaust Ventilation (LEV) would contribute to the evaporation of diglyme. If diglyme would evaporate at a higher rate, the potential length of time that workers could be exposed via the dermal route would be shorter, reducing the exposure potential. The applicant's argumentation is that the use of LEV would therefore result in lower exposure and RCRs below 1 and, hence, adequate control would be demonstrated.

RAC did not accept this argument. As diglyme is a substance with a low vapour pressure at ambient temperature, the effect of LEV would only be relevant for tasks where diglyme is used at elevated temperatures, where LEV would facilitate the evaporation of diglyme. RAC argued that, according to the applicant's description of the process, such temperatures are actually not achieved in the processes described; the information provided by the applicant indicates that the substance is used at ambient temperature, at which diglyme does not evaporate easily. Consequently, RAC argued that LEV would not be effective in reducing the exposure duration and the level of risk resulting from the use of diglyme as described by the applicant would lead to the RCRs above 1.

RAC also noted the overreliance on personal protective equipment, including respiratory protection and skin protection, in the processes described by the applicant.

For the downstream users (Use 2), RAC concluded the following on the basis of the arguments outlined above.

Du in first application	RAC conclusion	DU in second application	Reason for not applying
DU 1	No adequate control demonstrated for workers, adequate control demonstrated for humans via the environment	DU1	N/A
DU 2	Adequate control demonstrated for workers, adequate	N/A	Discontinued use of Acton's product

[27] Use 1: https://echa.europa.eu/documents/10162/c4b4d55e-99cb-e875-1da8-796b3a3fbe72,

	control demonstrated for humans via the environment		
DU 3	No adequate control demonstrated for workers, adequate control demonstrated for humans via the environment	DU2	N/A
DU 4	No adequate control demonstrated for workers, adequate control demonstrated for humans via the environment	N/A	Discontinued use of Acton's product
DU 5	Adequate control demonstrated for workers, adequate control demonstrated for humans via the environment	N/A	Discontinued use of Acton's product

The draft opinions were sent to the commission on 24/11/207. Until the date of this draft opinion the Commission has not issued a decision yet.

In this second applicant, Acton reports on the changes made to the operational actions and risk management measures at the applicant's own site as well at the Downstream users' sites.

The applicant undertook the following actions:

- Upgraded ventilation system (Feb 2018)
- Pump transfer instead of manual transfer (Jun 2018)
- Carbon filter on process air (Mar 2019)
- Robotic handling (Apr 2019)
- Dermal (2018, 2019) and surface monitoring (2019)

Actions by DU1 (previous DU1):

- Inhalation, dermal and surface monitoring data
- Separation of etching equipment
- Re-design of the etchant pouring process (not explained in detail)
- Tip etching process will be reviewed (not explained in detail)

Actions by DU2 (previous DU3):

- Mechanized bottle pouring, no worker contact
- Monitoring campaign to be performed in 2020 (emission, inhalation, dermal, surface)

For the downstream users (Use 2), RAC concluded the following on the basis of the arguments outlined above.

	First application for authorisation (2016)			**Current application for authorisation**		
	WCS combined	Route of exposure	Exposure value (8-h TWA)	WCS combined	Route of exposure	Exposure value (8-h TWA)
DU1	PW1: 1+2+4*	inhalation	0.612 mg/m³	PW1: 1+2+4**	inhalation	0.57 mg/m³
		dermal	0.010 mg/kg bw/day		dermal	0.039 mg/kg bw/day
	PW2: 3*	inhalation	0.084 mg/m³	PW2: 3**	inhalation	0.419 mg/m³
		dermal	0.69 mg/kg		dermal	0.069 mg/kg

			bw/day			bw/day
				PW3: 4+5**	inhalation	0.505 mg/m³
					dermal	0.068 mg/kg bw/day
DU2	1+2*	inhalation	1.1 mg/m³	1+2**	inhalation	0.695 mg/m³
		dermal	0.010 mg/kg bw/day		dermal	5.5×10^{-3} mg/kg bw/day
DU3	1+2*	inhalation	0.154 mg/m³			
		dermal	0.347 mg/kg bw/day			
DU4	1+2*	inhalation	0.07 mg/m³			
		dermal	1.03 mg/kg bw/day			
DU5	1*	inhalation	0.04 mg/m³			
		dermal	0.001 mg/kg bw/day			

* As assigned in first application for authorisation
** As assigned in the current application for authorisation

As stated above it is not clear which current DU corresponds to the DU in the first application for authorisation, but DU5 on the left side can be excluded as there is no corresponding DU covered by the respective WCS on the right side. Also, in case of DU1 the WCSs used in the exposure scenario to describe the processes are very similar in the first and the current application for authorisation. Comparison of the exposure values for all combined DU scenarios of the current application for authorisation with the values in first application for authorisation show a significant reduction of dermal exposures for all scenarios and also lower inhalation exposure values for the scenarios DU1-PW1 and DU2, but not so when comparing DU2 inhalation exposure values of the current application for authorisation with the inhalation exposure values for DU3 and DU4 of the first application for authorisation, which are all covered by the same WCSs. The same holds true for comparison of inhalation exposure estimates for DU1-PW2.