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 formulation and subsequent application of sodium naphthalide etchant for fluoropolymer surface modification whilst preserving article structural integrity (in-house processes)

Submitting applicant

Acton Technologies Limited

ECHA/RAC/SEAC: AFA-O-0000006947-58-01/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: downstream)
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)
Use title	**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)**
	Other connected uses: use ID 0217-02
	Same uses applied for:
Use performed by	☒ Applicant ☐ Downstream User(s) of the applicant
Use ID (ECHA website)	0217-01

Reference number	11-2120852860-52-0001
RAC Rapporteur	SCHLÜTER Urs supported by 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/applications-for-authorisation-previous-consultations/-/substance-rev/26010/del/200/col/synonymDynamicField_302/type/asc/pre/2/view
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/26010/del/200/col/synonymDynamicField_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 the current 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 the risks** from the use applied for, provided that the OCs and RMMs 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 also took note of RAC's conclusion that the risk 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 €0.4-4 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 human health and 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 8 of the justification to this opinion.

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

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

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.

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 ☒ downstream user
Number and location of sites covered	1 location: Kilfinny, Adare, Co Limerick, Ireland
Annual tonnage of Annex XIV substance used per site (or total for all sites)	10-20 t 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	Formulation for the reductive defluorination (etching) of fluoropolymer surfaces
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 (in the formulation/mixture) ☒No (in the etched products) ☐Unclear ☐Not relevant
Number of workers exposed per site (or total for all sites)	Directly: 8 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 used by applicant for risk characterisation	Workers: Inhalation: 0.47 mg/m³ (RCR 0.279) Dermal: 6.96×10^{-3} mg/kg bw/day (RCR 0.029)[2] Humans via environment: Inhalation: 1.83×10^{-6} mg/m³ Dermal: - Oral: 4.77×10^{-5} mg/kg bw/day

[2] This value for dermal exposure corresponds to the estimate of the worker scenario with the highest combined risk (production worker 2). The highest dermal exposure value is found in the combined assessment for production worker 3, i.e. 0.037 mg/kg bw/day (RCR 0.156).

	Environment: Air: 2.4 kg/year (0.012%) Water: 0.8 kg/year Soil: -
Risk Characterisation	Workers: RCR 0.308 Humans via environment: 1.83 x 10^{-6} mg/m³ (inhalation) 4.77 x 10^{-5} mg/kg_{bw}/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 in Ireland; potential relocation outside the EU
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	applicant expects that after relocation no profit losses will be incurred
Society's benefits of continued use	€0.2-2 million
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	Permanent loss of 8 jobs in the EU, evaluated at €0.4-4 million

SUMMARY OF RAC AND SEAC CONCLUSIONS[3]

1. Operational Conditions and Risk Management Measures

1.1. Conclusions of RAC

Conclusion for workers

The applicant follows the hierarchy of control principles in controlling the risks for workers. This is achieved by use of containment, including robotic handling equipment, pump transfer systems, enclosed booths with local exhaust ventilation (LEV) for filling operations etc.) and LEV at the point of use for all transfer and sampling 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.

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

[3] The numbering of the sections below corresponds to the numbers of the relevant sections in the Justifications.

2. Exposure Assessment

Exposure level used by RAC for risk characterisation:

Workers: highest level of individual, shift-long exposure[4]

- Inhalation: 0.47 mg/m³
- Dermal: 3.74×10^{-2} mg/kg bw/day

Humans via environment

- Inhalation: 1.83×10^{-6} mg/m³
- Dermal: -
- Oral: 4.77×10^{-5} mg/kg bw/day

Releases to the environmental compartments

- Air: 2.4 kg/year
- Water: 0.8 kg/year
- Soil: 0 kg/year

Conclusions of RAC

The exposure assessments are based on measurement data, both for workers (inhalation and dermal measurements) and the environment (air emission monitoring and wastewater concentration measurements and mass balance calculations).

In case of the worker exposure measurements, the presented data are considered reliable for air monitoring. For dermal measurements the data is considered to be less reliable , as the sampling strategy applied is not suited for volatile (and easily absorbed) substances such as diglyme.

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.

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 were engineering controls (semi-closed processes or LEV) in place. Additional protection for workers was provided by personal protective equipment (RPE, gloves, protective clothing).

However, the applicant undertook significant efforts to improve the RMMs and OCs in accordance with the hierarchy of control principle and was able to demonstrate the effectiveness of the measures with the available air monitoring data. It is therefore plausible to assume that the same measures (closed systems, robotic handling) that are effective for reducing inhalation exposure are also effective in controlling dermal exposure. This is also

[4] 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

supported by the modelling data for dermal exposure.

Does RAC propose additional conditions[5] related to exposure assessment for the authorisation?

☐Yes ☒No

Does RAC propose monitoring arrangements[6] 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: 0.308 (combined inhalation and dermal)

Humans via environment: 5.9×10^{-4}

Conclusions of RAC

Overall, the risk characterisation is plausible and robust.

RAC concludes that:

- The highest calculated RCR for workers for one WCS is 0.095 (WCS 5).
- The highest calculated combined RCR for workers is 0.308 (for Production Worker 2 – Etching).
- 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.

[5] 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.
[6] 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.

4. Analysis of alternatives and substitution plan[7]

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

10-20 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)?

☐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

[7] 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*".

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

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 actions 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), hereafter Acton, 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 of the Diglyme mixture as well as the use of the Diglyme mixture by the applicant itself in its own, on-site, etching processes (Use 1) and by two regular Downstream users (Use 2) to whom Acton supplies the Diglyme mixture.

The applicant indicates that the foreseen annual tonnage of diglyme is 10-20 tonnes per year (the actual figure is claimed confidential but known to RAC/SEAC).

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

Table 1: Contributing Scenarios presented in the Use

Contributing scenario	ERC / PROC	Name of the contributing scenario
ECS 1	ERC 4	Use of diglyme as a carrier solvent in the formulation and use of FSS etchant
WCS 1[8]	PROC 3	Formulation: Addition of components to FSS reaction vessel
WCS 2	PROC 1	Formulation: Formulation of FSS etchant
WCS 3	PROC 3	Formulation: Bottling of FSS
WCS 4	PROC 3	Batch Etching: Filling of etchant reservoir
WCS 5	PROC 1	Batch Etching – Robotic Handling
WCS 6	PROC 3	Continuous Etching: Filling of etchant reservoir
WCS 7	PROC 1	Continuous Etching: Operation of tubeline etching
WCS 8	Background operations at site	N/A: No direct exposure
WCS 9	PROC 3	Cleaning of Etchant Reservoir
WCS 10	Background operations in office	N/A: No direct exposure

[8] The applicant starts with ECS1 and then begins the WCS with WCS 2, in this document the WCS are numbered starting with 1.

WCS 1: Addition of components to FSS reaction vessel

Diglyme is pumped from a drum into the FSS formulation reactor via a charging lance within an enclosed booth which is under Local Exhaust Ventilation (LEV). The operator holds the wand handle outside the enclosed booth and there is no dermal contact with diglyme foreseen during normal operations. Sodium naphthalide is manually added to the reactor (in 5 kg bags) under an LEV via an open manway under nitrogen blanketing.

WCS 2: Formulation of FSS etchant

The manway is then closed, and the reaction mixture automatically stirred until all sodium naphthalide is dissolved (within approx. 2 hours). The reaction vessel is sealed and under nitrogen inertion during the mixing, with no potential for exposure.

WCS 3: Bottling of FSS

After completion of the formulation, the etchant is discharged from the reaction vessel into plastic bottles with a volume of 4 litres. The operator inserts the empty plastic bottles into the enclosed booth (equipped with LEV). The operator closes the enclosure door and operates a handle that controls the flow of FSS from outside the enclosure. When the bottle is filled, the operator turns off the flow of FSS from outside of the enclosure, opens the door and removes the filled plastic bottle. This action is repeated until the formulation tank is empty.

WCS 4: Filling of etchant reservoir

The transfer happens within an enclosed booth under LEV. The operator holds a wand handle outside the enclosure, avoiding dermal contact with diglyme during normal operations.

WCS 5: Robotic batch etching process

The batch etching runs in a fully enclosed process where the need for manual operation and the reliance on respiratory protection that was previously required has been eliminated. The automated line performs the etching, rinsing, and water washing processes while the operator monitors the process from outside the enclosure. The enclosure is under LEV. The door cannot be opened until all etching and washing is complete.

WCS 6: Continuous Etching: Filling of etchant reservoir

This operation involves the continuous feeding of fluoropolymer tubing through sequential troughs containing the FSS etchant and methanol wash. The first task is the filling of the 4 litre FSS reservoir and transfer of FSS to etchant bath via a pump transfer enclosure, with the same specifications as detailed in WCS 4.

WCS 7: Continuous Etching: Operation of tubeline etching

This operation involves the continuous feeding of fluoropolymer tubing through baths containing the heated FSS etching liquid. The etchant bath is enclosed during the operation of

this line.

WCS 8: Background Production

This WCS relates to any potential background concentration of diglyme in the production area that may arise from fugitive emissions and in areas of the site where diglyme is not used directly. PPE is not worn, however dermal protection equipment is worn when the worker is in contact with equipment / surfaces, irrespective of previous contact with diglyme or FSS solution.

WCS 9: Cleaning / Emptying of FSS Reservoir (PROC 3)

The process involves a pump transfer of FSS into an empty drum within the moveable LEV enclosure described in WSC1. The operator inserts the charging lance into the empty drum by moving the wand into position from outside the enclosure.

WCS 10: Background Office (PROC 1)

This WCS relates to the background concentration of diglyme in the office area. The work carried out at this location is standard office administrative work and there is no handling or use of diglyme or the etchant.

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, because 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 need 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

The applicant itself uses diglyme primarily for the etching of gaskets for automotive clients

and sells the etchant to Downstream Users (10-100) for R&D purposes, two of the downstream users utilise the product in commercial processes for the manufacture and supply of etched products to the medical devices, aerospace, electronics, and automotive sectors.

1. Operational Conditions and Risk Management Measures

1.1. Workers

The applicant (Acton Technologies Ltd) confirms, in their application, to follow the hierarchy of control principle in controlling the risks for workers handling diglyme. This is achieved using containment (including robotic handling equipment, pump transfer systems, enclosed booths with LEV for filling operations etc.) and LEV at points of use for all transfer and sampling 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 that was provided by the applicant.

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)**+ effectiveness as stated by the applicant**	**PPE** (RPE and Skin protection used) **+ effectiveness as stated by the applicant**	**Organisational controls** (access control, procedures, training)
WCS 1[9] Addition of components to FSS reaction vessel PROC: 3	100 %	10 mins per batch; 2 batches per week	Diglyme pumped into the reaction vessel via a lance inserted into the diglyme drum. Charging takes place in an enclosed pump transfer station operating under LEV	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) Respiratory protection: 3M	Training Manuals for operation available OH monitoring of production worker (PW) completed

[9] The applicant starts with ECS1 and then begins the WCS with WCS 2, in this document the WCS are numbered starting with 1.

			Dissolution takes place in a nitrogen purged sealed vessel Nitrogen blanketing and purge through vessel headspace during mixing Basic general ventilation (1-3 air changes per hour)	Versaflo Jupiter fan unit with an M-100 series face shield – classed as TH2. (APF:20)	
WCS 2 Formulation of FSS etchant PROC: 1	90 %	2 hours per batch; 2 batches per week	Closed system (minimal contact during routine operations) Dissolution takes place in a nitrogen purged sealed vessel	N/A – closed system	The hierarchy of control is used Training Manuals for operation available
WCS 3 Bottling of FSS PROC: 3	90 %	45 mins per batch; 2 batches per week	Bottling takes place in an enclosed pump transfer station operating under LEV 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) Respiratory protection: 3M Versaflo Jupiter fan unit with an M-100 series face shield – classed as TH2. (APF:20)	The hierarchy of control is used Training Manuals for operation available OH monitoring of (PW) completed
WCS 4	90 %	15 mins per	Transfer	Dermal	The hierarchy of

Batch etching: Filling of etchant reservoir PROC: 3		batch; 1 batch per month	happens within the LEV enclosure Basic general ventilation (1-3 air changes per hour)	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) Respiratory protection: 3M Versaflo Jupiter fan unit with an M-100 series face shield – classed as TH2. (APF:20)	control is used Training Manuals for operation available OH monitoring of (PW) completed
WCS 5 Batch etching: Robotic handling PROC: 1	90 %	≤ 5 hours per day	Closed system (minimal contact during routine operations) The etching process is controlled by a robotic handling system	N/A – closed system	The hierarchy of control is used Training Manuals for operation available OH monitoring of (PW) completed
WCS 6 Continuous etching: Filling of etchant reservoir PROC: 3	90 %	1 min per batch; 1-2 fills per month	Transfer happens within the LEV enclosure 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) Respiratory protection: 3M Versaflo Jupiter fan unit	The hierarchy of control is used Training Manuals for operation available OH monitoring of (PW) completed

				with an M-100 series face shield – classed as TH2. (APF:20)	
WCS 7 Continuous Etching: Operation of tubeline etching PROC: 1	90 %	1 min per day 1-2 days per month	Closed system (minimal contact during routine operations) LEV in operation. Primary and secondary containment	N/A – closed system	The hierarchy of control is used Training Manuals for operation available
WCS 8 Background operations at site PROC: N/A	N/A	8 hours per day	N/A: No direct exposure	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) Worn if coming into contact with any equipment	N/A: No direct exposure
WCS 9 Cleaning of etchant reservoir PROC: 3	90 %	15 mins per event; 6 events per year	Emptying takes place in an enclosed pump transfer station operating under LEV 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) Respiratory protection: 3M Versaflo Jupiter fan unit	The hierarchy of control is used Training Manuals for operation available OH monitoring of (PW) completed

				with an M-100 series face shield – classed as TH2. (APF:20)	
WCS 10 Background operations in office PROC: N/A	N/A	8 hours per day	N/A: No direct exposure	N/A	N/A: No direct exposure
**If changing through the process*					

Since February 2016, and their initial application for authorisation, Acton made significant engineering advances and investments to ensure that risks involved in the use of diglyme is adequately controlled. These improvements (described in the CSR for the current application) include the following new engineering controls:

- Use of containment (i.e. fully enclosed robotic handling equipment line has replaced the manual batch etching process with fixed piping for the recirculation of the FSS)
- Use of upgraded local exhaust ventilation (LEV), (via enclosed booths or flexible ducting at the point of use for all transfer and sampling operations)
- Carbon filter on process air extraction system (applies to ERC 1)
- Utilization of pump transfer systems (previously manual transfers have been converted to pump transfers)

Administrative / procedural controls that were introduced after the previous application for authorisation include:

- Limiting the amount of time a worker is exposed to diglyme during the individual WCS
- Employee training (conducted annually)
- Comprehensive induction training for any new staff hires
- Full Health and Safety Compliance and Risk Assessment Audit (at least every three years by an external Health and Safety professional services firm)

Personal protective equipment (PPE): workers are required to wear protective clothing for specific contributing scenarios:

- Fit tested respiratory protection (e.g. 3M Versaflo Jupiter fan unit with an M-100 series face shield, designed to standard EN 12941 TH2)
- Dermal protection (e.g. a combination of a Linear Low Density Polyethylene (LLDPE) liner under chemical resistant butyl rubber glove with a breakthrough time > 480 mins)
- Goggles

As far as the etching processes are run in the fully enclosed robotic line, neither dermal nor inhalation exposure is to be expected and no RPE is needed to achieve adequate control of inhalation exposure.

1.2. Environment/Humans via Environment

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

Air

Emissions from the air extraction system are filtered via activated carbon before it is released into the atmosphere.

Water

According to the applicant all process water is contained and shipped off site for treatment in municipal WWTP.

Soil

There is no release to soil expected.

Waste

All other solid waste removed and disposed of by licenced waste contractors.

Table 3: Environmental RMMs - summary

Compartment	RMM	Stated Effectiveness
Air	LEV exhaust vented to the atmosphere via carbon filter	99.98 % (based on measured emissions)
Water	All process water collected and tanked to local sewage treatment plant	100 % to sewer
Soil	All other solid waste removed and disposed of by licenced waste contractors	No release to soil

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.

Releases rates into environment used for modelling, were calculated based on mass balances and on monitoring results of air emissions and measured concentration in wastewater.

Distribution in the environment and concentrations relevant for secondary exposure of humans (oral and inhalation) were calculated using conventional algorithms (EUSES 2.1.2).

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

The applicant describes the use of closed systems (where possible) and LEV wherever release

of diglyme is expected. The exhaust air is filtered over carbon before being vented into the atmosphere. Provided that the carbon is regularly regenerated or exchanged before its absorption capacity is reached, the stated effectiveness of the RMMs can be assumed.

However, the number of measurement data provided by the applicant is rather limited for the situation after implementation of closed systems and improved RMMs. Acton stated that "due to socio-economic issues and the current Covid-19 pandemic the monitoring schedule in Q1 and Q2 2020 was impacted".

1.4. Conclusions on OCs and RMMs

The applicant follows the hierarchy of control principle in controlling the risks for workers. This is achieved by use of containment (including robotic handling equipment, pump transfer systems, enclosed booths with LEV for filling operations etc.) and LEV at the point of use for all transfer and sampling 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.

Comparison of the monitoring data provided before and after upgrading and extending the RMMs (i.e. installation of closed systems and a robotic handling for batch etching) show that the exposure levels were effectively minimized. The OCs and RMMs in place at Acton therefore are appropriate and effective in limiting the risk for workers and humans via the environment. (Consumer and environment exposure are not relevant in this case).

Overall conclusion

Are the operational conditions and risk management measures appropriate[10] and effective[11] 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 monitoring arrangements for authorisation presented in section 8.

[10] 'Appropriateness' – relates to the following of the principles of the hierarchy of controls in application of RMMs and compliance with the relevant legislation.
[11] '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. Exposure assessment

2.1. Inhalation exposure

Monitoring

The applicant provided air monitoring data, both static and personal, recorded between September 2015 (before) and October 2019 (after the installation of further RMMs; see above), Overall 37 personal and 11 static measurement data were submitted in the Annex of the CSR for Use 1. However, only the data from the latest measurement campaign (from October 2019) were used by the applicant for the exposure assessment as they reflect the situation after the upgrade and implementation of further RMMs. This dataset, consisting of only four personal (2 × Etching and Rinse, 1 × Formulation and bottling, and 1 × Maintenance) and two static measurements (Lobby and Production (background)), is rather limited. As these work situations consist of several WCSs, the exposure values for the individual WCSs were derived from the highest concentration measured and calculated by adjusting these exposure values to the duration of the WCS.

As can be seen from the exposure data in Annex I, the monitoring values presented in this Application are systematically lower than those presented in the first Application. In both cases, the assessments of inhalation exposure were based on measurement data supported by modelling. Based on the measurement data, the applicant was able to demonstrate that the changes in OCs and RMMs taken (upgraded LEV, enclosed pump transfer system, enclosed robotic handling system) are effective in significantly reducing the inhalation workplace exposure to diglyme.

Modelling

In the 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.

2.2. Dermal exposure

Modelling

The applicant modelled dermal exposures with ECETOC TRA Worker v3. In the initial CSR the modelled data was only used to support the dermal measurement data. As RAC is of the opinion that the dermal measurement (sampling) method applied is not suited for volatile substances, 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 large uncertainties, but the approach taken in the revised version seems plausible within the domain of the model.

Monitoring

The applicant based the dermal exposure assessment in the current application for authorisation initially on monitoring data. However, in the opinion of RAC the first chosen sampling method was 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)).[12] 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.

To overcome the shortcomings of the first measurement method (see above) the applicant developed with third party monitoring consultants and accredited laboratories a new protocol to perform patch testing for dermal exposure measurements. In this approach, the worker wears a charcoal patch (SKC Permatec pads for solvents) on the palm of the hand (in the glove) for 60 minutes while the worker is conducting normal duties. The patch supposedly absorbs any substance that permeates the glove and is then sealed into VOC vials and transported to be tested by an accredited laboratory to determine diglyme concentration. This sampling methodology follows the OSHA online technical manual for Surface Contaminants, Skin Exposure, Biological Monitoring and Other Analyses, Section II, Chapter 2, subsection III (d) which recommends sorbent type 'dosimeter' skin patches. The applicant carried out overall four dermal measurements following this approach on 13/10/2020. For all samples, the measured concentration of diglyme was below the limit of quantification of 0.0018 mg/kg bw/day.

In the opinion of RAC, this patch method is much more suitable for the measurement of dermal exposure to diglyme than the first method adopted from Fenske, R. A. et al. (1999). As it is plausible to assume that activated carbon would absorb diglyme effectively, this allows assessing the exposure of at least of the region of skin where the patch is placed, which overall lowers the uncertainties of the assessment. On the other hand, to the best of knowledge of RAC, the adopted patch method has not been validated yet and therefore some uncertainties of this method remain.

However, in addition to the dermal measurements 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.

The dermal exposure estimates in the first application for authorisation were based on modelling (CHESAR 2 and RISKofDERM). In the current application for authorisation the applicant provided dermal measurement data (with limited explanatory power, see below) and modelled estimates (ECETOC TRA worker).

[12] 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.

2.3. Biomonitoring

Biomonitoring was not carried out in the current assessment of the applicant. However, in the opinion of RAC biomonitoring[13] would be a viable option (if not the only suitable one) to access the total exposure to diglyme including the impact of dermal exposures, in a robust manner.

Table 4: Exposure – dermal and inhalation

Contributing scenario	Route of exposure	Method of assessment	Exposure value (8h TWA)	Exposure value corrected for PPE	Exposure value corrected for PPE and frequency and duration*
WCS 1 Addition of components to FSS reaction vessel	Inhalation	measurement [modelling]	0.01 mg/m³	0.01 mg/m³	3.13×10^{-4} mg/m³ (0.25 hours per day) [8.39×10^{-3} mg/m³]
	Dermal	measurement [modelling]	1.8×10^{-3} mg/kg bw/day * [3.45×10^{-3} mg/kg bw/day]	[3.45×10^{-3} mg/kg bw/day]	[3.45×10^{-3} mg/kg bw/day]
	Biomonitoring	N/A			
WCS 2 Formulation of FSS etchant	Inhalation	measurement [modelling]	0.13 mg/m³	0.13 mg/m³	3.25×10^{-2} mg/m³ (2.0 hours per day) [3.4×10^{-2} mg/m³]
	Dermal	measurement [modelling]	1.8×10^{-3} mg/kg bw/day * [1.02×10^{-3} mg/kg bw/day]	[1.02×10^{-3} mg/kg bw/day]	
	Biomonitoring	N/A			
WCS 3 Bottling of FSS	Inhalation	measurement [modelling]	<0.13 mg/m³	0.01 mg/m³	5.63×10^{-4} (0.75 hours per day) [1.7×10^{-2} mg/m³]
	Dermal	measurement [modelling]	1.8×10^{-3} mg/kg bw/day * [3.45×10^{-3} mg/kg bw/day]	[3.45×10^{-3} mg/kg bw/day]	

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

	Biomonitoring	N/A			
WCS 4 Batch etching: Filling of etchant reservoir	Inhalation	measurement [modelling]	0.217 mg/m³	0.217 mg/m³	6.78×10^{-3} mg/m³ (0.25 hours per day) [8.39×10^{-3} mg/m³]
	Dermal	measurement [modelling]	1.8×10^{-3} mg/kg bw/day * [3.45×10^{-3} mg/kg bw/day]	[3.45×10^{-3} mg/kg bw/day]	
	Biomonitoring	N/A			
WCS 5 Batch Etching – Robotic Handling	Inhalation	measurement [modelling]	0.217 mg/m³	0.217 mg/m³	0.136 mg/m³ (5.0 hours per day) [5.6×10^{-2} mg/m³]
	Dermal	measurement [modelling]	1.8×10^{-3} mg/kg bw/day * [3.45×10^{-3} mg/kg bw/day]	[3.45×10^{-3} mg/kg bw/day]	
	Biomonitoring	N/A			
WCS 6 Continuous Etching: Filling of etchant reservoir	Inhalation	measurement [modelling]	0.01 mg/m³	0.01 mg/m³	3.20×10^{-4} mg/m³ (0.25 hours per day) [8.39×10^{-3} mg/m³]
	Dermal	measurement [modelling]	1.8×10^{-3} mg/kg bw/day * [3.45×10^{-3} mg/kg bw/day]	[3.45×10^{-3} mg/kg bw/day]	
	Biomonitoring	N/A			
WCS 7 Continuous Etching: Operation of tubeline etching	Inhalation	measurement [modelling]	0.01 mg/m³	0.01 mg/m³	3.20×10^{-4} mg/m³ (0.25 hours per day) [5.59×10^{-3} mg/m³]
	Dermal	measurement [modelling]	1.8×10^{-3} mg/kg bw/day * [1.7×10^{-3} mg/kg bw/day]	[1.7×10^{-3} mg/kg bw/day]	
	Biomonitoring	N/A			
WCS 8 Background operations at site	Inhalation	measurement [modelling]	0.21 mg/m³	0.21 mg/m³	0.122-0.25 mg/m³ (4.75-9.75 hours per day) [5.6×10^{-2} mg/m³]
	Dermal	measurement	1.8×10^{-3}	[3.45×10^{-3}	

		[modelling]	mg/kg bw/day * [3.45 × 10^{-3} mg/kg bw/day]	mg/kg bw/day]	
	Biomonitoring	N/A			
WCS 9 Cleaning of Etchant Reservoir	Inhalation	measurement [modelling]	0.086 mg/m³	0.086 mg/m³	2.69 × 10^{-3} mg/m³ (0.25 hours per day) [8.39 × 10^{-3} mg/m³]
	Dermal	measurement [modelling]	1.8 × 10^{-3} mg/kg bw/day * [3.45 × 10^{-3} mg/kg bw/day]	[3.45 × 10^{-3} mg/kg bw/day]	
	Biomonitoring	N/A			
WCS 10 Background operations in office	Inhalation	measurement [modelling]	0.06 mg/m³	0.06 mg/m³	3.88 × 10^{-2} mg/m³ (5.0 hours per day) [5.6 × 10^{-2} mg/m³]
	Dermal	measurement [modelling]	1.8 × 10^{-3} mg/kg bw/day * [3.40 × 10^{-2} mg/kg bw/day]	[3.40 × 10^{-2} mg/kg bw/day]**	
	Biomonitoring	N/A			

**dermal measured values for all measured values are all below LOD of 0.0018 mg/kg/bw/day*

*** The modelled dermal exposure is highest for office workers (WCS 10) because gloves are not considered for this activity, while for all other WCSs gloves are taken into account with a protective efficiency of 95 %. The modelled level of dermal exposure for office workers is therefore likely to overestimate the actual exposure, as no diglyme should be present at all in the office area.*

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

In the first application for authorisation for the use of diglyme submitted by Acton Technologies Ltd the applicant calculated three different combinations of WCS for production workers (PW). In the current application for authorisation the combined exposure assessment also covers three types of production worker, but further differentiation is made for combined tasks for PW1 and PW2. The resulting exposure values from the current application for authorisation are systematically lower than those presented in the first application for authorisation. The full comparison can be found in in the table below and in Annex I.

Table 5: 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)**
PW1	1+2+3+ 7+8+9*	inhalation	0.462 mg/m³	1+2+ 3+8** (Formulation)	inhalation	0.25 mg/m³
		dermal	1.818 mg/kg bw/day		dermal	0.0113 mg/kg bw/day
				6+7+8** (Etching)	inhalation	0.24 mg/m³
					dermal	0.0103 mg/kg bw/day
PW2	4+5+ 6+9*	inhalation	0.726 mg/m³	4+5+8** (Etching)	inhalation	0.47 mg/m³
		dermal	0.707 mg/kg bw/day		dermal	0.00696 mg/kg bw/day
				9+8** (Cleaning and maintenance)	inhalation	0.25 mg/m³
					dermal	0.00696 mg/kg bw/day
PW3	9+10*	inhalation	0.463 mg/m³	8+10**	inhalation	0.17 mg/m³
		dermal	-		dermal	0.0374 mg/kg bw/day
* *As assigned in first application for authorisation* ** *As assigned in the current application for authorisation*						

Table 5 clearly demonstrates that the exposure values in the second application are systematically lower than those presented in the first application for authorisation. In both

cases (i.e. the application for authorisation submitted in 2016 and the current one) estimates of inhalation exposures are based on measurement data supported by modelling, therefore supposed to reflect the workplace situations more accurately than only modelled data. The dermal exposure estimates in the first application for authorisation were based on modelling (CHESAR 2 and RISKofDERM). In the current application for authorisation the applicant provided dermal measurement data and modelled estimates (ECETOC TRA worker). Based on the measurement data the applicant was able to demonstrate that the changes in OCs and RMMs taken (upgraded LEV, enclosed pump transfer system, enclosed robotic handling system) are effective in reducing the dermal workplace exposure to diglyme significantly.

2.4. Environmental exposure

Water

The exposure assessment is based on measurement of the concentration of diglyme in the wastewater and the amount of wastewater. All process water and in-factory drains are diverted to an underground storage tank. The process water is sent off-site for treatment via municipal wastewater treatment plant (MWWTP) when the tank reaches a water volume of 20 m³. The process water that is sent for treatment at the MWWTP was tested to determine the concentration of diglyme in aqueous waste.

Air

Emissions of diglyme to air have been measured. Local exhaust ventilation (LEV) is in operation at the site. Since March 2019 exhaust air from the LEV is processed through a carbon filter and then released to the atmosphere.

Soil

No local release to soil is expected and was not further taken into account for the assessment.

Table 6: Summary of environmental emissions

Release route	Release factor	Release per year (tonnes or kilograms)	Release estimation method and details
Water	4×10^{-2} kg/day	7.04 kg	Measured release rate based on concentration in process water and amount of wastewater sent for treatment in MWWTP.
Air	0.12 kg/day	19.1	Measured release rate based on overall air emissions.
Soil	No release to soil	Not relevant	Not relevant
Waste	30 % as per mass balance	Not relevant	Not relevant

Table 7: Summary of indirect exposure to the environment[14] and humans via the environment

Parameter	Local	Regional
PEC in air (mg/m^3)	1.83 × 10^{-6} mg/m³	7.27 × 10^{-11} mg/m³
PEC in surface water (mg/L)	Not applicable	Not applicable
Daily dose via oral route (mg/kg bw/d)	4.77 × 10^{-5} mg/kg bw/day	Not applicable

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

Workers exposure

The workers exposure assessment is based on measurement data, both for inhalation and dermal exposures. The applicant provided air monitoring data covering the period from September 2015 to October 2019. The applicant undertook significant efforts in upgrading and installing further RMMs (closed systems, enhanced LEV, robotic handling system) in 2019 and therefore only measurement data since the introduction of the robotic handling system were used for the exposure and risk assessments, i.e. from October 2019. As there is only little measurement data for this period of time (four personal and two static measurements), 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 without specific modifications to adjust to the properties of diglyme. 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. 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. However, as the air monitoring data clearly demonstrates the effectiveness of the newly installed engineering RMMs (enclosures, robotic handling, enhanced LEV), RAC considers it reasonable to assume that also dermal exposures are controlled by these measures as by closed systems and robotic handling dermal contact is avoided. As a precautionary measure, workers also wear protective gloves whenever carrying out operations involving diglyme.

Humans via the environment

Release rates into the environment are based on measurement data of emissions or

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

concentrations in wastewater and mass balances. Distribution in the environment and concentrations relevant for secondary exposure of humans (oral and inhalation) were calculated using conventional algorithms (EUSES 2.1.2) and seem plausible. However the exposure assessment is supported by only one point of measurement data.

2.6. Conclusions on exposure assessment

The exposure assessments are mostly based on measurement data. In case of worker air monitoring data, the approach taken seems reasonable, but not so for the dermal measurements, 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. However, the applicant underwent significant efforts to improve the RMMs and OCs in accordance with the hierarchy of control principle and is able to demonstrate the effectiveness of the measures with air monitoring data. It is therefore plausible to assume that the same measures (closed systems, robotic handling) effective for reducing inhalation exposure are also effective in controlling dermal exposure, as it is supported by the modelling data.

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 RAC 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 8: Combined exposure and risk characterisation

Contributing scenario	Route	Exposure value corrected for PPE and frequency	RCR	
				Combined
WCS 1	Inhalation	3.13×10^{-4} mg/m³	< 0.01	0.01
	Dermal	1.44×10^{-2} mg/kg bw/day	0.01	
WCS 2	Inhalation	3.25×10^{-2} mg/m³	< 0.01	< 0.01
	Dermal	4.25×10^{-3} mg/kg bw/day	< 0.01	
WCS 3	Inhalation	5.63×10^{-4} mg/m³	< 0.01	0.01
	Dermal	1.44×10^{-2} mg/kg bw/day	0.01	
WCS 4	Inhalation	4.04×10^{-3} mg/m³	< 0.01	0.01
	Dermal	1.44×10^{-2} mg/kg bw/day	0.01	
WCS 5	Inhalation	0.136 mg/m³	0.081	0.095
	Dermal	1.44×10^{-2} mg/kg bw/day	0.01	
WCS 6	Inhalation	3.2×10^{-4} mg/m³	< 0.01	0.01
	Dermal	1.44×10^{-2} mg/kg bw/day	0.01	

WCS 7	Inhalation	3.2×10^{-4} mg/m³	< 0.01	< 0.01
	Dermal	7.08×10^{-3} mg/kg bw/day	< 0.01	
WCS 8	Inhalation	0.122-0.25 mg/m³	0.073-0.149	See combined RCRs
	Dermal	1.44×10^{-2} mg/kg bw/day	0.01	
WCS 9	Inhalation	2.69×10^{-3} mg/m³	< 0.01	0.01
	Dermal	1.44×10^{-2} mg/kg bw/day	0.01	
WCS 10	Inhalation	0.039 mg/m³	0.023	0.03
	Dermal	1.44×10^{-2} mg/kg bw/day	0.01	

Table 9: Combined exposure and risk characterisation for production workers

Contributing scenario	**Route**	**Exposure value corrected for PPE and frequency**	**RCR**	
				Combined
WCS 1 + WCS 2 + WCS 3 + WCS 8 (PW1-Formulation)	Inhalation	0.25 mg/m³	0.148	0.196
	Dermal	1.13×10^{-2} mg/kg bw/day	0.047	
WCS 6 + WCS 7 + WCS 8 (PW1-Etching)	Inhalation	0.24 mg/m³	0.145	0.188
	Dermal	1.03×10^{-2} mg/kg bw/day	0.043	
WCS 4 + WCS 5 + WCS 8 (PW2-Etching)	Inhalation	0.47 mg/m³	**0.279**	**0.308**
	Dermal	6.96×10^{-3} mg/kg bw/day	**0.029**	
WCS 9 + WCS 8 (PW2-Cleaning and Maintenance)	Inhalation	0.25 mg/m³	0.150	0.179
	Dermal	6.96×10^{-3} mg/kg bw/day	0.029	
WCS 8 + WCS 10 (PW3)	Inhalation	0.17 mg/m³	0.099	0.055
	Dermal	3.74×10^{-2} mg/kg bw/day	0.156	
Highest total exposure for 8 hours	**Inhalation**	0.47 mg/m³	**0.279**	**0.308**
	Dermal	6.96×10^{-3} mg/kg bw/day	**0.029**	

The applicant identified three different categories of worker exposure by the tasks carried out in combination by different members of the workforce:

Production Worker 1 (PW1): One worker works on Formulation (WCS1, WCS2 and WCS3), Continuous Etching (WCS6 and WCS 7), and general production areas (WCS8). These work streams are never carried out on the same day.

Production Worker 2 (PW2): Two workers work on batch etching (WCS4 and WCS5), cleaning and Maintenance (WCS 9) and in general production areas (WCS8).

Production Worker 3 (PW3): This production worker is the office manager (one person) who works in the general production (WC8), and the reception / front office (WCS10).

PW1 and PW2 were split between their two workstreams, as the different routines will not be carried out on the same day and therefore the exposures from these were not combined when assessing daily exposure.

Using the conservative daily RCR (i.e. the highest combined RCR as shown above) it is demonstrated that the applicant adequately controls the use of Diglyme as the RCR is below 1.

3.2. Humans via Environment

The risk assessment for Humans via Environment includes the excess risks on the regional scale only as local exposure via the environment were not seen as relevant by the applicant as no widespread uses are covered in the CSR. As the modelled emission estimates are supported by measurement data the assessment appears reasonable.

Table 10: 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	1.83×10^{-6} mg/m³	6.1×10^{-5}	7.27×10^{-11} mg/m³	2.42×10^{-10}
Human via Environment – Oral	4.77×10^{-5} mg/kg bw/day	5.3×10^{-4}	N/A	N/A
Human via Environment - Combined		5.9×10^{-4}	7.27×10^{-11} mg/m³	2.42×10^{-10}

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

As the measurement data basis for the exposure assessment is limited (only few measurement data for a short period of time) this also affects the quality and robustness of the risk assessment. On the other hand, comparison of the measurement data before and after improvements of the RMMs and OCs (i.e. after installation of a closed robotic handling system and enhanced LEV) clearly demonstrate the effectiveness of the measures taken. Overall, the shortcomings or uncertainties in the risk characterisation are considered to be low.

3.5. Conclusions on risk characterisation

Overall, the risk characterisation is plausible and robust.

RAC concludes that:

- The highest calculated risk for workers for one WCS is 0.095 (WCS 5).
- The highest calculated combined risk for workers is 0.308 (for Production Worker 2 – Etching).
- 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[15]

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

The applicant indicates that the foreseen annual tonnage of diglyme is 10-20 tonnes per year (the actual figure is claimed confidential but known to RAC/SEAC).

All purchased diglyme is formulated into the FluoroEtch Safety Solvent (FSS) which is used both for internal custom etching applications (Use 1); another part of the formulation is sold by Acton to downstream users within and outside the EU (Use 2).

Less than 10 tonnes are used by DU 1, less than 2.5 tonnes are used by DU 2

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.

[15] 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*".

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[16], have concluded that although these 2 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 or 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 0.25 mm 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 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:

[16] 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

1. Flame treatment;
2. Corona discharge treatment;
3. Plasma treatment at reduced pressures (LPT);
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:

1. Ability to treat complex tribologies (surfaces with complex interaction of shape, friction and lubrification)
2. Do not produce chemical wastes;
3. Can be modified to deliver specific surface modifications;
4. Can be used to treat heat sensitive materials;
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.

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 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.

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 arisen. 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 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 (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

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)?

☐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. However, 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 installation, 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.

Ammonia-system 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 automotive, 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 up-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 his own plasma treatment system. According to them 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, as 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. One of the possible explanations is the shorter shelf life of the material etched with plasma technology.

Finally, the applicant demonstrates that the operation 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.

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

SEAC considers 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 recognises 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. SEAC furthermore remarks that operating this type of plant would require a completely different type of professional skill and industrial structure.

SEAC points out that no R&D with experimental tests was conducted on the electrochemical system. The fact that only academic reports exist on this system does not exempt 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 infeasibility 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 sunset date, 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 their customers.

SEAC recognises that the only really promising alternative technique, plasma treatment using LPT technique, has not yet been accepted by customers,.

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

In the substitution plan, 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 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 produced by the 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 an 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 will focus on economic feasibility, this phase aims at investigating the economic and technical feasibility, and comprises of 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.

Part of Acton's customer group also cover medical devices. These customers would therefore have to revalidate their products, an expensive process in both time and money, with a new validation taking years to approve.

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 with 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 companies operating in Acton's downstream supply chain 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 processes including qualification processes in the medical sector which SEAC understands to be of such length that a long year review period could well be justified.

In a similar application for authorisation covering a similar use for authorisation in which

adequate control was demonstrated. SEAC proposed that case a 12-year review period was justified.

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))
- 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 five shortlisted alternative 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 DNELs. Therefore, the application can proceed under the 'adequate control' route. On this basis, the monetised human health impacts for the reprotoxic endpoint are effectively zero.

The applicant has, despite this, provided a break-even analysis, demonstrating that the number of infertility cases that are needed for the monetized risks to exceed the costs of continued use is 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 1 the applicant presented two non-use scenarios:

1. Permanent closure of etchant formulation in Ireland and stop supplying FluoroEtch® Safety Solvent (FSS) to the downstream users (DU 1 and DU2);
2. Relocation of in-house etching operations to outside of the EU and continue to provide etching services to its EEA customers.

The applicant provided a detailed cost analysis of the **relocation** scenario assuming a permanent closure of the etchant formulation activities and all etching operations in Ireland, with etched articles to be imported from Turkey or the US to the European Economic Area.

Since the applicant is already operating a plant in the US with enough space. Construction of a new plant in 2020, a restart of production in the US in 2021 is considered possible. This would allow to the forecasted stream of profits to continue, and to contribute to Acton's strategic business objective of a stable long-term commitment with its customers in the EU.

On request, the applicant clarified that long-term customer relationships in a variety of business sectors leads to a better understanding of the industry and thus drives more effective sales and marketing.

The applicant provides as a worst-case scenario, the **closure** of the etchant formulation business and of in-house etching. Although the profit losses of closure are lower that the profit loss of relocation, the closure scenario was not selected since it does not coincide with the strategic business objectives of long-standing customer relationships.

Furthermore, the applicant expects that closure of etchant formulation and in-house etching processes and to stop supplying the etchant to downstream users DU 1 and DU2 could, have negative impacts on Acton's European operations in terms of reputation and market share.

However, the applicant considered the relocation of its etching operations as the most likely non-use scenario since it already operates a production site in the US with enough space to expand its capacities.

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 8 jobs would be permanently lost in the European Union if the use would cease altogether

Economic impacts of continued use

Economic impacts

The applicant bases his estimate of the direct economic impact of the relocation of the processes of formulation of the etchant and the in-house etching from Ireland to the US on:

- the construction costs of a new plant,
- higher production costs in the US,
- and additional costs for shipment from US to EU.

The applicant states that after relocation the company will continue to supply its European customers from a plant in the USA. The applicant argues that after relocation there will be **no loss of profits** for the applicant, but additional ongoing costs would be expected due to higher production costs in the US, and costs associated with importing and exporting to and from the EU. However, there would also be significant revenues from the sale of assets and land in Ireland which would be used to off-set these costs. SEAC did not scrutinise this further.

Redundancy costs of its employees in Ireland (€0.01-0.1 million), but also income from sale of assets and land in Ireland (€0.01-0.1 million) was taken into account for calculation of the costs of the non-use scenario for Acton. However, redundancy costs and income from asset and land sales represent distributional impacts and cannot be considered as socioeconomic impacts. Since both effects cancel each other out, the applicant's net relocation costs (buildings, set up of robotic system, and services) for Acton in the range €0.2-2 million over the entire requested review period of 12 years (2021-2032; NPV in 2021, discount rate 4 %)[17] were taken forward in the socio-economic assessment.

The downstream user market of Action is dominated by one customer (DU1) with a share of the total EU-sales volume of FluoroEtch® Safety Solvent (FSS) above 50 %[18]. This customer uses FSS mainly for the etching of Polytetrafluoroethylene (PTFE) in the manufacture of medical applications such as catheter liners, artificial tendons and ligaments, blood vessel prosthetics, and vascular grafts. In this growing market it is the main supplier and has a global market share on the guiding catheter market of more than 50 %[19]. 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.

Social impacts related to job losses

For estimating the job losses, the applicant has assumed relocation of etchant formulation and etching activities to US resulting in redundancy of 8 employees at Acton. The job losses correspond to welfare losses in the range €0.2-2 million for Acton[20].

The calculation of social impacts follows the approach outlined in Dubourg (2016)[21] and

[17] Actual costs of relocation are claimed confidential but are known to SEAC.
[18] Actual share of sales is claimed confidential but are known to SEAC.
[19] Actual share is claimed confidential but is 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

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 own and their customers' operations are offering 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 the ability of competitors 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 the EU, Acton's own and the DU's expertise would be lost to the EU, having a negative impact on the competitiveness of the EU industry.

Table 11: Socio-economic benefits of continued use

Description of major impacts	**Quantification of impacts (over the 12 year review 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	After relocation: no loss of profits foreseen by applicant.
1.2 Avoided profit loss due to ceasing the use applied for[23]	Not applicable
1.3 Avoided relocation or closure cost	€0.2-2 million (construction costs, increase in production costs)
1.4 Avoided residual value of capital	Not applicable
1.5 Avoided additional cost for transportation, quality testing, etc.	Not available
Sum of benefits to the applicant and / or their supply chain	€0.2-2 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]	€0.2-2 million

[22] SEAC (2016): https://echa.europa.eu/documents/10162/13555/seac_unemployment_evaluation_en.pdf/af3a487e-65e5-49bb-84a3-2c1bcbc35d25

[23] Profit losses to be counted in only for the first 1 years, 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).

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	€0.2-2 million
3. Aggregated socio-economic benefits (1+2)	€0.4-4 million

Notes:

1. 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 estimates that the quantified economic and social benefits for Acton are €0.4-4 million and outweigh the costs of continued use for human health. The cost for human health is effectively zero since the use is adequately controlled. In terms of wider economic impacts, the applicant states that a refused authorisation would cause loss of expertise in the EU, and be detrimental for competitiveness of the EU industry.

Table 12: 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]	0.2-2	Monetised excess risks to workers directly exposed in the use applied for	the monetised human health impacts for the reprotoxic endpoint are effectively zero
Quantified impacts of the continuation of the SVHC use applied for [€ million over 12 year assessment period]	0.2-2	Monetised excess risks to the general population and indirectly exposed workers	the monetised human health impacts for the reprotoxic end-point are effectively zero
Additional qualitatively assessed impacts	Shortage in supply of PTFE-catheters at least over short-term Loss of expertise in EU	Additional qualitatively assessed risks	Not applicable
Summary of socio-economic benefits [€ million over 12 year assessment period]	**Economic impacts: 0.2-2** **Social impacts: 0.2-2** **Sum: 0.4-4** **Shortage in supply of PTFE-catheters at**	**Summary of excess risk**	**Not applicable**

	least over short-term **Loss of expertise in EU**		

5.4. SEAC's view on Socio-economic analysis

SEAC considers the applicant's most likely non-use scenario of relocation to the US where Acton already operates a production site with sufficient space for capacity expansion plausible. This would allow to continue the long-term relationship with customers in EU and to keep the forecasted future stream of profits. Furthermore, Acton expects negative knock-on impacts of a closure of business on its overall European business operations in terms of reputation and market shares.

The main economic impact considered by the applicant are costs of relocation to the US, consisting mainly of the costs of production capacity expansion in the US. These costs cannot be verified, but it is plausible that costs in the range €0.2-2 million for new buildings and for shipment from US to EU will arise. Since Acton's main customer operates in the medical devices sector, also costs for the process of regulatory re-approval have to be taken into account as welfare costs of the non-use scenario.

The applicant has also provided the quantified costs of the closure of business scenario which lower than the relocation costs as a lower bound of the costs of non-use.

SEAC considers that the most plausible non-use scenario would result in unemployment of 8 of the applicant's workers. The assumption of a longer average duration of unemployment compared with the EU-28 average is plausible, as is the assumed average wage cost for Ireland. 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. The main customer of Acton has claimed to have a market share of above 50 % in the PTFE-based guiding catheter market in the EU. Although no information on production capacities and the dependency of catheter production on diglyme etchants is available, it seems plausible (given the claimed market share), 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 gives no advice regarding the length of 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

N/A

7.2. Justification

RAC concludes that adequate control is demonstrated for this use of Diglyme in case the described OCs and RMMs are adhered to. Therefore, no additional conditions for authorisation are necessary.

8. Proposed monitoring arrangements for the authorisation

Were monitoring arrangements[26] proposed for the authorisation?

☒ Yes

☐ No

8.1. Description

The applicant shall continue air and dermal monitoring activities, given that for dermal monitoring an appropriate method is now available. The applicant shall additionally investigate the feasibility of biomonitoring and 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 applicant 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.

The applicant shall continue its 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.

[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.
[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.

8.2. Justification

Even though the applicant has made major improvements in its management of occupational risks related to the use of diglyme, the applicant has (partly due to unforeseen situations) compiled only a limited set of monitoring data (air and dermal) to base its exposure assessment on. Although the current dataset allows for drawing conclusion on adequate control and indeed support the conclusion that the applicant adequately controls 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 the 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 section 8.1 must be included in any subsequent authorisation review report submitted

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 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	DU1	N/A

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

	environment		
Du 2	Adequate control demonstrated for workers, adequate control demonstrated for humans via the environment	N/A	Discontinued use of Acton's product
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)

	First application for authorisation (2016)			Current application for authorisation		
	WCS combined	**Route of exposure**	**Exposure value (8h TWA)**	**WCS combined**	**Route of exposure**	**Exposure value (8h TWA)**
PW1	1+2+3+ 7+8+9*	inhalation	0.462 mg/m³	1+2+ 3+8** (Formulation)	inhalation	0.25 mg/m³
		dermal	1.818 mg/kg bw/day		dermal	0.0113 mg/kg bw/day
				6+7+8** (Etching)	inhalation	0.24 mg/m³
					dermal	0.0103 mg/kg bw/day
PW2	4+5+ 6+9*	inhalation	0.726 mg/m³	4+5+8** (Etching)	inhalation	0.47 mg/m³
		dermal	0.707 mg/kg bw/day		dermal	0.00696 mg/kg bw/day
				9+8** (Cleaning and maintenance)	inhalation	0.25 mg/m³
					dermal	0.00696 mg/kg bw/day
PW3	9+10*	inhalation	0.463 mg/m³	8+10**	inhalation	0.17 mg/m³
		dermal	-		dermal	0.0374 mg/kg bw/day

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

As can be seen the presented exposure values are systematically lower than those presented in the first application for authorisation. In both cases (i.e. the application for authorisation submitted in 2016 and the current one) estimates of inhalation exposures are based on measurement data supported by modelling, therefore supposed to reflect the workplace situations more accurately than only modelled data. The dermal exposure estimates in the first application for authorisation were based on modelling (CHESAR 2 and RISKofDERM). In the current application for authorisation the applicant provided dermal measurement data and modelled estimates (ECETOC TRA worker). Based on the measurement data the applicant was able to demonstrate that the changes in RMMs taken (upgraded LEV, enclosed pump transfer system, enclosed robotic handling system) are effective in reducing the dermal workplace exposure to diglyme significantly.