Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

Industrial use of an epoxy resin hardener containing technical MDA aimed at immobilising spent ion exchange resins in a high containment matrix

ECHA/RAC/SEAC: Opinion N° AFA-O-0000006533-75-04/F

Consolidated version

Date: 15/03/2017

Consolidated version of the

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

on an Application for Authorisation

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

Chemical name:	**technical MDA**
EC No.:	**500-036-1**
CAS No.:	**25214-70-4**

for the following use:

Industrial use of an epoxy resin hardener containing technical MDA aimed at immobilising spent ion exchange resins in a high containment matrix

Intrinsic property referred to in Annex XIV:

Article 57 (a) of the REACH Regulation

Applicant:

Polynt Composites France

Reference number:

11-2120114715-62-0001

Rapporteur, appointed by the RAC:	**João Carvalho**
Co-rapporteur, appointed by the RAC:	**Urs Schlüter**
Rapporteur, appointed by the SEAC:	**Stavros Georgiou**
Co-rapporteur, appointed by the SEAC:	**Silva Kajić**

This document compiles the opinions adopted by RAC and SEAC.

PROCESS FOR ADOPTION OF THE OPINIONS

On **01/02/2016 Polynt Composites France** submitted an application for authorisation including information as stipulated in Articles 62(4) and 62(5) of the REACH Regulation. On **26/04/2016** ECHA received the required fee in accordance with Fee Regulation (EC) No 340/2008. The broad information on uses of the application was made publicly available at http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation on **27/04/2016**. Interested parties were invited to submit comments and contributions by **22/06/2016**.

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

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

The draft opinions of RAC and SEAC were sent to the applicant on **10/02/2017**.

On **15/03/2017** the applicant informed ECHA that they did not wish to comment on the opinions. The draft opinions of RAC and SEAC were therefore considered as final on **15/03/2017.**

ADOPTION OF THE OPINION OF RAC

The draft opinion of RAC

The draft opinion of RAC, which assesses the risk to human health and the environment arising from the use of the substance – including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives – was reached in accordance with Article 64(4)(a) of the REACH Regulation on **09/12/2016**.

The draft opinion of RAC was agreed by consensus.

The opinion of RAC

Based on the aforementioned draft opinion and in the absence of comments from the applicant, the opinion of RAC was adopted as final on **15/03/2017.**

ADOPTION OF THE OPINION OF SEAC

The draft opinion of SEAC

The draft opinion of SEAC, which assesses the socio-economic factors and the availability, suitability and technical and economic feasibility of alternatives associated with the use of the substance as described in the application was reached in accordance with Article 64(4)(b) of the REACH Regulation on **15/09/2016**.

The draft opinion of SEAC was agreed by consensus.

The opinion of SEAC

Based on the aforementioned draft opinion and in the absence of comments from the applicant, the opinion of SEAC was adopted as final on **15/03/2017.**

THE OPINION OF RAC

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

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

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

RAC confirmed that the operational conditions and risk management measures described in the application limit the risk, provided that they are adhered to as described in the application.

THE OPINION OF SEAC

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

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

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

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

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

SUGGESTED CONDITIONS AND MONITORING ARRANGEMENTS

Description for additional conditions and monitoring arrangements for the authorisation:

None.

AND / OR

Description of conditions and monitoring arrangements for review reports:

None.

REVIEW

Taking into account the information provided in the application for authorisation prepared by the applicant the duration of the review period for the use is recommended to be **twelve years**.

The justifications for the opinion are as follows:

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

☒ Carcinogenic (Article 57(a))

☐ Mutagenic (Article 57(b))

☐ Toxic to reproduction (Article 57(c))

☐ Persistent, bioaccumulative and toxic (Article 57(d))

☐ Very persistent and very bioaccumulative (Article 57(e))

☐ Other properties in accordance with Article 57(f) [please specify]:

2. Is the substance a threshold substance?

☐ YES

☒ NO

Justification:

Formaldehyde, oligomeric reaction products with aniline (Technical MDA, tMDA) does not have a harmonised classification. However, tMDA contains MDA (CAS No 101-77-9) in the range [47 to < 65%] which has a harmonised classification of:

H317: Skin sensitisation Category 1

H341: Germ cell mutagenicity Category 2

H350: Carcinogenicity Category 1B

H370: Specific target organ toxicity – single exposure Category 1

H373: Specific target organ toxicity – repeated exposure Category 2

H411: Chronic aquatic toxicity Category 2

Based on studies which show its carcinogenicity potential, the Risk Assessment Committee (RAC) has concluded that tMDA should be considered as a non-threshold carcinogen with respect to risk characterisation (reference to the studies examined are included in the RAC document RAC/32/2015/11 rev 1 Agreed).

3. Hazard assessment. Are appropriate reference values used?

Justification:

RAC has established a reference dose-response relationship for the carcinogenic effect following exposure to technical MDA (RAC/32/2015/11 rev.1). Based on experimental animal data (cited in the RAC document), a potentially increased risk of cancer occurring due to genotoxicity of the substance was noted.

The following cancer risk estimates were calculated by RAC and used by the applicant:

It is assumed that air concentration of 1 µg/m^3 (corresponding to an absorbed dose of 0.14 µg/kg bw, with 100% absorption via inhalation (10 m^3/work shift)) corresponds to a cancer risk of 5.6 x 10^{-6} (derived from the risk estimates above).
Then, assuming linearity of cancer risk with absorbed dose, the urinary level of:

- 1 µg/l in post-shift sample corresponds to a cancer risk of 0.44 x 10^{-5}
- 1 µg/l in next morning pre-shift sample corresponds to a cancer risk of 0.9 x 10^{-5}
- 10 µg/l in post-shift sample corresponds to a cancer risk of 0.44 x 10^{-4}
- 10 µg/l in next morning pre-shift sample corresponds cancer risk of 0.9 x 10^{-4}

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

Are all appropriate and relevant endpoints addressed in the application?

Cancer risk was estimated using the dose-response curve developed by RAC for all relevant routes of exposure and exposed populations. All endpoints identified in the Annex XIV entry are addressed in the application. The applicant asses risk arising due to the inhalation and dermal exposure for workers and for the general population - due to inhalation and oral exposure.

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

Description:

Short description of the use

The applicant, Polynt Composites France, is a downstream user of technical MDA (tMDA) and is applying for authorisation for it is own use (use 1) and the use of his downstream user SOCODEI (use 2). This assessment covers use 2 of tMDA:

Use 2: Industrial use of an epoxy resin hardener containing technical MDA aimed at immobilising spent ion exchange resins in a high containment matrix.

According to the applicant, the exposure scenarios (Table 1) include all relevant processes and tasks associated with the use of tMDA that could result in either environmental or worker exposure. Use 2 is composed of 17 WCSs and one ECS.

All tasks in use 2 are conducted at 19 sites in France. The worst case tonnage use is 28.8 tonnes/year and represents the volume of the substance used in development of the epoxy resin hardener formulation described in use 1, consequently applied in use 2.

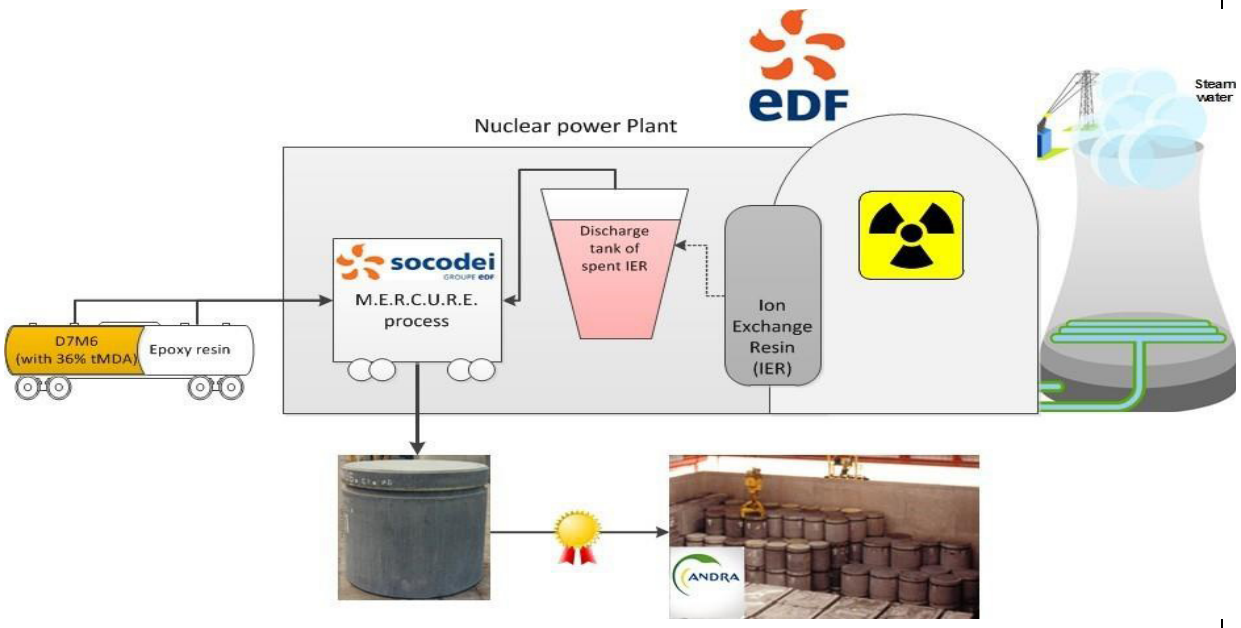
Table 1: Contributing Scenarios for use 2

Contributing scenario	ERC / PROC	Name of the scenario
ECS 2	ERC 6d	Use of reactive process regulators in polymerisation processes at industrial site (inclusion or not into/onto article)
WCS2A	PROC 8b	Manual opening of the manhole of the operating tank
WCS2B	PROC 4	Temperature sensor placed in the control container
WCS2C	PROC 4	Temperature sensor placed in the containers reaching 40°C
WCS2D	PROC 4	Injection of a product in the container to stop the polymerisation reaction
WCS2E	PROC 1	Adjustment of the position of the lid placed on the container
WCS2F	-	Storage of the containers during the remaining time of the polymerisation reaction
WCS2G	PROC 8b	Loading of the operating tank with the supply tank: manhole opening
WCS2H	PROC 8b	Connection of the flexible pipe of the supply tank to the valve of the operating tank
WCS2I	PROC 8b	Visual control of the loading of the operating tank
WCS2J	PROC 8b	Equipment removal: automated scraping of the flexible pipe in the controlled room
WCS2K	PROC 8b	Equipment removal: automated scraping of the flexible pipe outside, in the controlled CMR area.
WCS2L	PROC 8b	Equipment removal: connection of the cleaning equipment to the rigid pipe outside, in the CMR area
WCS2M	PROC 8b	Equipment removal: connection of the cleaning equipment to the rigid pipe inside, in the controlled area
WCS2N	PROC 3	Maintenance of the hardener pump: disassembling, cleaning, change of seals
WCS2O	PROC 3	Maintenance of the hardener valves, disassembled, all seals replaced
WCS2P	PROC 8b	Cleaning of the measuring hardener vessel: connection of a flexible pipe
WCS2Q	PROC 3	Manual cleaning of the hardener measuring vessel (scrubbed)

Workers exposure

The hardener formulated in use 1 is supplied to a downstream user to treat spent ion exchange resins produced in nuclear power plants in France. The figure below provides an overall illustration of **use 2**.

Figure 2: Use 2 Overall process



The process can be briefly summarised as follows:

- Cooling water in nuclear power plants becomes charged over time with radioactive ions and needs to be decontaminated on a regular basis. To that purpose, it is circulated through ion exchange resins (IER) that remove the radioactive ions.
- Once saturated, the IER needs to be replaced. The spent IER must be treated as radioactive waste. In France this treatment uses hardeners manufactured with use of tMDA.
- The treatment consists in immobilizing the spent IER in a matrix. The spent IER are mixed in a concrete container with:
  - A pre polymer (also named epoxy resin),
  - The hardener formulated in use 1 and containing tMDA.
- The mixture of these three elements triggers the polymerization. The tMDA enables the formation of a cross-linked polymer network in order to produce a "containment matrix", also named 'immobilized waste form'. When the polymerization ends, the spent IER are then blocked in the matrix.
- The concrete container is then sealed and becomes a confined immobilised waste package that is sent to French authorised disposal facility for this radioactive waste.

For use 2 risk assessment follows a different approach than in use 1 as – due to the nature of the process - it is not possible to allocate different tasks to different operators. In total 40 **operators** are trained, qualified and authorised to perform the tasks of the process (WCS2A to WCS2Q). There are two sets of equipment available, which travel from site to site. 10 workers per set of equipment are needed for one campaign on one site (i.e. 20 workers in total). There is a regular rotation among the 40 operators to minimise the potential for radioactive exposure. 10 additional workers can potentially participate in the maintenance (but not in the process operations).

As a worst case approach, the applicant summed all exposures as if one person was doing all tasks consecutively. RAC agrees with this approach. However, the next step of dividing

the result by 10 is not accepted by RAC. This division was done to take into account the fact that 10 workers are needed at the same time to operate one set of equipment and the tasks are distributed among them. However it is not documented clearly if 10 people are exposed to precisely a one tenth of the estimated exposure level or all of them to the full level.

This approach by the applicant does not take into account the regular rotation among the 40 operators to minimise the potential exposure of the concerned workers or the rotation among the 50 operators in total, when including the other workers that can perform maintenance. Maintenance activities have a rather high potential for exposure as can be seen in the biomonitoring results.

Additionally, it is necessary to differentiate between exposure during the immobilization of the spent IER in the so called M.E.R.C.U.R.E machine (WCS2A – WCS2M) and the exposure during maintenance activities (WCS2N – WCS2Q). The first activities are performed all year long, with a lower exposure. The latter are performed less than once a year for less than a week, but with a relatively high exposure caused by disassembling, cleaning, replacing of contaminated parts.

Exposure estimation methodology:

Inhalation and Dermal:

Use of modelling

Occupational exposure via the inhalation route was assessed with the Advanced REACH Tool (ART, version 1.5). The evaluated WCSs are within the scope of ART. Site specific information – such as operational conditions (OC) and risk management measures (RMM) were collected and were used as input parameters for ART. A comparison of the workplace specific information and their "translation" into ART input parameters is available. The applicant chose to use the 90^{th} percentile of the ART-generated results as a basis of the exposure assessment.

Corrections are introduced for the effectiveness of RMMs (mainly PPE), the duration of tasks within a day and frequency of the tasks per year.

Originally the applicant did not provide a quantitative dermal exposure assessment, because the concerned uses do not include operations with direct manual contact or exposure. Dermal exposure can only occur through accidental spilling or contact with potentially contaminated objects. Following a request of RAC, the applicant performed dermal exposure modelling using ECETOC TRA v3. Input parameters have been made available. After analysing the modelling results and having in mind the availability of biomonitoring data (covering also dermal exposure) RAC concurs with the applicant that dermal modelling does not provide realistic estimates of exposure in this case.

Use of measured data

The applicant has a monitoring programme in place and available measured data were gathered and assessed for their reliability and relevance. Three types of data were available and evaluated for this application.

- Indoor workplace air measurements,
- Biomonitoring data (urine measurements)

- Surface sampling measurements

The applicant did not provide all available data, but selected a representative (assessment of the applicant) sample and used these values for risk assessment.

Measurements were performed according to international standards and are supported by relevant contextual information (provided on RAC's request) about the sampling and analytical methods and about the related conditions at the monitored workplaces.

RMMs applied

The risk management measures applied by the applicant for this use include the following:

- The equipment in which the main steps are performed (mixing and polymerisation in a concrete container for use 2) is essentially closed. However, several open handling steps are necessary, mainly related to process monitoring.
- Several RMMs are in place to restrict the potential exposure of workers to tMDA during the process and maintenance:
  - Automated vents are placed on the operating tank to reduce the exposure when opening the manhole.
  - A containment protective tarpaulin is placed under the operating tank to avoid spreading of contamination in case of spillage or accidental leakage.
  - General ventilation (approx. 1 ACH) is systematically available in the room where use 2 is performed, in each nuclear power plant.
  - Operations that can potentially generate significant vapours of tMDA are performed with LEV.
  - Where exposure cannot be prevented, PPE is used and includes helmet with safety glasses, coverall, chemical-resistant gloves (90% protection), RPE (half-face mask with ABE1P2 filter, 90% protection).

RAC considers the above-mentioned protection factors as standard for PPE in industrial settings. Documentation of the used PPE is (after a request of RAC) sufficient as technical information for protective suits, gloves and RPE was provided.

Table 2: Operational Conditions and Risk Management Measures

WCS	Duration and frequency of exposure	Concentration of the substance in %*	LEV used + air flow	PPE used + effectiveness	Other RMMs	
WCS2A	2 min/d 40/y	36	--	*1*	Outdoors	
WCS2B	1 min/d 4/y	6	LEV 100m³/h	*2*	General ventilation	
WCS2C	1 min/d 5/y	6	LEV 100m³/h	*2*	General ventilation	
WCS2D	15 min/d 1/6y	6	LEV 100m³/h	*2*	General ventilation	
WCS2E	30 s/d 1/container	6	--	Tyvec type coverall, butyl gloves (thickness 0.35 mm)	General ventilation	
WCS2F	Not relevant					
WCS2G	7 min/d 7/y	36	--	*1*	Outdoors	
WCS2H	10 min/d 7/y	36	--	*1*	Outdoors	
WCS2I	60 min/d 7/y	36	--	*1*	Outdoors	
WCS2J	10 min/d 8/y	36	--	*1*	General ventilation	
WCS2K	10 min/d 8/y	36	--	*1*	Outdoors	
WCS2L	5 min/d 8/y	36	--	*1*	Outdoors	
WCS2M	5 min/d 8/y	36	--	*1*	General ventilation	
WCS2N	30 min/d 1/y	36	--	*1*	General ventilation	
WCS2O	360 min/d 1/y	36	--	*1*	General ventilation	
WCS2P	2 min/d 1/y	36	--	*2*	General ventilation	
WCS2Q	360 min/d 1/y	36	--	*2*	General ventilation	

1 - Helmet, protective full face shield, half-face mask 3M4277 (ABE1P2) type, compliant with the EU standard 405:2002 with filters - APF 10 (90% protection), chemical-resistant butyl gloves, thickness 0.35 mm, Tyvec type protective overall

2 - Full suit against radioactive contamination including a ventilated hood compliant with the EU standard 1073, class 5 APF 50 (98% protection), chemical-resistant butyl gloves, thickness 0.35 mm

Other risk management measures used to control exposure:

Additionally, apart from specific RMMs related to the use of tMDA mentioned above, the company has in place an effective occupational safety and health system including:

- Workplace risk assessment, including chemical risks management (raw material SDS analysis, exposure control & follow-up),
- Access restrictions,
- Personal hygiene provisions (e.g. washing hands after handling of substances, changing contaminated clothes),
- Regular training for workers, including integration of newcomers at workplace (information & training) and continuous retraining,
- PPE Management,
- Accidents/Incidents/Deviations RCA (Root Causes Analysis), CAPA (Corrective Actions/Preventive Actions) including a thorough documentation that enabled the applicant to provide detailed information about single incidents leading to elevated exposure.

Obviously the situation for use 2 is more difficult as the process equipment travels from site to site. Therefore exposure situations will change frequently, RMMs need to be more flexible and organisational measures will have a higher relevance.

Discussion of the exposure information:

Inhalation exposure

Inhalation exposure measurements are worst case values for this use as the applicant decided to perform static measurements close to the source of emissions, in a location where workers are not present. These measurements were carried out when the container is in the M.E.R.C.U.R.E machine, just above the surface of the mixture inside a protective skirt inserted in the container, on the edges, to avoid any spilling. Obviously, operators can never be exposed in this manner. The highest value for this measurement is **2.6 µg/m³** as the full shift TWA. The limited number of measurements (2 measurements carried out when the container is in the M.E.R.C.U.R.E machine and 2 measurements on the containers in the storage room) does not allow to use a lower percentile for the further risk assessment.

For operators during **maintenance** no specific workplace air measurements are available. However the applicant decided to evaluate the inhalation exposure of maintenance workers using the same value of 2.6 µg/m³ as this is the only available measurement value. Duration and frequency is lower than for formulation operators as maintenance for each M.E.R.C.U.R.E machine is only performed every second year and takes less than a week per maintenance event.

Next to the measurements, inhalation exposure was also modelled. It is, however, for several reasons questionable whether the chosen modelling approach is very meaningful:

- Input parameters of the model (ART reports) do not fit in all cases exactly the workplace conditions described in CSR (an illustrative example of this difficulty is described in the opinion of use 1 for this application)

- Meaning of the modelling results (8 h TWA or task-specific exposure value) is not defined (as described in the example provided in the opinion of use 1 for this application)
- Corrections "outside the model" (e.g. correction for PPE used, duration and frequency of the tasks) are not entirely transparent

Modelling results are below the value of the measured exposure. This is surprising as models are supposed to be more conservative than measurements. But it can be explained having in mind the selection of the worst case sampling results.

Dermal exposure

Use 2 does not include operations with direct manual contact or exposure, such as immersion or manual handling of drenched objects. The only dermal exposure that could occur would be through accidental spilling or contact with potentially contaminated surfaces or objects. The activities with highest potential for dermal exposure are open handling steps, sampling and process control. Dermal exposure reduction only relies on chemical protective gloves. Regarding PPE, the applicant has documented (on RAC's request) which gloves are used and how an effectiveness of 90% is achieved. The explanations provided are considered to be satisfactory.

Given the physical properties of tMDA (high boiling point, low vapour pressure) dermal exposure is considered relevant only for situations where tMDA is handled manually or the system is not closed. It was considered by the applicant that the available modelling tool (ECETOC TRA) was much too unrealistic (as stated by the applicant, without a robust justification) and did not help in the assessment considering the available measured data (biomonitoring). Nevertheless the applicant performed a modelling of the dermal exposure to answer RAC's request.

Biomonitoring

According to the applicant, biomonitoring is carried out during each campaign (process phase) and during the maintenance phase for each M.E.R.C.U.R.E machine. Consequently - a substantial set of data are available. However, the applicant chose to present only a limited but representative (assessment of the applicant) sample from 3 recent campaigns conducted in 2015 (sites NPP1 - 3) and – on RAC's request – additionally measurements that were performed after the submission of the application, in April and May 2016 (NPP5). RAC has no knowledge which machine was used in this campaign, as all information was anonymised. RAC however accepts this, understanding the possible sensitivity of this information vis-a-vis the security issues related to nuclear waste.

The information available to RAC does not detail exhaustively all the operations carried out by the concerned operator. Consequently, a strict link between the measurements and the WCSs is not possible. However the main tasks performed are documented and it shows that the measurements represent exposure resulting from various tasks with high exposure potential such as:

- Loading of the operating tank (WCS2G),
- Connection of flexible pipes (WCS2H),
- Equipment removal including the scraping of the pipes (WCS2K, 2L).

Among the total of 74 values presented:

- 77% are below the LoQ (1µg/L),

- 23% show an external exposure.

Whilst developing their application for authorisation, the applicant noted a potential underestimation of the exposure to tMDA represented by biomonitoring performed in the past because of the timing of the collection of the urine sample in relation to exposure period: only post-shift samples were collected. The applicant therefore put in place an action plan to perform urine sampling:

- at the end of the worker shift (post-shift) and
- on the day following tasks identified as potentially the most exposing tasks to tMDA - before the beginning of the next shift (pre-shift).

First biomonitoring results collected in accordance with this action plan (NPP5) were provided on RAC's request and show good conformance with older biomonitoring measurements. The new values, for the M.E.R.C.U.R.E operators show a slightly lower exposure compared to previous biomonitoring campaigns. The available data related to plant operators' exposure are summarised in the table below The range for all measurements is between the LoQ and a max value of 9.6 µg/L.

Table 3 Biomonitoring results, per Nuclear Power plant.

Site	Period of sampling	Timing of sampling	Total number of samples	Number of results with a concentration < LoQ (1µg/L)	Max value µg/L
NPP1	09/01/2015 to 04/03/2015	Post-shift samples	13	7	3.3.
NPP2	18/03/2015 to 06/05/2015	Post-shift samples	7	5	5.1
NPP3	17/04/2015 to 16/07/2015	Post-shift samples	19	15	9.6
NPP5	05/04/2016 to 26/05/2016	Post- & Pre-shift samples (23 post, 12 pre)	35	30	4.2

RAC concludes that assessment of exposure to workers measured by biomonitoring is the most meaningful method (see the chapter on biomonitoring for technical MDA in RAC/32/2015/11 rev.1). RAC compared the available biomonitoring data for post-shift samples with pre-shift samples and decided to use the 90th percentile value of the pre-shift samples for exposure assessment covering inhalation and dermal contact to tMDA as a starting point for the risk assessment: **3.5 µg/L urine**. The corresponding result of biomonitoring directly after the exposure (post-shift sample) was 3.3 µg/L urine.

The range of the biomonitoring results reported by the applicant cover the area of < 1 µg/L urine up to the maximum value of 9.6 µg/L urine for post-shift samples and from <

1 µg/L urine up to the maximum value of 4.0 µg/L urine for pre-shift samples. Most of the values are below the LoQ of 1 µg/L urine.

Biomonitoring data (12 values, 9 below LoQ and 3 values above LoQ) obtained during the **maintenance** of an M.E.R.C.U.R.E. machine that took place in 2014 show a range from below LoQ to a maximum value of 24.8 µg/L urine. The 90th percentile is **15.5 µg/L urine**. Maintenance activities for this use are associated with fewer technical RMMs (no LEV), more direct or closer contact to tMDA, a longer duration of some of the activities and some necessary manual tasks. Additionally, the LoQ for these measurements was 5 µg/L urine instead of 1 µg/L urine for more recent measurements. On the other hand the frequency of maintenance is limited to once a year.

As exposure during maintenance is significantly higher than for the M.E.R.C.U.R.E. process RAC considers that the critical review of the maintenance process, with assessment of the RMMs is necessary RAC however considers the current analysis as robust with low uncertainty attached to it. .

Table 4: Exposure – dermal and inhalation

Profile, WCS	Route of exposure	Method of assessment	Exposure value	Exposure value corrected for PPE
Operators WCS2A to WCS2M	Inhalation	Measured	2.6 µg/m³	0.26 µg/m³
	Dermal	Modelled	Not relevant	
	Biomonitoring	Measured	3.5 µg/L urine	--
Maintenance WCS2N to WCS2Q	Inhalation	Measured	2.6 µg/m³	0.26 µg/m³
	Dermal	Modelled	Not relevant	
	Biomonitoring	Measured	15.5 µg/L urine	--

Combined exposure

Biomonitoring results, representing both exposure via inhalation and skin, were used for the risk characterisation. As the monitoring is conducted after full shift – the measured values are considered to include exposure resulting from all tasks performed within this shift.

Uncertainties related to the exposure assessment:

RAC considers the exposure assessment performed by the applicant to be thorough and representative of all tasks with potential for exposure.

In summary, RAC considers that there are only relatively minor residual uncertainties associated with the worker exposure assessment; these would not lead to an increase in the exposure estimate, should they be further investigated. Moreover, it is easy to find those pointing at overestimation in the application, e.g.:

- Use by the applicant of the highest values of measured exposure (biomonitoring, air monitoring) instead of the 90th percentile.

RAC decided to use the relevant 90th percentile values.

Environmental releases / Indirect exposure to humans via the environment

Given that the process involves radioactive material, the applicant is confident that measures to prevent/limit the release to the environment during its operations to be of best practice.

Release to air: This use consists in immobilising spent ion exchange resins in a matrix initiated by the mixture of epoxy resin with the hardener containing tMDA. The mixture causes a polymerisation resulting in a cross-linked polymer network. Consequently, as soon as the reaction starts, the tMDA begins to be entrapped and the more the reaction progresses, the less free tMDA is potentially released to air. The applicant therefore initially considered that releases to air from this use were negligible.

At the request of RAC, the applicant confirmed that there is no available data on stack emission measurements. However, atmospheric measurements were performed in 2014 and 2015 for the operation with the highest potential for exposure, i.e. when the container is in the M.E.R.C.U.R.E machine in the controlled room. During this operation, the hardener containing the tMDA, the epoxy resin and the IER are being mixed to initiate the polymerisation. The measurement is carried out inside the protective skirt, just above the surface of the mixture. This measurement has been identified by the applicant as a worst case since this is the operation that is expected to lead to the maximum release of tMDA. These measurements are considered by the applicant to be representative of the tMDA emissions occurring during the production of the confined immobilised waste packages.

All measurement results were below the limit of quantification (LoQ) of 75 ng per filter corresponding to values of < 2.6µg/m^3 in the air. The latter was used as the basis for a worst case estimation of tMDA concentration in air. At RAC's request, the releases to air of tMDA for tasks conducted outside were re-assessed. The applicant assessed these releases based on the INERIS[1] Guidance on VOC estimation emissions from batch processes, in which emissions from each task are calculated separately. This methodology was thus able to calculate emissions from outdoor tasks. The sum of emissions from all tasks was carried forward to the risk characterisation. Detailed calculation of emissions for each task are presented in Annex I and summarised in the table below. It is important to note that the tasks used in this methodology differ from the WCS listed in the worker's risk assessment.

[1] INERIS (French National Institute for Industrial Safety and Environmental Protection), 2009. Estimation des émissions de COV par modélisation dans l'industrie chimique / estimate of VOC emissions by modelling for the chemical industry, DRC-09-103316 03785A, 13/03/2009, 70p., available at http://www.ineris.fr/centredoc/Estimation_COV_chimie.pdf

Table 5: Releases to air per task

Task*	Releases to air of tMDA (kg/day)
Manhole opening of the operating tank at the beginning of the campaign (all other inspections)	7.47×10^{-09}
Manhole opening of the operating tank at the end of the campaign	3.43×10^{-09}
Loading of the operating tank	3.75×10^{-09}
Supply tank depressurization at the end the loading of the operating tank	1.35×10^{-08}
Connection/disconnection of the flexible pipe	Negligible release
Purge and scraping of the flexible pipe with compressed air	1.98×10^{-09}
Rinsing of the rigid pipe with solvent injection, in closed loop	Negligible release
Transfer of the containers in a "stabilisation building" complete polymerization	1.3×10^{-7}
Total emissions per day from outdoor tasks	1.6×10^{-7}

* Tasks used in this methodology differ from the WCS listed in the worker's risk assessment.

Release to surface water: Effluents generated during cleaning operations are strictly collected on site in specific wastes drums for subsequent treatment as dangerous wastes. No releases to environment or STP occur from the operation.

Release to soil: tMDA is neither directly nor indirectly released to soil, hence releases to soil are considered negligible

Wastes: All wastes potentially containing tMDA are collected on site in specific waste drums for subsequent treatment as dangerous wastes.

RMMs applied

Since use 2 deals with radioactive waste, strict conditions are necessary, independent of the fact that tMDA is used, to prevent releases to all environmental compartments. RMMs are in place to collect all waste water into drums which are treated as dangerous waste. No RMMs are in place for air releases.

The applicant considers that there are no emissions to water and soil, the relevant release fraction assessed was to the air.

Table 6: Summary of environmental emissions

Release route	Release rate	Release estimation method and details
Water	NA	NA
Air	*Indoor:* Fraction of tonnage release to air: 9.59 x 10^{-8} Local emissions: 9.36 x 10^{-6} kg/day Regional release:7.57 x 10^{-6} kg/day *Outdoor:* Fraction of tonnage release to air: 1.64 x 10^{-9} Local emissions: 0.16 x 10^{-6} kg/day Regional release:1.2 x 10^{-7} kg/day *Total emissions (indoor & outdoor):* Fraction of tonnage release to air: 9.75 x 10^{-8} Local emissions: 9.52 x 10^{-6} kg/day Regional release:7.69 x 10^{-6} kg/day	*Indoor:* Local emission to air during episode was calculated as follow: LOQ/2 x general ventilation x number of containers per day x time to produce one container. The fraction of tonnage release to air was calculated as follow: local emission to air during episode x number of emission days per year / annual tonnage used *Outdoor:* Emissions to air during episode were calculated according to the method described in INERIS guidance document. Task specific release result in Annex I. Local emission 4.72 x 10^{-05} kg/year is divided by annual tonnage of tMDA to determine Flocal outdoor Fair local is the sum of Flocal outdoor and Flocal indoor.
Soil	NA	NA

The applicant considered two exposure routes - inhalation and oral intake (through ingestion of drinking water and consumption of fish, leaf crops, root crops, meat & milk) for the exposure of the general population.

Indirect exposure for indoor tasks was assessed based on the results of air measurements conducted under worst case conditions as explained previously. Exposures from outdoor tasks were assessed individually for each task based on the INERIS guidance on VOC estimation emissions from batch processes (referred to above). The sum of indoor and outdoor emissions was used as inputs for EUSES modelling. The combined (resulting from

outdoor and indoor emissions) local and regional PEC values are presented in the table below.

There is no consumer exposure since tMDA is only used for industrial purposes.

Table 7: Summary of indirect exposure to humans via the environment

Protection target	Exposure estimate and details (i.e. methodology and relevant spatial scale)
Man via Environment – Inhalation	Local PEC: 2.1 x 10^{-9} mg/m^3 Regional PEC: 1.5 x 10^{-15} mg/m^3
Man via Environment – Oral	Drinking water Local PEC: 3.24 X 10^{-11} mg/kg bw/day Sum of drinking water & food consumption Local PEC: 2.4 x 10^{-7} mg/kg bw/day Regional PEC: 5.3 x 10^{-12} mg/kg bw/day

Uncertainties related to the environmental releases exposure / assessment of exposure to humans via the environment:

- related to RMMs

Since there are no RMMs used, there are no uncertainties associated with them.

- related to environmental exposure estimation methodology

The use of the methodology described in the INERIS guidance (referred above) allows for a detailed assessment and the estimation of air releases from outdoor activities. In this methodology, each task in the process that can lead to air releases is assessed based on thermodynamic equations of liquid-vapour equilibrium. Diffuse emissions from indoor process are also estimated. It is important to point out that this methodology was initially developed for VOCs, that have high saturated vapour pressure at room temperature or in the temperature range of the tMDA implementation process (25°C – 80°C). tMDA[2], by definition, is not a VOC, however the applicant has used this methodology since it represents a conservative approach when applied to a non VOC substance such as tMDA. This approach considers that liquid-vapour equilibrium is reached instantaneously in the considered volume, the latter remaining saturated with tMDA vapours. Emissions of tMDA are thus overestimated with these methods.

RAC agrees with the applicant that due to its low volatility, at atmospheric pressure and ambient temperature, releases of tMDA in the ambient atmosphere are likely to be low. Nevertheless, these were estimated based on a conservative approach which the applicant considers could overestimate releases as it was developed for VOCs with much greater vapour pressure than tMDA. RAC agrees with the applicant that although tMDA is not a

[2] tMDA vapour pressure equals to 0.000336 Pa at 25 °C (conversion performed with EUSES according to the measured data of 0.0016 at 50°C) and 1.3 Pa at 100 °C.

VOC, this methodology can be used to estimate tMDA emissions expecting that these will be overestimated.

RAC notes that the applicant provides site-specific air monitoring data based on measured tMDA, in order to reduce uncertainties. However, the number of samples taken on the plant premises was very limited (n=2), as well as the time scale, limiting the representativeness of this dataset. Since all measurements were below the LoQ, the applicant used a value of LoQ/2 for the monitoring data as per the REACH guidance. RAC considers the use of the LoQ/2 value acceptable since the use of the actual LoQ would still result in the same order of magnitude of exposure when compared to LoQ/2.

Taking the uncertainties mentioned above into account, RAC considers that the exposure calculated by the applicant is suitable for risk characterisation and impact assessment.

Conclusion

RAC considers that:

- The description of use provided allows to draw conclusions related to exposure situations.

- The methodology used to derive exposure levels for workers and men via the environment is suitable.

- No information is provided regarding indirectly exposed workers.

- The number of measurements and the overall quality of the data presented by the applicant are considered to be sufficient to draw reliable conclusions on exposure. Therefore, the information provided related to exposure resulting from the use applied for is considered to be sufficient to use it in a risk assessment and in the risk characterisation

- The exposure values taken forward for risk assessment by the applicant are worst case values and represent an overestimation of exposure and level of risk.

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

☐ YES

☐ NO

☒ NOT RELEVANT, NON THRESHOLD SUBSTANCE

Justification:

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

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

☒ YES

☐ NO

Justification:

Workers

Evaluation of the risk management measures

RAC concludes that the applicant made considerable efforts to implement technical RMMs, where possible'. For those activities where the applicant identifies potential for exposure, effective occupational health and safety practices are implemented. In addition to engineering RMMs, OSH management system includes organisational measures and personal measures (e.g. PPE). Additionally the applicant already performs personal (biomonitoring) and stationary (air monitoring) measurements and will continue to do so.

Risk characterisation

Risk characterisation for workers is based on ECHA's dose-response relationship for tMDA carcinogenicity:

Lifetime excess cancer risk (workers, inhalation): 5.6×10^{-6} per µg/m³

Lifetime excess cancer risk (workers, dermal): 1.9×10^{-5} per µg/kg bw/d

Lifetime excess cancer risk (biomonitoring, post-shift): 4.4×10^{-6} per µg/L urine

Lifetime excess cancer risk (biomonitoring, pre-shift): 9.0×10^{-6} per µg/L urine

An assessment by SCOEL[3] concludes that "any excretion of 4,4'-diaminodiphenylmethane above the detection limit is indicative of an external exposure, as the compound does not occur naturally or as an environmental pollutant. On this basis, a Biological Guidance Value (BGV) can be recommended that is equivalent to the analytical detection limit of 1 µg/L urine."

Inhalation exposure for workers was measured directly by workplace air monitoring. Also biomonitoring is performed already for years. In addition, inhalatory exposure was modelled using ART v.1.5 and dermal exposure was modelled using ECETOC TRA.

RAC concludes that exposure to workers measured by biomonitoring is the most meaningful method and was under worst case conditions on a level of **3.5 µg/L urine** (90^{th} percentile for a pre-shift sampling) for the M.E.R.C.U.R.E **process worker** and **15.5 µg/L urine** (90^{th} percentile, post-shift value, not corrected for frequency of the tasks) for **maintenance worker**.

It is therefore reasonable to assume that lifetime cancer excess risk for inhalation and dermal exposure for all workers (according to the applicant 50 workers involved) across all activities is a below **3.2×10^{-5}** during the M.E.R.C.U.R.E process and **6.8×10^{-5}** for maintenance.

[3] Recommendation from the Scientific Committee on Occupational Exposure (SCOEL) - Limits for 4,4'-Diaminodiphenylmethane [MDA] – SCOEL/SUM/107, March 2012

Table 8: Excess cancer risk estimates for 40 years exposure for workers

use	Biomonitoring		combined route excess risk
	exposure (mg/L urine)	excess risk	
Overall exposure operators of the M.E.R.C.U.R.E process	**3.5**	**3.2×10^{-5}**	**3.2×10^{-5}**
Overall exposure operators for maintenance	**15.5**	**6.8×10^{-5}**	**6.8×10^{-5}**

Indirect workers' exposure

No assessment of indirect worker exposure is provided by the applicant. RAC however, agrees that the risks calculated for man via the environment (i.e. the general population) should in principle cover indirect exposure to workers as well.

MvE exposure / local and regional

The applicant has estimated cancer risk for inhalation and oral exposures of general population.

The applicant initially considered air releases to be zero based on the EUSES release estimate module. At RAC request for a more refined assessment, the applicant submitted a new risk assessment with indoor air emissions based on monitoring data and outdoor air emissions based on calculations using the INERIS methodology described above.
The total of the indoor and outdoor emissions is used in EUSES to calculate the PECs.

Risk assessment has been made according to the RAC reference dose-response relationship for carcinogenicity of tMDA (RAC/32/2015/11 rev 1 Agreed). The following excess life-time cancer risks were used[4]:

- General population inhalation exposure: An excess lifetime cancer risk = 3.2×10^{-5} per µg/m^3
- General population oral exposure: An excess lifetime cancer risk = 1.1×10^{-4} per µg/kg bw/day

The resulting excess life-time cancer risks for the general population according to the local scale EUSES exposure was estimated as 2.6×10^{-8}. The risk from ingestion of tMDA contaminated foods dominates the local assessment.

The applicant also calculated the risk related to regional exposure, with excess life-time cancer risk of 5.8×10^{-13}. The risk at the regional scale is almost entirely due to the modelled tMDA intake via food consumption.

[4] In the initial risk assessment, the applicant used a different general population (oral) excess life-time cancer risk value. At request from RAC for clarification why a different value was used, the applicant explained that this had been a typing error and subsequently used the values now presented in this opinion document.

Table 9: Summary of indirect exposure to humans via the environment

	Inhalation route		Oral route		Combined inhalation & oral route excess risk
	Exposure (ug/m^3)	Excess risk	Exposure (ug/kg bw/d)	Excess risk	
Local	2.1×10^{-6}	6.8×10^{-11}	2.4×10^{-4}	2.6×10^{-8}	2.6×10^{-8}
Regional	1.5×10^{-12}	4.7×10^{-17}	5.3×10^{-9}	5.8×10^{-13}	5.8×10^{-13}

Conclusion

- The RMMs and OCs implemented are appropriate and effective in limiting the risks to workers (and the general population).
- RAC considers the methodology used for cancer risk calculation to be appropriate and that the estimates of excess cancer risk for workers and for indirect exposure to humans via the environment are acceptable for use in health impact assessment.
- Current air releases of tMDA to the environment were estimated on the basis of monitoring data to account for tMDA releases associated with indoor tasks and modelling approaches to account for outdoor tasks.
- Uncertainties related to monitoring data involve the use of the 0.5 of LoQ value because the monitoring data was all below the LoQ and that the monitoring dataset was small. Overall, these uncertainties were considered to be minor and the risk estimates, whilst potentially overestimating risks, are considered to be suitable for use in impact assessment.
- Subsequently exposure and excess risks to human via the environment were assessed taking into consideration emissions from indoor and outdoor emissions.

Overall, the uncertainties related to the assessment of the risk for workers and humans via the environment are considered to be low. The risk assessment for workers tend to overestimate the risk level, as the underlying exposure value represents the worst case conditions.

7. Justification of the suitability and availability of alternatives

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

Description:

Summary of the analysis of alternatives undertaken by the applicant

Polynt Composites France, hereafter referred to as the applicant is a formulator of D7M6 hardener which contains the substance which is the subject of this authorisation application- tMDA.

The applicant jointly considers two uses of the substance within their application given that they are interlinked. Two main actors (Polynt and Socodei) within the supply chain have worked closely together on the search for alternatives.

Use 1 is the formulation of an epoxy resin hardener, which is called "D7M6", containing approximately 36% of technical MDA (tMDA). Use 1 takes place at the POLYNT Composites France facility and the formulation is manufactured to the requirements of their client, SOCODEI.

Use 2 is the industrial use of the epoxy resin hardener containing tMDA in the process of immobilizing radioactive wastes in a high containment matrix with the M.E.R.C.U.R.E process operated by SOCODEI. SOCODEI is a subsidiary of EDF (the national company producing electricity in France) specialising in the management of radioactive waste.

The radioactive wastes considered here are ion exchange resins (IER) which are spent during water treatment of Nuclear Power Plants (NPP). The water treatment with IER enables the chemical control of the process water in all NPPs operated by EDF. The water treatment ensures the complete integrity of the NPP primary circuits and limits the radioactivity discharged via the authorised releases.

Spent IERs cannot be moved out of the NPPs without first being treated. A specific treatment for the radioactive wastes is required, such that the waste is resistant to various degradation processes. Therefore any new alternative process has to meet with the related nuclear waste management constraints in this respect. The current treatment, using the so-called MERCURE process (direct immobilization treatment) is specifically designed to fit in with those constraints, and involves the substance tMDA.

For the spent IER category of waste, the waste packages must be durable and resistant over a long period of time. The substance tMDA is, according to the applicant, crucial to obtain a cross-linked polymer network, that meets the durability and resistance requirements specified by the French Nuclear waste authority as follows:

- limited exudation of water

- low exothermic reaction

- an homogeneity in the waste

- a high mechanical compression strength of the package

- a stability under ionizing radiations

- a leaching resistance: a high resistance against leaching by water of the waste packages

- the chemical compatibility of all components of the package

- a maximum surface dose rate of the waste packages of 2 mSv/h but the French Nuclear Safety Authority has required a maximum dose rate of 0,75 mSv/h

- an inflammation resistance: resistance against fire of the waste packages.

The polymerisation of the epoxy matrix is an irreversible reaction within which tMDA is cross-linked in a three dimensional solid and insoluble polymer, which is then placed in a concrete container. Following polymerisation, the hazardous character of tMDA is no longer present in the immobilised end waste. The waste packages are resistant to leaching and are stored in closed disposal facilities.

The research to substitute tMDA was begun even before the substance was placed on Annex XIV. The analysis of possible alternative processes was carried out between 2006 and 2013 when the development of a hardener without tMDA was difficult, and given the development of the new generation NPP (i.e. European Pressurized Reactor) was taking place. The search included literature reviews of the alternative processes, as well as through contacts in several other countries. The conclusion of the search process was that there are numerous processes already used or proposed throughout the world, though there is no consensus on any one process, mainly due to the variety of regulations in the different countries. It should be noted that prior to the development of the M.E.R.C.U.R.E. process, spent IERs were immobilized in a matrix with the PRECED process. This process had a high fire hazard level (due to the catalyzer) associated with it, this being a critical safety factor requirement at NPPs. Consequently, research was undertaken to develop a new process, the so called M.E.R.C.U.R.E. process, in order to replace it.

The applicant describes the technical feasibility of a number of alternatives to the use of tMDA substance. The basis of the applicants search has been to either look for an alternative process to the MERCURE process, or to search for a new containment matrix without tMDA, that can be used under the present MERCURE process.

In terms of alternatives that would replace the MERCURE process, the applicant has considered 2 broad types of methods: destructive methods for spent resin treatments; and the direct immobilization and encapsulation of spent IERs.

Regarding the destructive methods for spent resin treatments, these are intended to alter the chemical, radiological and/or physical characteristics of the spent ion exchange materials. A number of such processes, including thermal and non-thermal treatments, were listed by the applicant, but considered to be irrelevant for detailed evaluation of technical feasibility due to a number of constraints that make them unsuitable and have led to their exclusion from the French waste management system.

The direct immobilisation and encapsulation of spent IER alternatives considered by the applicant include cement immobilisation, bitumen immobilisation, polymer immobilisation (such as the one currently used) and immobilisation in high integrity containers. The description of technical feasibility for these alternatives was rather brief, but provided sufficient detail to understand why the alternatives (aside from the polymer immobilisation processes) cannot be considered feasible.

According to the applicant, the analysis they undertook has reinforced the fact that it was more relevant to find a new epoxy resin matrix without tMDA whilst keeping the

M.E.R.C.U.R.E. process. Therefore the applicant focused their efforts on the research and development of a new containment matrix hardener, which is similar to the existing hardener D7M6 (epoxy resin matrix), but without containing tMDA. The research for an alternative hardener without tMDA has been undertaken since 2003.

POLYNT and SOCODEI have worked together jointly towards the research and development of the alternative hardener. In this respect a shortlist of alternatives was considered and one particular alternative taken forward for further development: the hardener D8M2.

According to the applicant, the development of this new hardener formulation, D8M2 has taken more than ten years of research. The composition of D8M2 is not identified in the application and its components are referenced only anonymously, due of the need for commercial protection of the applicants Research and Development work and results. The description and discussion regarding technical feasibility is sufficiently detailed to assess the constraints in it being used as a suitable alternative.

Economic feasibility was not assessed according to the applicant because it was apparently "too difficult to obtain comparable data due to the use of inhomogeneous evaluation methods". Although SEAC did not understand the specifics of this reasoning, the applicant did provide some information on costs with respect to the MERCURE process and has clearly identified an alternative which they are working to implement within that process following testing and approval, such that economic feasibility is clearly not a constraint.

Conclusion

One alternative has been identified as the applicant's preferred substitute, though it is still going through extensive testing and validation and awaits approval by ANDRA. Given the strict waste management regime in place, it has been hard to find a proper replacement that fits all the technical and safety requirements necessary. Some other alternative immobilisation matrices for spent IER's are available and exist but they were all rejected because of technical feasibility issues (See next section). Nevertheless, the applcants research has led to a promising alternative with the new composition (i.e. the "D8M2 hardener"). This hardener alternative is the best option to date but it has not yet been validated by the French nuclear waste authority - ANDRA. The applicant thus requires some time to continue to use tMDA within the existing process whilst the technical testing and validation by ANDRA take place. As such, the application for authorisation is essentially a 'bridging application' to enable the applicant to continue operations whilst their preferred alternative undergoes regulatory approval.

7.2 Are the alternatives technically and economically feasible before the sunset date?

☐ YES

☒ NO

Justification:

As discussed in the previous section, several alternative immobilization matrices for spent IER's exist and were considered by the applicant, including: cement, bitumen, high integrity containers and polymer immobilisation processes.

Immobilization with cement, bitumen or high integrity containers were all rejected by the applicant because of technical reasons as detailed below.

Cement immobilization was not adopted as a solution because of a significant increase of waste volume and the lack of conformity with the necessary compactness and durability (due to the presence of micro cracks) requirements of ANDRA. Moreover the specific research and development works carried out have failed to validate the feasibility of spent IER cement immobilization at an industrial scale.

Bitumen immobilization was not adopted as a solution due to its low melting temperature and the possibility of combustion in the case of an accidental fire. Considering that the risk of fire is the most important risk identified on a nuclear (production or disposal) site, any sources of increased risk of fire are prohibited.

Immobilization in high integrity containers was not adopted as a solution because this process, in which there is no immobilisation in an additional matrix, is totally incompatible with ANDRA's requirements of an unalterable waste form package which must be durable and resistant, and with an appropriate physico-chemical form.

The alternatives above cannot be considered technically feasible as they would not comply with ANDRA's technical approval requirements.

With regards to Polymer immobilisation processes, the most widely used are the polyester and epoxy polymers. Both of these are ambient temperature processes and are comparatively simple considering the equipment and operations involved. Given that the applicant has been active in developing an alternative hardener (D8M2) for use with their existing polymer-based immobilisation process, then validating a new theoretical/or existing process with another polymer would take much longer than taking forward D8M2 as the preferred option, from a technical and regulatory point of view (with no guarantee of success).

Technical feasibility of D8M2

ANDRA has set up strict waste requirements in order to receive confined, durable and resistant immobilized waste packages. Those requirements are controlled with strict technical tests.

SOCODEI, with the help of POLYNT, have conducted those technical tests, which have been undertaken between 2010 and 2014. Some good results have been obtained with this new formulation of hardener. The formulation of the new D8M2 hardener has been retained from 2012 onwards.

However, one test is missing at this time. The leaching test has not been totally carried out yet. In this respect, a key property of a matrix containing radioactive waste is its leaching resistance. The leaching resistance determines how well the radionuclides are retained within the waste form when it is subjected to wet conditions. This property is complex and difficult to obtain.

Strict leaching behaviour results are required by ANDRA. The leaching test measures the release speed of radiochemical elements from a matrix. This leaching test requires significant resources and time (for example, on another occasion it took 6 years).

In seeking regulatory approval for D8M2, the applicant noted that there was a small possibility of ANDRA approving the need to only perform a short leaching test (180 days). However, as became clear in a response to SEAC's questions, the applicant clarified that according to the ANDRA's technical specifications - a long leaching test would in fact have to be performed.

Economic feasibility

Economic feasibility was not assessed because, according to the applicant, it was apparently "too difficult to obtain comparable data due to the use of inhomogeneous evaluation methods". Whilst SEAC do not understand the specifics of this reasoning, the applicant nevertheless discusses the difficulty and cost of developing the existing M.E.R.C.U.R.E process as corroborating evidence of the issues here. They explain that the M.E.R.C.U.R.E. process development took 20 years and the costs were more than €10 Million. Moreover, the applicant states that a completely new alternative process would require a new supply chain to be determined, as well as the training of dedicated staff.

Research and development of a hardener alternative took several years and has involved technical and financial resources. The new D8M2 hardener will be produced by POLYNT. Although there will be some costs to adapt the production process, those costs will be fairly limited. There will also be some costs for the new technical approval process with ANDRA. The development of this alternative (polymer) allows the M.E.R.C.U.R.E. process to be kept, thereby minimising costs as compared to a new process being developed. Given the ongoing work on developing the new alternative, it is clear that the applicant does not consider economic feasibility to be a constraint to the eventual implementation of the alternative.

Conclusion about technically feasibility and technical approval process launching

SOCODEI has to request a new technical approval from ANDRA to use the new D8M2 hardener. Given the promising technical results obtained with the D8M2 hardener, SOCODEI has chosen to launch the technical approval process, which was started in 2012.

The technical approval of the new D8M2 hardener has not been issued yet by the French authorities. As such, SOCODEI cannot implement this new solution without a technical approval by ANDRA for the new confinement immobilized waste package.

If SOCODEI could no longer use tMDA, they would no longer be able to encase spent IER at each NPP after the sunset date, until such a time as an alternative was available (i.e until the new hardener is approved by ANDRA). At the same time, those NPPs would continue producing radioactive wastes.

French NPPs provide around 75% of electricity for France. Stopping NPP production is therefore not an option. NPPs will thus still need to be operating and will still produce spent IER which they would not be able to store anymore in discharge tanks. There would still be spent IERs, to be treated.

In this case, the non-use scenario developed by the applicants consists of a temporary solution being adopted whilst the aforementioned alternative new hardener approved by French Competent Authority awaits approval. The temporary soultion consists of building temporary storage facilities to store the spent IERs temporarily, until such a time that they can be moved to the permanant storage facilites once the MERCURE process is operational again using the new hardener.

SEAC thus consider this application to be a form of bridging application, whilst regulatory approval is sought for the applicants preferred alternative solution.

In assessing the applicant's arguments concerning technical feasibility, SEAC's scrutiny involved informal consultation with relevant experts in nuclear waste regulatory authorities in other EU members states, who confirmed the plausibility of the applicants portrayal and timing of the regulatory approvals process for the new alternative.

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

Description:

The applicant in cooperation with partners made efforts to find a new hardener that would make keeping the M.E.R.C.U.R.E. process possible. In order to protect the applicant's work and results and to avoid potential harm to the company commercial interests, the composition of this new hardener – called D8M2 – is not detailed and its components are anonymized in the AoA. Only information regarding classification and labelling (for the hardener and three of its components are provided.

Hazard classes; categories and statements for D8M2

Acute Tox. 4 - H302:	Harmful if swallowed
Skin Corr. 1B - H314:	Causes severe skin burns and eye damage
Skin Sens. 1 - H317:	May cause an allergic skin reaction
Eye Dam. 1 - H318:	Causes serious eye damage
STOT RE 2 - H373:	May cause damage to organs through prolonged or repeated exposure
Aquatic Acute 1 - H400:	Very toxic to aquatic life
Aquatic Chronic 1 - H410:	Very toxic to aquatic life with long lasting effects)

RAC concludes:

- Obviously, a final and concluding assessment of the risks of alternatives described and compared with the Annex XIV substance is not possible.

D8M2 is not classified for carcinogenicity.

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

☒ YES

☐ NO

☐ NOT APPLICABLE

Justification:

The information available for the identified alternative is deficient and the reasoning for anonymizing relevant information is insufficient.

Conclusion

If the provided information regarding classification and labelling is correct, the alternative might lead to an overall reduction of risk of developing cancer.

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

☐ YES

☐ NO

☒ NOT RELEVANT

Justification:

See 7.1 and 7.2

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

☒ YES

☐ NO

☐ NOT RELEVANT, THRESHOLD SUBSTANCE

Justification:

Additional statistical cancer cases

The estimated number of additional statistical cancer cases has been calculated using the excess risk value presented in section 6 and the estimation of the number of exposed people provided by the applicant. It reflects the expected statistical number of cancer case for an exposure over the working life of workers and entire life for general population.

The information of the applicant states that not more than 50 workers are exposed to tMDA.

RAC notes that these calculations are based on the estimation of exposed populations as provided by the applicant

- No inhabitant for the 19 sites up to 400 m from point source.
- 1 km from release:

  no inhabitant for 18 of the 19 sites (ref: INSEE, 2011)

  943 inhabitants for 1 site (ref: INSEE, 2011)

- 100 km from release:

  < 5,000,000 inhabitants for the majority of the sites.

  Population for 13 of the 19 sites is between 700,000 to 5,000,000 inhabitants (ref: INSEE, 2011)

  < 10,000,000 inhabitants for the other 6 sites (ref: INSEE, 2011)

As a worst case the applicant estimated statistical local cancer risk assuming a local population of 943 inhabitants and statistical regional cancer risk assuming a regional population of 10 000 000 inhabitants.

Table 10: Estimated additional statistical cancer cases

	Excess cancer risk	**Number of exposed people**	**Estimated statistical cancer cases**
Workers, 40y exposure			
Overall exposure operators of the M.E.R.C.U.R.E process	3.2×10^{-5}	50	1.6×10^{-3}
Overall exposure operators for maintenance	6.8×10^{-5}	50	3.4×10^{-3}
General population exposed via environnement, 70y exposure			
Local	2.6×10^{-8}	943	2.5×10^{-5}
Regional	5.8×10^{-13}	10 000 000	5.8×10^{-6}
TOTAL – General population			3.1×10^{-5}

Approach to Assessment of Impacts

The Assessment of impacts associated with this authorisation application and which has been undertaken by the applicant includes a comparative quantitative assessment between the monetised impacts associated with the "applied for use" and the "non-use" of tMDA. . As such, the perspective of the analysis is such that it can be used to show that the benefits to society of continuing to use tMDA exceed the risks of continued use over the analytical timeframe considered in the applicant's analysis. Although the assessment does not provide an overall "net benefit" ("net loss") estimate for the *applied for use* (*non-use*) scenario, a comparison of the benefits and costs estimated by the applicant makes

this straightforward. The analytical timeframe (temporal boundary) considered in the applicant's analysis is based on a period of 12 years (post sunset date: August 2017), which is the period of authorisation being sought by the applicant. The applicant explicitly justifies the 12 year analytical boundary on the grounds that a review period of 12 years most closely coincides with the period necessary to implement their preferred alternative technology as outlined in the analysis of alternatives. In essence, the application for authorisation is a bridging application, albeit over a somewhat extended period given the nature of nuclear regulatory approvals required for the alternative. Although the analytical period thus covers the decision making time horizon, some of the impacts concern effects that take place over longer timescales. Specifically, the inclusion of latent cancer burden risk estimates (see benefits section below) is based on a 40 year exposure-response relationship duration – the exposure period for workers - whereas the health impacts associated with this latent cancer burden are all assumed to occur within the 12 year analytical boundary. Nevertheless the approach is acceptable since any bias introduced will tend to induce conservatism (overestimation) in the economic burden of health impact estimates derived. Since no calculation spreadsheet was made available, it is not possible to determine whether the discounting period used is consistent with assessing the present value of all impacts at the date of drafting the analysis. However, given the timing and magnitude of impacts, any inconsistency will have no effect on the outcome and conclusions derived.

The assessment of impacts is based on impacts occurring in France and which are incremental to the respective baselines under the "applied for use" and "non-use" scenarios considered by the applicant. Although the applicant does not therefore use a single analytical baseline (i.e. define the baseline in terms of either one of the scenarios), the comparison of benefits and risks of granting authorisation is consistent in that the applicant compares the monetised impact of the risks of the 'applied for use" scenario with the avoided costs (benefits) of the "non-use" (applied for use) scenarios. With respect to the "non-use" scenario, the applicant, in line with their analysis of alternatives (see earlier sections), posits that they will have to introduce a temporary solution to deal with their nuclear waste whilst they await the testing, approval and implementation of their preferred alternative. This temporary solution would involve the building of a temporary specific protected area to store the nuclear wastes at each of the nuclear power plant facilities. SEAC considers this 'non-use' scenario entirely credible and the most likely to be implemented, given the French States strategic and economic reliance on nuclear power, as well as the regulatory approvals context for the storage of radioactive waste more generally. Given this, the applicant's socioeconomic assessment of the "non-use" scenario considers the direct financial resource costs associated with the building of the temporary storage facilities at each of the nuclear power plant facilities. The analysis of economic impacts is thus based on a well-established methodological approach to societal costs assessment, such that, in principle, a methodologically robust measure of the net economic cost to society of the non-use scenario is calculated (see cost section for details). The analysis of the economic burden of human health impacts is based on established procedures for the calculation of economic welfare changes as a result of human health risk reductions, albeit with the proviso noted above about the time period regarding latent effects associated with cancer exposures.

Overall, an acceptable economic valuation methodology underpins the assessment of health impacts, whilst an appropriate methodological approach underpins the assessment of economic impacts of non-use. Although the analysis contains some minor deficiencies

(in terms of correctly incorporating the timing trajectory of some of the impacts), these are not serious and make no difference to the conclusion that benefits exceed risks.

Costs of continued use (HH)

The quantitative analysis of the costs of continued use is based on a human health impact assessment using a methodology following the SEA guidance. The applicant estimates the physical health impacts (disease burden) associated with the exposures as described in the CSR as a result of the "applied for use" scenario. The approach is based on linking quantitative relationships between exposure and the health impact of interest. This general procedure is widely used for the assessment of benefits related to pollutants and is considered to be an appropriate methodological approach. In this respect, the applicant makes use of the linear exposure-response relationships for liver cancer as a result of exposure to tMDA, as estimated by and in accordance with the related ECHA paper (ECHA 2015). Using this general approach to quantitative health impact assessment, the applicant then estimates the disease burden associated with liver cancer as a result of the exposure to Cr(VI) under the "applied for use" scenario. The disease burden is estimated in terms of the number of cases of fatal and non-fatal cancer cases arising from exposures to tMDA under the "applied for use" scenario. It should be noted that the estimates presented by the applicant are likely to be a conservative (overestimate) assessments of the cancer burden since they do not apply any discounting in order to account for latency effects related to the exposures.

The number of cases of excess liver cancer has thus been estimated by the RAC at 1.6 * 10^{-3} cases for M.E.R.C.U.R.E process, 3.4* 10^{-3} for maintenance operators and 2.45 * 10^{-5} for MvE local and 5.8*10^{-6} for MvE regional fatal cases for workers. SEAC adjusted these figures assuming a 46/54 %[5] split for fatal/non-fatal cancer cases and corrected the corresponding figures for the review period requested for. It should be noted that the exposure response relationships are based on an exposure duration of 40 years, and hence the applicant treats exposures as 'separable' over time in order to derive annual cases. SEAC considers such an approach appropriate and consistent with existing practice in authorisation applications.

[5] Source: GLOBOCAN 2012, IARC 20.1.2016

Table 11: Overview of monetised socio-economic impacts[6].

	excess risk (estimated by RAC) total consisting of 46% fatal and 54% non-fatal cases	number of workers	total cases	total cases over the review period	mortality	norbidity	
MERCURE process	3.20E-05	40	1.28E-03	3.84E-04	896.64 €	82.30 €	978.94 €
maintenance	6.80E-05	10	6.80E-04	2.04E-04	552.47 €	0.00 €	552.47 €
local	2.60E-08	943	2.45E-05	7.36E-06	0.00 €	0.00 €	0.00 €
regional	5.80E-13	10 000 000	5.80E-06	1.74E-06	0.00 €	0.00 €	0.00 €
total							1 531.41 €

Although there are uncertainties then with the disease burden analysis, SEAC in its assessment considers the estimates are likely to provide an adequate order of magnitude estimate of the expected level of cancer impacts relevant to the length of review period sought by the applicant.

Concerning the estimation of economic welfare losses associated with the disease burden, the applicant assesses only the 'human' welfare losses associated with morbidity and mortality. The valuation of the human welfare related morbidity and mortality effects follows the updated ECHA WTP values (ECHA 2016) based on a Willingness To Pay (WTP) value of €5 million to avoid a fatality and €396,000 for a non-fatal cancer case. It should be noted that the applicant incorrectly uses the value of a statistical cancer case rather than the pure morbidity value. Nevertheless the difference is relatively small and makes no difference to the conclusions. In any case the applicant also applies an upper bound sensitivity value. This does not result in any change in the conclusions reached. It should also be noted that the applicant applies a discount rate of 4% to the assessment of health impacts. Some commentators argue for the use of a reduced discount rate for health risks, and whilst this could have been included as a sensitivity check, it would not have resulted in any material change to the conclusions.

Based on applying the WTP values for fatal and non-fatal cancer to the disease burden estimates described above, the applicant estimates that the central value estimate of the human health costs of the "applied for use" scenario are € 1 530 for workers. SEAC finds that the specific approaches and assumptions used to derive the health costs of the "applied for use" are on the whole clear, transparent and based on standard assessment practices, such that the estimates derived are robust and valid in terms of their order of magnitude.

Benefits of continued use (cost of non-use scenario)

The applicant's analysis of the benefits of continued use is based on a "non-use" scenario in which they build a temporary specific protected area to store the nuclear wastes at each of the nuclear power plant facilities whilst they await the testing, approval and implementation of their preferred alternative. In its assessment of this scenario, the

[6] The estimation of excess risk corresponds to worst case scenarios.

applicant estimates the economic impacts in terms of the economic costs associated with the direct financial resource costs associated with the building of the temporary storage facilities at each of the nuclear power plant facilities. No substantive assessment of any other (social, wider economic, etc) impacts is undertaken. Given the applicant is effectively seeking a bridging authorisation to cover the period until they can fully implement their preferred alternative, SEAC considers the 'non-use' scenario entirely credible (as explained in the analysis of alternatives) and the most likely to be implemented, given the French States strategic and economic reliance on nuclear power, as well as the regulatory approvals context for the storage of radioactive waste more generally.

Regarding the applicant's calculation of economic costs, SEAC considers these to represent an acceptable order of magnitude estimate of the situation faced by the applicant. The specific cost items are set out in tabulated form in rather general terms. Whilst it was not originally possible for SEAC to scrutinise the precise derivation of these calculations, further clarifications provided by the applicant established that the estimates were based on internal engineering experience and technical knowledge from similar construction projects. SEAC is satisfied that they represent appropriate order of magnitude cost estimates.

Conclusion

Overall, given the very small negative human health impacts associated with the applicants use of tMDA, the benefits of the "non-use" scenario are negligible, whilst the additional costs associated with the building of temporary storage facilities to house the nuclear waste are larger, albeit relatively modest in terms of absolute magnitude. As such, SEAC concludes that the benefits of the "applied for use" of tMDA exceed the corresponding risks. Any uncertainties are inconsequential and would in any case tend to magnify the magnitude by which the benefits exceed the risks. The total net cost of the "non-use" scenario (and hence the net benefits from granting the authorisation) are estimated at several tens of millions for a period of 12 years (the authorisation period being sought).

9. Do you propose additional conditions or monitoring arrangements

☐ YES

☒ NO

Description for additional conditions and monitoring arrangements for the authorisation:

None.

AND / OR

Description of conditions and monitoring arrangements for review reports:

None.

Justification:

Taking into consideration the low remaining uncertainties in the workers and MvE risk assessment, and as well as the observation that a significant proportion of air monitoring data was below the LoQ, additional monitoring is not likely to reduce the uncertainties in the risk assessment.

At the same time, the applicant intends to continue biomonitoring.

10. Proposed review period:

☐ Normal (7 years)

☒ Long (12 years)

☐ Short (…. _years)

☐ Other:

Justification:

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

RAC's advice:

RAC has no advice to SEAC regarding the length of the review period.

Other socio economic considerations

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

- The human-health related costs of the "applied for use" of tMDA by the applicant are low;
- Although there is no technically feasible alternative to implement by the sunset date, the applicant has identified a promising alternative which is in the process of being tested for technical approval to replace the use of tMDA. However, the technical and regulatory approvals process for nuclear waste is extensive and the applicant estimates that this may realistically take around 10 years from the sunset date before all the tests are complete, regulatory approval has been granted by the French nuclear authorities and implementation completed. In this respect the applicant has set out substitution planning timeline setting out the various activities for transition to the alternative within a period of 10 years.
- Although a 10 year transition period is deemed sufficient by the applicant there are uncertainties regarding the precise timing of the transition activities, and since the various step in the regulatory approvals process are not governed by mandated deadlines, the possibility of unexpected delays to the transition cannot be discounted. The applicant thus requested a 12 year review period. SEAC sees some merit in agreeing with a slightly longer review period than the 10 year minimum, in order to allow for some 'schedule padding' in line with the 12 year review period requested.

SEAC, having taken into account the above points, considers that realistic prospects for substitution will not be possible within the timelines of a short or normal review period, in particular keeping in mind that the internal and external regulatory approval processes (in accordance with the applicants claims) will prevent its implementation before 2027 at the earliest.

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

11. Did the Applicant provide comments to the draft final opinion?

☐ YES

☒ NO

11a. Action/s taken resulting from the analysis of the Applicant's comments:

☐ YES

☐ NO

☒ NOT APPLICABLE

Justification:

Reasons for introducing the changes

Changes made to the opinion OR Reasons for not amending the opinion